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The Iowa Administrative Code Supplement is published biweekly pursuant to Iowa Code section 17A.6. The Supplement contains replacement chapters to be inserted in the loose-leaf Iowa Administrative Code (IAC) according to instructions included with each Supplement. The replacement chapters incorporate rule changes which have been adopted by the agencies and filed with the Administrative Rules Coordinator as provided in Iowa Code sections 7.17 and 17A.4 to 17A.6. To determine the specific changes in the rules, refer to the Iowa Administrative Bulletin bearing the same publication date.

In addition to the changes adopted by agencies, the replacement chapters may reflect objection to a rule or a portion of a rule filed by the Administrative Rules Review Committee (ARRC), the Governor, or the Attorney General pursuant to Iowa Code section 17A.4(6); an effective date delay imposed by the ARRC pursuant to section 17A.4(7) or 17A.8(9); rescission of a rule by the Governor pursuant to section 17A.4(8); or nullification of a rule by the General Assembly pursuant to Article III, section 40, of the Constitution of the State of Iowa.

The Supplement may also contain replacement pages for the IAC Index or the Uniform Rules on Agency Procedure.

INSTRUCTIONS

FOR UPDATING THE

IOWA ADMINISTRATIVE CODE

Agency names and numbers in bold below correspond to the divider tabs in the IAC binders. New and replacement chapters included in this Supplement are listed below. Carefully remove and insert chapters accordingly.

Editor's telephone (515)281-3355 or (515)242-6873

Insurance Division[191]

Replace Analysis
Replace Chapter 37

Human Services Department[441]

Replace Chapter 73
Replace Chapter 176

Natural Resources Department[561]

Replace Analysis
Remove Reserved Chapters 16 to 101
Insert Chapter 16 and Reserved Chapters 17 to 101

Natural Resource Commission[571]

Replace Chapter 61

Public Health Department[641]

Replace Chapters 95 and 96
Replace Chapters 98 and 99
Replace Chapter 154

Professional Licensure Division[645]

Replace Analysis
Replace Chapter 5
Replace Chapter 31
Replace Chapter 33

Pharmacy Board[657]

Replace Analysis
Replace Chapter 37
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Replace Chapter 181
Replace Chapter 520
Replace Chapter 529
Replace Chapter 607

INSURANCE DIVISION[191]

[Prior to 10/22/86, see Insurance Department[510], renamed Insurance Division[191] under the "umbrella" of Department of Commerce by the 1986 Iowa Acts, Senate File 2175]

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CHAPTER 37
MEDICARE SUPPLEMENT INSURANCE

191—37.1(514D) Purpose and authority. The purpose of this chapter is to provide for the reasonable standardization of coverage and simplification of terms and benefits of Medicare supplement policies; to facilitate public understanding and comparison of such policies; to eliminate provisions contained in such policies which may be misleading or confusing in connection with the purchase of such policies or with the settlement of claims; and to provide for full disclosures in the sale of accident and sickness insurance coverages to persons eligible for Medicare. This chapter is issued pursuant to the authority vested in the commissioner under Iowa Code chapter 514D.
[**ARC 4394C**, IAB 4/10/19, effective 5/15/19]

191—37.2(514D) Applicability, scope, and appendices.

37.2(1) *Applicability and scope.*

a. Except as otherwise specifically provided in rules 191—37.6(514D), 191—37.22(514D), 191—37.23(514D), 191—37.28(514D) and 191—37.32(514D), this chapter shall apply to:

(1) All Medicare supplement individual or group policies delivered or issued for delivery in this state on or after May 15, 2019, unless otherwise stated; and

(2) All certificates issued under group Medicare supplement policies, which certificates have been delivered or issued for delivery in this state on or after May 15, 2019, unless otherwise stated.

b. This chapter shall not apply to a policy or contract of one or more employers or labor organizations, or of the trustees of a fund established by one or more employers or labor organizations, or combination thereof; for employees or former employees, or a combination thereof; or for members or former members, or a combination thereof, of the labor organizations.

37.2(2) *Appendices.* The following appendices can be found at the end of this chapter:

a. Appendix A: Medicare Supplement Refund Calculation Form. This form is to be completed pursuant to subrule 37.23(3).

b. Appendix B: Disclosure Statements. The applicable notice from the choices in Appendix B shall be used on Medicare supplement applications, pursuant to subrule 37.26(2).

c. Appendix C: Statements and Questions for Application Forms Related to Duplicate or Replacement Coverage. The statements and questions in Appendix C shall be included with the outline of coverage and delivered with any application form for Medicare supplement policies or certificates to an applicant, as required by subrules 37.27(1) and 37.27(2).

d. Appendix D: Notice to Applicant Regarding Replacement of Medicare Supplement Insurance or Medicare Advantage. The notice form of Appendix D shall be provided as required by subrules 37.27(4) and 37.27(5).

e. Appendix E: Outline of Coverage: Benefit Charts. The items in the applicable tables in this Appendix E, displaying the features of each benefit plan offered by the issuer, shall be included in the outline of coverage in the order prescribed, pursuant to subrule 37.28(4).

f. Appendix F: Form for Reporting Medicare Supplement Policies or Certificates. This form is to be completed pursuant to subrule 37.32(1).
[**ARC 4394C**, IAB 4/10/19, effective 5/15/19]

191—37.3(514D) Definitions. For purposes of this chapter, in addition to the definitions in Iowa Code section 514D.2, the following definitions shall apply, unless otherwise specified:

"1990 standardized Medicare supplement benefit plan" or *"1990 plan"* means a group or individual Medicare supplement policy issued on or after January 1, 1992, and with an effective date for coverage prior to June 1, 2010, and includes Medicare supplement insurance policies and certificates renewed on or after June 1, 2010, which are not replaced by the issuer at the request of the insured.

"2010 standardized Medicare supplement benefit plan" or *"2010 plan"* means a group or individual Medicare supplement policy issued with an effective date for coverage on or after June 1, 2010.

"Applicant" means:

1. In the case of an individual Medicare supplement policy, the person who seeks to contract for insurance benefits; and

2. In the case of a group Medicare supplement policy, the proposed covered individual, unless stated otherwise.

"Basic core benefits" are benefits defined in subrule 37.7(2) for 1990 plans, subrule 37.8(2) for 2010 plans, and subrule 37.9(1) for Medicare supplement policies or certificates delivered or issued for delivery to individuals newly eligible for Medicare on or after January 1, 2020.

"Certificate" means any certificate of coverage delivered or issued for delivery in this state to a covered individual under a group Medicare supplement policy.

"Certificate form" means the form (as defined in Iowa Code section 514D.2(2)) on which the certificate is delivered or issued for delivery by the issuer.

"Certificate holder" means the named individual to whom the certificate of coverage under a group policy is issued, or a spouse, if applicable.

"CMS" means the Centers for Medicare and Medicaid Services of the U.S. Department of Health and Human Services.

"Commissioner" means the Iowa insurance commissioner, and includes the insurance division as delegated.

"Covered individual" means an individual who may receive benefits under an individual or group Medicare supplement policy because the individual is one of the following: the named insured under an individual Medicare supplement policy; the named certificate holder under a group Medicare supplement policy; or an individual such as a spouse covered by way of the named certificate holder's group Medicare supplement policy. For purposes of rule 191—37.20(514D), "covered individual" means an individual who may receive benefits under an individual or group Medicare Select policy because the individual is one of the following: the named insured under an individual Medicare Select policy; the named certificate holder under a group Medicare Select policy; or an individual such as a spouse covered by way of the named certificate holder's group Medicare Select policy.

"Creditable coverage."

1. "Creditable coverage" means, with respect to an individual, health coverage of the individual provided under any of the following:

- A group health plan;
- Health insurance coverage;
- Part A or Part B of Title XVIII of the Social Security Act (Medicare);
- Title XIX of the Social Security Act (Medicaid), other than coverage consisting solely of benefits under Section 1928;
- Chapter 55 of Title 10, United States Code (CHAMPUS);
- A medical care program of the Indian Health Service or of a tribal organization;
- A state health benefits risk pool;
- A health plan offered under Chapter 89 of Title 5, United States Code (Federal Employees Health Benefits Program);
- A public health plan as defined in federal regulation; and
- A health benefit plan under Section 5(e) of the Peace Corps Act (22 United States Code 2504(e)).

2. "Creditable coverage" shall not include one or more of, or any combination of, the following:

- Coverage only for accident or disability income insurance, or any combination thereof;
- Coverage issued as a supplement to liability insurance;
- Liability insurance, including general liability insurance and automobile liability insurance;
- Workers' compensation or similar insurance;
- Automobile medical payment insurance;
- Credit-only insurance;
- Coverage for on-site medical clinics; and
- Other similar insurance coverage, specified in federal regulations, under which benefits for medical care are secondary or incidental to other insurance benefits.

3. "Creditable coverage" shall not include the following benefits if they are provided under a separate policy, certificate or contract of insurance or are otherwise not an integral part of the plan:

- Limited scope dental or vision benefits;
- Benefits for long-term care, nursing home care, home health care, community-based care, or any combination thereof; and
- Such other similar limited benefits as are specified in federal regulations.

4. "Creditable coverage" shall not include the following benefits if offered as independent, noncoordinated benefits:

- Coverage only for a specified disease or illness; and
- Hospital indemnity or other fixed indemnity insurance.

5. "Creditable coverage" shall not include the following if it is offered as a separate policy, certificate or contract of insurance:

- Medicare supplemental health insurance as defined under Section 1882(g)(1) of the Social Security Act;
- Coverage supplemental to the coverage provided under Chapter 55 of Title 10, United States Code; and
- Similar supplemental coverage provided to the coverage under a group health plan.

"File" or *"filing,"* when used in reference to filing information with the commissioner or with the insurance division, means submitting information as set forth in these rules through the System for Electronic Rate and Form Filing (SERFF), www.serff.com, or as otherwise directed by the insurance division through its website, iid.iowa.gov.

"Group member" means the individual who is a member of the group entity to which the group policy is issued.

"Group policyholder" means the group entity to which a group Medicare supplement policy is issued.

"Insolvency" means that an issuer, licensed to transact the business of insurance in this state, has had a final order of liquidation entered against it with a finding of insolvency by a court of competent jurisdiction in the issuer's state of domicile.

"Insurance division" means the Iowa insurance division.

"Issuer" includes insurance companies, fraternal benefit societies, health care service plans, health maintenance organizations, and any other entity delivering or issuing for delivery in this state Medicare supplement policies or certificates.

"Medicare" means the Health Insurance for the Aged Act, Title XVIII of the Social Security Amendments of 1965, as then constituted or later amended.

"Medicare Advantage plan" means a plan of coverage for health benefits under Medicare Part C (as defined in 42 U.S.C. 1395w-28(b)(1)), and includes:

1. Coordinated care plans which provide health care services, including but not limited to health maintenance organization plans (with or without a point-of-service option), plans offered by provider-sponsored organizations, and preferred provider organization plans;
2. Medical savings account plans coupled with a contribution into a Medicare Advantage medical savings account; and
3. Medicare Advantage private fee-for-service plans.

"Medicare Select policy," "Medicare Select certificate,""Medicare Select issuer," and *"Medicare Select network provider"* are defined in subrule 37.20(2).

"Medicare supplement policy" means a group or individual policy of accident and sickness insurance or a subscriber contract of hospital and medical service associations or health maintenance organizations, other than a policy issued pursuant to a contract under Section 1876 of the federal Social Security Act (42 U.S.C. Section 1395 et seq.) or an issued policy under a demonstration project specified in 42 U.S.C. Section 1395ss(g)(1), which is advertised, marketed or designed primarily as a supplement to reimbursements under Medicare for the hospital, medical or surgical expenses of persons eligible for Medicare. "Medicare supplement policy" does not include Medicare Advantage plans, outpatient

prescription drug plans established under Medicare Part D, or any health care prepayment plan (HCPP) that provides benefits pursuant to an agreement under Section 1833(a)(1)(A) of the Social Security Act.

"MMA" means the Medicare Prescription Drug, Improvement, and Modernization Act of 2003, Pub. L. No. 108-173, 117 Stat. 2066.

"PACE program" means a program of all-inclusive care for the elderly, operated by an approved PACE organization (an entity that is approved as a PACE program by the Iowa department of human services and that has in effect a PACE program agreement between the entity, CMS, and the Iowa department of human services to operate a PACE program) that provides comprehensive health care services to enrollees in Iowa, pursuant to Section 1894 of the Social Security Act (42 U.S.C. 1395eee) and Iowa Administrative Code rules 441—88.21(249A) through 441—88.28(249A).

"Person" means any individual, corporation, association, or partnership.

"Policy form" means the form (as defined by Iowa Code section 514D.2(2)) on which the policy (as defined by Iowa Code section 514D.2(4)) is delivered or issued for delivery by the issuer.

"Policyholder" means the individual person to whom or group entity to which an individual or group Medicare supplement policy is issued.

"PPS" means prospective payment system.

"Prestandardized Medicare supplement benefit plan" or *"prestandardized plan"* means a group or individual Medicare supplement policy issued prior to January 1, 1992.

"Producer" means a person licensed in this state pursuant to Iowa Code chapter 522B and Iowa Administrative Code 191—Chapter 10 to sell, solicit, negotiate, effect, procure, deliver, renew, continue or bind policies of insurance for persons residing or located, or for policies to be performed, in this state.

"Secretary" means the Secretary of the U.S. Department of Health and Human Services.

"SMSBP" or *"standardized Medicare supplement benefit plan"* means a 1990 plan, a 2010 plan, or a plan described in subrule 37.9(1) for Medicare supplement policies or certificates delivered or issued for delivery to individuals newly eligible for Medicare on or after January 1, 2020.

[**ARC 4394C**, IAB 4/10/19, effective 5/15/19]

191—37.4(514D) Policy definitions and terms. No policy or certificate may be advertised, solicited or issued for delivery in this state as a Medicare supplement policy or certificate unless such policy or certificate contains definitions or terms which conform to the requirements of this rule.

"Accident," "accidental injury," or *"accidental means"* shall be defined to employ "result" language and shall not include words which establish an accidental means test or use words such as "external, violent, visible wounds" or similar words of description or characterization.

1. The definition shall not be more restrictive than the following: "Injury or injuries for which benefits are provided means accidental bodily injury sustained by the covered individual which is the direct result of an accident, independent of disease or bodily infirmity or any other cause, and occurs while insurance coverage is in force."

2. Such definition may provide that injuries shall not include injuries for which benefits are provided or available under any workers' compensation, employer's liability or similar law, or motor vehicle no-fault plan, unless prohibited by law.

"Benefit period" or *"Medicare benefit period"* shall not be defined more restrictively than as defined by Medicare.

"Convalescent nursing home," "extended care facility," or *"skilled nursing facility"* shall not be defined more restrictively than as defined by Medicare.

"Hospital" may be defined in relation to its status, facilities and available services or to reflect its accreditation by the Joint Commission on Accreditation of Hospitals, but not more restrictively than as defined by Medicare.

"Medicare" shall be defined in the policy and certificate. Medicare may be substantially defined as "The Health Insurance for the Aged Act, Title XVIII of the Social Security Amendments of 1965 as then constituted or later amended," or "Title I, Part I of Pub. L. No. 89-97, as Enacted by the Eighty-Ninth Congress of the United States of America and popularly known as the Health Insurance for the Aged Act, as then constituted and any later amendments or substitutes thereof," or words of similar import.

"Medicare-eligible expenses" shall mean expenses of the kinds covered by Medicare Parts A and B, to the extent recognized as reasonable and medically necessary by Medicare.

"Physician" shall not be defined more restrictively than as defined by Medicare.

"Sickness" shall not be defined to be more restrictive than the following: "Sickness means illness or disease of a covered individual which first manifests itself after the effective date of insurance and while the insurance is in force." The definition may be further modified to exclude sicknesses or diseases for which benefits are provided under any workers' compensation, occupational disease, employer's liability or similar law.

[**ARC 4394C**, IAB 4/10/19, effective 5/15/19]

191—37.5(514D) Policy provisions.

37.5(1) *Coverage restrictions related to Medicare.* Except for permitted preexisting condition clauses as described in paragraphs 37.6(1)*"a,"* 37.7(1)*"d,"* and 37.8(1)*"d,"* no policy or certificate may be advertised, solicited or issued for delivery in this state as a Medicare supplement policy or certificate if such Medicare supplement policy or certificate contains limitations or exclusions on coverage that are more restrictive than those permitted by Medicare.

37.5(2) *Waivers of preexisting conditions.* No Medicare supplement policy or certificate may use waivers to exclude, limit or reduce coverage or benefits for specifically named or described preexisting diseases or physical conditions.

37.5(3) *Duplicate benefits.* No Medicare supplement policy or certificate in force in the state shall contain benefits which duplicate benefits provided by Medicare insurance.

37.5(4) *Renewal of pre-2006 coverage.* Subject to paragraphs 37.6(1)*"d," "e,"* and *"g"* and 37.7(1)*"d"* and *"e,"* a Medicare supplement policy or certificate with benefits for outpatient prescription drugs in existence prior to January 1, 2006, shall, at the option of a currently covered individual who does not enroll in Medicare Part D, be renewed for that covered individual.

37.5(5) *Coverage of prescription drugs after 2005.* A Medicare supplement policy or certificate with benefits for outpatient prescription drugs shall not be issued after December 31, 2005.

37.5(6) *Renewal of coverage of prescription drugs after 2005 for enrollees of Part D.* After December 31, 2005, a Medicare supplement policy or certificate with benefits for outpatient prescription drugs may not be renewed after the covered individual enrolls in Medicare Part D unless:

a. The policy or certificate is modified to eliminate outpatient prescription coverage for expenses of outpatient prescription drugs incurred after the effective date of the covered individual's coverage under a Medicare Part D plan; and

b. Premiums are adjusted to reflect the elimination of outpatient prescription drug coverage at the time of Medicare Part D enrollment, accounting for any claims paid, if applicable.

[**ARC 4394C**, IAB 4/10/19, effective 5/15/19]

191—37.6(514D) Minimum benefit standards for prestandardized Medicare supplement benefit plan policies or certificates issued for delivery prior to January 1, 1992 (prestandardized plans). No policy or certificate may be advertised, solicited or issued for delivery in this state as a prestandardized plan policy or certificate unless it meets or exceeds the following minimum standards. These are minimum standards and do not preclude the inclusion of other provisions or benefits which are not inconsistent with these standards.

37.6(1) *General standards.* The following standards apply to prestandardized plans and are in addition to all other requirements of this chapter.

a. A prestandardized plan shall not exclude or limit benefits for losses incurred more than six months from the effective date of coverage because it involved a preexisting condition. The prestandardized plan shall not define a preexisting condition more restrictively than a condition for which medical advice was given or treatment was recommended by or received from a physician within six months before the effective date of coverage.

b. A prestandardized plan shall not indemnify against losses resulting from sickness on a different basis than losses resulting from accidents.

c. A prestandardized plan shall provide that benefits designed to cover cost-sharing amounts under Medicare will be changed automatically to coincide with any changes in the applicable Medicare deductible, copayment, or coinsurance amounts. Premiums may be modified to correspond with such changes.

d. A "noncancelable," "guaranteed renewable," or "noncancelable and guaranteed renewable" prestandardized plan shall not:

(1) Provide for termination of coverage of a spouse of a group member solely because of the occurrence of an event specified for termination of coverage of the group member, other than the nonpayment of premium; or

(2) Be canceled or nonrenewed by the issuer solely on the grounds of deterioration of health.

e. Except as authorized by the commissioner, an issuer shall neither cancel nor nonrenew a prestandardized plan policy or certificate for any reason other than nonpayment of premium or material misrepresentation.

f. Group Medicare supplement policies.

(1) If a group prestandardized plan is terminated by the group policyholder and not replaced as provided in subparagraph 37.6(1)*"f"*(3), the issuer shall offer to each of the covered individuals under the group prestandardized plan an individual Medicare supplement policy. The issuer shall offer each of the group prestandardized plan's covered individuals at least the following choices:

1. An individual Medicare supplement policy currently offered by the issuer having comparable benefits to those contained in the terminated group prestandardized plan; and

2. An individual Medicare supplement policy which provides only such benefits as are required to meet the basic core benefits minimum standards as defined in subrule 37.7(2).

(2) If a covered individual's membership with the group entity that is the group policyholder is terminated, the issuer shall:

1. Offer the covered individual such conversion opportunities as are described in subparagraph 37.6(1)*"f"*(1); or

2. At the option of the group policyholder, offer the covered individual continuation of coverage under the group prestandardized plan.

(3) If a group prestandardized plan is replaced by another group Medicare supplement policy purchased by the same group policyholder, the issuer of the replacement group Medicare supplement policy shall offer coverage to all covered individuals under the replaced group prestandardized plan on its date of termination. Coverage under the new replacement group Medicare supplement policy shall not result in any exclusion for preexisting conditions that would have been covered under the replaced group prestandardized plan.

(4) If a prestandardized plan eliminates an outpatient prescription drug benefit as a result of requirements imposed by the MMA, the modified policy shall be deemed to satisfy the guaranteed renewal requirements of this subrule.

g. Termination of a prestandardized plan policy or certificate shall be without prejudice to any continuous loss which commenced while the prestandardized plan policy or certificate was in force, but the extension of benefits beyond the period during which the prestandardized plan policy or certificate was in force may be predicated upon the continuous total disability of the covered individual, limited to the duration of the prestandardized plan policy or certificate benefit period, if any, or to payment of the maximum benefits. Receipt of Medicare Part D benefits will not be considered in determining a continuous loss.

37.6(2) *Minimum benefit standards.* The following are minimum benefit standards for prestandardized plans:

a. Coverage of Part A Medicare-eligible expenses for hospitalization to the extent not covered by Medicare from the sixty-first day through the ninetieth day in any Medicare benefit period;

b. Coverage for either all or none of the Medicare Part A inpatient hospital deductible amount;

c. Coverage of Part A Medicare-eligible expenses which are incurred as daily hospital charges during the covered individual's use of Medicare's lifetime hospital inpatient reserve days;

d. Upon exhaustion of all Medicare hospital inpatient coverage including the lifetime reserve days, coverage of 90 percent of all Medicare Part A eligible expenses for hospitalization not covered by Medicare subject to a lifetime maximum benefit of an additional 365 days;

e. Coverage under Medicare Part A for the reasonable cost of the first three pints of blood (or equivalent quantities of packed red blood cells, as defined under federal regulations) unless replaced in accordance with federal regulations or already paid for under Part B;

f. Coverage for the coinsurance amount, or in the case of hospital outpatient department services paid under a PPS, the copayment amount, of Medicare-eligible expenses under Part B regardless of hospital confinement, subject to a maximum calendar year out-of-pocket amount equal to the Medicare Part B deductible;

g. Effective January 1, 1990, coverage under Medicare Part B for the reasonable cost of the first three pints of blood (or equivalent quantities of packed red blood cells, as defined under federal regulations), unless replaced in accordance with federal regulations or already paid for under Part A, subject to the Medicare deductible amount.

[**ARC 4394C**, IAB 4/10/19, effective 5/15/19]

191—37.7(514D) Benefit standards for 1990 standardized Medicare supplement benefit plan policies or certificates issued for delivery on or after January 1, 1992, and with an effective date for coverage prior to June 1, 2010 (1990 plans). The following standards are applicable to all Medicare supplement policies or certificates delivered or issued for delivery in this state on or after January 1, 1992, and with an effective date for coverage prior to June 1, 2010. No policy or certificate may be advertised, solicited, delivered or issued for delivery in this state as a Medicare supplement policy or certificate unless it complies with these benefit standards. No issuer may offer any prestandardized Medicare supplement benefit plan for sale on or after January 1, 1992. Benefit standards applicable to Medicare supplement policies and certificates issued before January 1, 1992, remain subject to the requirements of rule 191—37.6(514D).

37.7(1) *General standards.* The following standards apply to 1990 plans and are in addition to all other requirements of this chapter.

a. Combinations of benefits other than standard not allowed. No groups, packages or combinations of Medicare supplement benefits other than those listed in this rule shall be offered for sale in this state, except as may be permitted in subrule 37.7(6) and in rule 191—37.20(514D).

b. Uniformity and conformity. All 1990 plans shall be uniform in structure, language, designation and format to the standardized Medicare supplement benefit plans A through L listed in subrule 37.7(4) and shall conform to the definitions in rules 191—37.3(514D) and 191—37.4(514D). Each benefit shall be structured in accordance with the format provided in this rule and list the benefits in the order shown in this rule. For purposes of this rule, "structure, language, and format" means style, arrangement and overall content of a benefit.

c. Other designations may be used. An issuer may use, in addition to the benefit plan designations required in paragraph 37.7(1)*"b,"* other designations to the extent permitted by law.

d. Preexisting conditions. A 1990 plan shall not exclude or limit benefits for losses incurred more than six months from the effective date of coverage because the claim involved a preexisting condition. The 1990 plan may not define a preexisting condition more restrictively than a condition for which medical advice was given or treatment was recommended by or received from a physician within six months before the effective date of coverage.

e. Sickness same as accident. A 1990 plan shall not indemnify against losses resulting from sickness on a different basis than losses resulting from accidents.

f. Automatic change of cost sharing. A 1990 plan shall provide that benefits designed to cover cost-sharing amounts under Medicare will be changed automatically to coincide with any changes in the applicable deductible, copayment, or coinsurance amounts set by Medicare. Premiums may be modified to correspond with such changes.

g. Termination of coverage of spouse. No 1990 plan shall provide for termination of coverage of a spouse solely because of the occurrence of an event specified for termination of coverage of the insured, other than the nonpayment of premium.

h. Guaranteed renewability. Each 1990 plan shall be guaranteed renewable.

(1) The issuer shall not cancel or nonrenew a 1990 plan solely on the ground of health status of the covered individual.

(2) The issuer shall not cancel or nonrenew a 1990 plan for any reason other than nonpayment of premium or material misrepresentation.

(3) If the 1990 plan is terminated by the group policyholder and is not replaced as provided under subparagraph 37.7(1)*"h"*(5), the issuer shall offer to the covered individual a conversion opportunity of an individual Medicare supplement policy which, at the option of the covered individual, either:

1. Provides for continuation of the benefits contained in the group 1990 plan; or

2. Provides for such benefits as otherwise meet the requirements of this subrule.

(4) If a covered individual under a group 1990 plan terminates membership in the group, the issuer shall either:

1. Offer the covered individual the conversion opportunity described in subparagraph 37.7(1)*"h"*(3); or

2. At the option of the group policyholder, offer the covered individual continuation of coverage under the group Medicare supplement policy.

(5) If a group 1990 plan is replaced by another group Medicare supplement policy purchased by the same group policyholder, the issuer of the replacement group Medicare supplement policy shall offer coverage under the replacement group Medicare supplement policy to all covered individuals of the replaced group 1990 plan effective on the date of termination of the replaced group 1990 plan. Coverage under the replacement group Medicare supplement policy shall not result in any exclusion of any covered individual's preexisting conditions that would have been covered under the replaced group 1990 plan.

(6) If a 1990 plan eliminates an outpatient prescription drug benefit as a result of requirements imposed by the MMA, the modified 1990 plan shall be deemed to satisfy the guaranteed renewal requirements of this paragraph.

i. Termination involving continuous loss. Termination of a 1990 plan shall be without prejudice to any continuous loss which commenced while the 1990 plan was in force, but the extension of benefits beyond the period during which the 1990 plan was in force may be conditioned upon the continuous total disability of the covered individual, limited to the duration of the 1990 plan benefit period, if any, or payment of the maximum benefits. Receipt of Medicare Part D benefits will not be considered in determining a continuous loss.

j. Suspension for Title XIX coverage.

(1) A 1990 plan shall provide that benefits and premiums under the 1990 plan shall be suspended at the request of the covered individual for the period (not to exceed 24 months) in which the covered individual has applied for and is determined to be entitled to medical assistance under Title XIX of the Social Security Act, but only if the covered individual notifies the issuer of such 1990 plan within 90 days after the date the covered individual becomes entitled to such assistance.

(2) If such suspension occurs and if the covered individual loses entitlement to such medical assistance, such 1990 plan shall be automatically reinstituted (effective as of the date of termination of such entitlement) if the covered individual provides notice of loss of such entitlement within 90 days after the date of such loss and pays the premium attributable to the period, effective as of the date of termination of such entitlement.

(3) Each 1990 plan shall provide that benefits and premiums under the 1990 plan shall be suspended for the period provided by federal regulation at the request of the covered individual if the covered individual is entitled to benefits under Section 226(b) of the Social Security Act and is covered under a group health plan as defined in Section 1862(b)(1)(A)(v) of the Social Security Act. If suspension occurs and if the covered individual loses coverage under the group health plan, the 1990 plan shall be automatically reinstituted effective as of the date of loss of coverage if the covered individual provides

notice to the issuer of loss of coverage within 90 days after the date of such loss and pays the premium attributable to the period, effective as of the date of termination of enrollment in the group health plan.

(4) Reinstitution of coverage as described in subparagraphs 37.7(1)*"j"*(2) and (3):

1. Shall not provide for any waiting period with respect to treatment of preexisting conditions;

2. Shall provide for resumption of coverage that is substantially equivalent to coverage in effect before the date of suspension. If the suspended 1990 plan provided coverage for outpatient prescription drugs, reinstitution of the 1990 plan for Medicare Part D enrollees shall be without coverage for outpatient prescription drugs and shall otherwise provide substantially equivalent coverage to the coverage in effect before the date of suspension; and

3. Shall provide for classification of premiums on terms at least as favorable to the covered individual as the premium classification terms that would have applied to the covered individual had the coverage not been suspended.

k. Exchange of 1990 plan to 2010 plan. If an issuer makes a written offer to a covered individual covered by one or more of the issuer's 1990 plans (as described in this rule) to allow, during a specified period, the covered individual to exchange coverage from the covered individual's 1990 plan (as described in this rule) to a 2010 plan (as described in rule 191—37.8(514D)), the offer and subsequent exchange shall comply with the following requirements:

(1) An issuer need not provide justification to the commissioner or comply with 191—Chapter 16 or rule 191—37.27(514D) if the covered individual exchanges a 1990 plan policy or certificate for an issue-age-rated 2010 plan policy or certificate using the same issue age and duration as was used for the covered individual's 1990 plan policy or certificate to be exchanged. If a covered individual's 1990 plan policy or certificate to be exchanged is priced on an issue-age-rate schedule at the time of such offer, the rate charged to the covered individual for the exchanged 2010 plan policy or certificate shall recognize the policy reserve buildup, due to the prefunding inherent in the use of an issue-age-rate basis, for the benefit of the covered individual. The rating method proposed to be used by an issuer must be filed with the commissioner pursuant to rule 191—37.24(514D).

(2) The rating class of the new exchanged 2010 plan policy or certificate shall be the class closest to the covered individual's rating class of the exchanged 1990 plan.

(3) An issuer may not apply new preexisting condition limitations or a new incontestability period to the covered individual's exchanged 2010 plan for those benefits contained in the exchanged 1990 plan, but may apply preexisting condition limitations of no more than six months to any added benefits contained in the exchanged 2010 plan that were not contained in the exchanged 1990 plan.

(4) The exchanged 2010 plan shall be offered to all covered individuals within a given 1990 plan, except where the offer or issue would be in violation of state or federal law.

37.7(2) *Standards for basic core benefits common to 1990 standardized Medicare supplement benefit plans A through J (1990 plans).* Every issuer shall make available a 1990 plan including only the following basic core benefits to each prospective covered individual. An issuer may make available to prospective covered individuals any of the issuer's other standardized Medicare supplement benefit plans in addition to the basic core benefits, but not in lieu thereof. The 1990 basic core benefits are the following:

a. Coverage of Part A Medicare-eligible expenses for hospitalization, to the extent not covered by Medicare, from the sixty-first day through the ninetieth day in any Medicare benefit period;

b. Coverage of Part A Medicare-eligible expenses incurred for hospitalization, to the extent not covered by Medicare, for each Medicare lifetime inpatient reserve day used;

c. Upon exhaustion of the Medicare hospital inpatient coverage including the lifetime reserve days, coverage of 100 percent of the Medicare Part A eligible expenses for hospitalization, paid at the applicable PPS rate or other appropriate Medicare standard of payment, subject to a lifetime maximum benefit of an additional 365 days. Medicare requires that the provider shall accept the issuer's payment as payment in full and that the provider may not bill the covered individual for any balance;

d. Coverage under Medicare Parts A and B for the reasonable cost of the first three pints of blood (or equivalent quantities of packed red blood cells, as defined under federal regulations) unless replaced in accordance with federal regulations;

e. Coverage for the coinsurance amount or, in the case of hospital outpatient department services paid under a PPS, the copayment amount of Medicare Part B eligible expenses regardless of hospital confinement, subject to the Medicare Part B deductible.

37.7(3) *Standards for additional benefits for plans B through J.* The following benefit descriptions apply to the additional benefits specified for 1990 plans B through J in subrule 37.7(4):

a. Medicare Part A deductible: coverage for all of the Medicare Part A inpatient hospital deductible amount per benefit period.

b. Skilled nursing facility care: coverage for the actual billed charges up to the coinsurance amount from the twenty-first day through the one hundredth day in a Medicare benefit period for post-hospital skilled nursing facility care eligible under Medicare Part A.

c. Medicare Part B deductible: coverage for all of the Medicare Part B deductible amount per calendar year regardless of hospital confinement.

d. Eighty percent of the Medicare Part B excess charges: coverage for 80 percent of the difference between the actual Medicare Part B charge as billed, not to exceed any charge limitation established by Medicare or by state law, and the Medicare-approved Part B charge.

e. One hundred percent of the Medicare Part B excess charges: coverage for all of the difference between the actual Medicare Part B charge as billed, not to exceed any charge limitation established by Medicare or by state law, and the Medicare-approved Part B charge.

f. Basic outpatient prescription drug benefit: coverage for 50 percent of outpatient prescription drug charges, after a $250 calendar year deductible, to a maximum of $1,250 in benefits received by the covered individual per calendar year, to the extent not covered by Medicare. The outpatient prescription drug benefit may be included for sale or issuance in a Medicare 1990 plan until January 1, 2006.

g. Extended outpatient prescription drug benefit: coverage for 50 percent of outpatient prescription drug charges, after a $250 calendar year deductible to a maximum of $3,000 in benefits received by the covered individual per calendar year, to the extent not covered by Medicare. The outpatient prescription drug benefit may be included for sale or issuance in a Medicare 1990 plan until January 1, 2006.

h. Medically necessary emergency care in a foreign country: coverage to the extent not covered by Medicare for 80 percent of the billed charges for Medicare-eligible expenses for medically necessary emergency hospital, physician and medical care received in a foreign country, which care would have been covered by Medicare if provided in the United States and which care began during the first 60 consecutive days of each trip outside the United States, subject to a calendar year deductible of $250 and a lifetime maximum benefit of $50,000. For purposes of this benefit, "emergency care" shall mean care needed immediately because of an injury or an illness of sudden and unexpected onset.

i. Preventive medical care benefit:

(1) Coverage for the following preventive health services not covered by Medicare:

1. An annual clinical preventive medical history and physical examination that may include tests and services from numbered paragraph "2" and patient education to address preventive health care measures.

2. Preventive screening tests or preventive services, the selection and frequency of which is determined to be medically appropriate by the attending physician.

(2) Reimbursement shall be for the actual charges up to 100 percent of the Medicare-approved amount for each service, as if Medicare were to cover the service as identified in American Medical Association current procedural terminology (AMA CPT) codes, to a maximum of $120 annually under this benefit. This benefit shall not include payment for any procedure covered by Medicare.

j. At-home recovery benefit: coverage for services to provide short-term, at-home assistance with activities of daily living for those recovering from an illness, injury or surgery.

(1) For purposes of this benefit, the following definitions shall apply:

"Activities of daily living" includes, but is not limited to, bathing, dressing, personal hygiene, transferring, eating, ambulating, assistance with drugs that are normally self-administered, and changing bandages or other dressings.

"At-home recovery visit" means the period of a visit required to provide at-home recovery care, without limit on the duration of the visit, except each consecutive four hours in a 24-hour period of services provided by a care provider is one visit.

"Care provider" means a duly qualified or licensed home health aide or homemaker, personal care aide or nurse provided through a licensed home health care agency or referred by a licensed referral agency or licensed nurses registry.

"Home" shall mean any place used by the covered individual as a place of residence, provided that such place would qualify as a residence for home health care services covered by Medicare. A hospital or skilled nursing facility shall not be considered the covered individual's place of residence.

(2) Coverage requirements and limitations.

1. At-home recovery services provided must be primarily services which assist in activities of daily living.

2. The covered individual's attending physician must certify that the specific type and frequency of at-home recovery services are necessary because of a condition for which a home care plan of treatment was approved by Medicare.

3. Coverage is limited to:

- No more than the number and type of at-home recovery visits certified as necessary by the covered individual's attending physician. The total number of at-home recovery visits shall not exceed the number of Medicare-approved home health care visits under a Medicare-approved home care plan of treatment.
- The actual charges for each visit up to a maximum reimbursement of $40 per visit.
- One thousand six hundred dollars per calendar year.
- Seven visits in any one week.
- Care furnished on a visiting basis in the covered individual's home.
- Services provided by a care provider as defined in this paragraph 37.7(3)*"j."*
- At-home recovery visits while the covered individual is covered under the policy or certificate and not otherwise excluded.
- At-home recovery visits received during the period the covered individual is receiving Medicare-approved home care services or no more than eight weeks after the service date of the last Medicare-approved home health care visit.

(3) Coverage is excluded for:

1. Home care visits paid for by Medicare or other government programs; and

2. Care provided by family members, unpaid volunteers or providers who are not care providers.

37.7(4) *Elements required in standardized 1990 Medicare supplement benefit plans.* The additional benefits described in subrule 37.7(3) shall be included in 1990 Medicare supplement benefit plans as specified for each 1990 plan as follows:

a. Plan A shall be limited to the basic core benefits, as defined in subrule 37.7(2).

b. Plan B shall include only the following: basic core benefits as set forth in subrule 37.7(2), plus the Medicare Part A deductible as defined in paragraph 37.7(3)*"a."*

c. Plan C shall include only the following: basic core benefits as set forth in subrule 37.7(2), plus the Medicare Part A deductible, skilled nursing facility care, Medicare Part B deductible, and medically necessary emergency care in a foreign country as defined in paragraphs 37.7(3)*"a,""b,""c,"* and *"h,"* respectively.

d. Plan D shall include only the following: basic core benefits as set forth in subrule 37.7(2), plus the Medicare Part A deductible, skilled nursing facility care, medically necessary emergency care in a foreign country, and the at-home recovery benefit as defined in paragraphs 37.7(3)*"a,""b,""h,"* and *"j,"* respectively.

e. Plan E shall include only the following: basic core benefits as set forth in subrule 37.7(2), plus the Medicare Part A deductible, skilled nursing facility care, medically necessary emergency care in a foreign country, and preventive medical care as defined in paragraphs 37.7(3)*"a,""b,""h,"* and *"i,"* respectively.

f. Plan F shall include only the following: basic core benefits as set forth in subrule 37.7(2), plus the Medicare Part A deductible, skilled nursing facility care, the Medicare Part B deductible, 100 percent of the Medicare Part B excess charges, and medically necessary emergency care in a foreign country as defined in paragraphs 37.7(3)*"a,""b,""c,""e,"* and *"h,"* respectively.

g. Plan G shall include only the following: basic core benefits as set forth in subrule 37.7(2), plus the Medicare Part A deductible, skilled nursing facility care, 80 percent of the Medicare Part B excess charges, medically necessary emergency care in a foreign country, and the at-home recovery benefit as defined in paragraphs 37.7(3)*"a,""b,""d,""h,"* and *"j,"* respectively.

h. Plan H shall consist of only the following: basic core benefits as set forth in subrule 37.7(2), plus the Medicare Part A deductible, skilled nursing facility care, basic prescription drug benefit, and medically necessary emergency care in a foreign country as defined in paragraphs 37.7(3)*"a,""b,""f,"* and *"h,"* respectively. The outpatient prescription drug benefit shall not be included in a 1990 plan sold after December 31, 2005.

i. Plan I shall consist of only the following: basic core benefits as set forth in subrule 37.7(2), plus the Medicare Part A deductible, skilled nursing facility care, 100 percent of the Medicare Part B excess charges, basic prescription drug benefit, medically necessary emergency care in a foreign country, and at-home recovery benefit as defined in paragraphs 37.7(3)*"a,""b,""e,""f,""h,"* and *"j,"* respectively. The outpatient prescription drug benefit shall not be included in a 1990 plan sold after December 31, 2005.

j. Plan J shall consist of only the following: basic core benefits as set forth in subrule 37.7(2), plus the Medicare Part A deductible, skilled nursing facility care, Medicare Part B deductible, 100 percent of the Medicare Part B excess charges, extended prescription drug benefit, medically necessary emergency care in a foreign country, preventive medical care, and at-home recovery benefit as defined in paragraphs 37.7(3)*"a,""b,""c,""e,""g,""h,""i,"* and *"j,"* respectively. The outpatient prescription drug benefit shall not be included in a 1990 plan sold after December 31, 2005.

k. High deductible Plan F shall include only the following: 100 percent of covered expenses following the payment of the annual high deductible Plan F deductible. The covered expenses include the basic core benefits as set forth in subrule 37.7(2), plus the Medicare Part A deductible, skilled nursing facility care, the Medicare Part B deductible, 100 percent of the Medicare Part B excess charges, and medically necessary emergency care in a foreign country as defined in paragraphs 37.7(3)*"a,""b,""c,""e,"* and *"h,"* respectively. The annual high deductible Plan F deductible shall consist of out-of-pocket expenses, other than premiums, for services covered by the Plan F policy, and shall be in addition to any other specific benefit deductibles. The annual high deductible Plan F deductible shall be $1,500 for 1998 and 1999, and shall be based on the calendar year. It shall be adjusted annually thereafter by the Secretary to reflect the change in the consumer price index for all urban consumers for the 12-month period ending with August of the preceding year, and rounded to the nearest multiple of $10.

l. High deductible Plan J shall consist of only the following: 100 percent of covered expenses following the payment of the annual high deductible Plan J deductible. The covered expenses include the basic core benefits as set forth in subrule 37.7(2), plus the Medicare Part A deductible, skilled nursing facility care, Medicare Part B deductible, 100 percent of the Medicare Part B excess charges, extended outpatient prescription drug benefit, medically necessary emergency care in a foreign country, preventive medical care benefit, and at-home recovery benefit as defined in paragraphs 37.7(3)*"a,""b,""c,""e,""g,""h,""i,"* and *"j,"* respectively. The annual high deductible Plan J deductible shall consist of out-of-pocket expenses, other than premiums, for services covered by the Medicare supplement Plan J policy, and shall be in addition to any other specific benefit deductibles. The annual deductible shall be $1,500 for 1998 and 1999, and shall be based on a calendar year. It shall be adjusted annually thereafter by the Secretary to reflect the change in the consumer price index for all urban consumers for the 12-month period ending with August of the preceding year, and rounded to the nearest multiple of $10. The outpatient prescription drug benefit shall not be included in a 1990 plan sold after December 31, 2005.

m. Plan K shall consist of the following:

(1) Coverage of 100 percent of the Part A hospital coinsurance amount for each day used from the sixty-first day through the ninetieth day in any Medicare benefit period;

(2) Coverage of 100 percent of the Part A hospital coinsurance amount for each Medicare lifetime inpatient reserve day used from the ninety-first day through the one hundred fiftieth day in any Medicare benefit period;

(3) Upon exhaustion of the Medicare hospital inpatient coverage, including the lifetime reserve days, coverage of 100 percent of the Medicare Part A eligible expenses for hospitalization paid at the applicable PPS rate, or other appropriate Medicare standard of payment, subject to a lifetime maximum benefit of an additional 365 days. The provider shall accept the issuer's payment in full and may not bill the covered individual for any balance;

(4) Medicare Part A deductible: coverage for 50 percent of the Medicare Part A inpatient hospital deductible amount per benefit period until the out-of-pocket limitation is met as described in subparagraph 37.7(4)*"m"*(10);

(5) Skilled nursing facility care: coverage for 50 percent of the coinsurance amount for each day used from the twenty-first day through the one hundredth day in a Medicare benefit period for post-hospital skilled nursing facility care eligible under Medicare Part A until the out-of-pocket limitation is met as described in subparagraph 37.7(4)*"m"*(10);

(6) Hospice care: coverage for 50 percent of cost sharing for all Part A Medicare-eligible expenses and respite care until the out-of-pocket limitation is met as described in subparagraph 37.7(4)*"m"*(10);

(7) Coverage for 50 percent, under Medicare Part A or B, of the reasonable cost of the first three pints of blood (or equivalent quantities of packed red blood cells, as defined under federal regulations) unless replaced in accordance with federal regulations until the out-of-pocket limitation is met as described in subparagraph 37.7(4)*"m"*(10);

(8) Except for coverage provided in subparagraph 37.7(4)*"m"*(9), coverage for 50 percent of the cost sharing otherwise applicable under Medicare Part B after the covered individual pays the Part B deductible until the out-of-pocket limitation is met as described in subparagraph 37.7(4)*"m"*(10);

(9) Coverage of 100 percent of the cost sharing for Medicare Part B preventive services after the covered individual pays the Part B deductible; and

(10) Coverage of 100 percent of all cost sharing under Medicare Parts A and B for the balance of the calendar year after the individual has reached the out-of-pocket limitation on annual expenditures under Medicare Parts A and B of $4,000 in 2006, indexed each year by the appropriate inflation adjustment specified by the Secretary.

n. Plan L shall consist of the following:

(1) The benefits described in subparagraphs 37.7(4)*"m"*(1), (2), (3), and (9);

(2) The benefits described in subparagraphs 37.7(4)*"m"*(4), (5), (6), (7) and (8), but substituting 75 percent for 50 percent in each subparagraph; and

(3) The benefit described in paragraph 37.7(4)*"m"*(10), but substituting $2,000 for $4,000.

37.7(5) *Elements required in Medicare supplement plans mandated by the MMA.* The 1990 plans mandated by the MMA, Plans K and L, shall include the benefits described for each plan, as follows:

a. Plan K mandated by the MMA shall consist of only those benefits described in paragraph 37.7(4)*"m."*

b. Plan L mandated by the MMA shall consist of only those benefits described in paragraph 37.7(4)*"n."*

37.7(6) *New or innovative benefits.* An issuer may, with the prior approval of the commissioner, offer policies or certificates with new or innovative benefits in addition to the benefits provided in a policy or certificate that otherwise complies with the applicable standards. The new or innovative benefits may include benefits that are appropriate to Medicare supplement insurance, new or innovative, not otherwise available, cost-effective, and offered in a manner which is consistent with the goal of simplification of Medicare supplement policies. After December 31, 2005, the innovative benefit shall not include an outpatient prescription drug benefit.

[**ARC 4394C**, IAB 4/10/19, effective 5/15/19]

191—37.8(514D) Benefit standards for 2010 standardized Medicare supplement benefit plan policies or certificates issued for delivery with an effective date for coverage on or after June 1, 2010 (2010 plans). The following standards are applicable to all Medicare supplement policies or certificates delivered or issued for delivery in this state with an effective date for coverage on or after June 1, 2010. No policy or certificate was to be advertised, solicited, delivered, or issued for delivery in this state as a Medicare supplement policy or certificate during that time period unless it complied with the benefit standards set forth in this rule. No issuer may offer any 1990 standardized Medicare supplement benefit plan for sale on or after June 1, 2010. Benefit standards applicable to Medicare supplement policies and certificates issued before June 1, 2010, remain subject to the requirements of rule 191—37.6(514D) or 191—37.7(514D).

37.8(1) *General standards.* The following standards apply to 2010 plans and are in addition to all other requirements of this chapter.

a. Combinations of benefits other than standard not allowed. No groups, packages or combinations of Medicare supplement benefits other than those listed in this rule shall be offered for sale in this state, except as may be permitted in subrule 37.8(5) and rule 191—37.20(514D).

b. Uniformity and conformity. All 2010 plans shall be uniform in structure, language, designation and format to the standardized benefit plans listed in subrule 37.8(4), and shall conform to the definitions in rules 191—37.3(514D) and 191—37.4(514D). Each benefit plan shall be structured in accordance with the format provided in subrules 37.8(2), 37.8(3) and 37.8(4), or in the case of Plan K or L, each benefit plan shall be structured in accordance with the format provided in paragraph 37.8(4)*"h"* or *"i."* Each plan shall list the benefits in the order shown. For purposes of this rule, "structure, language, and format" means style, arrangement and overall content of a benefit.

c. Other designations may be used. An issuer may use, in addition to the benefit plan designations required in paragraph 37.8(1)*"b,"* other designations to the extent permitted by law.

d. Preexisting conditions. A 2010 plan shall not exclude or limit benefits for losses incurred more than six months from the effective date of coverage because the losses involved a preexisting condition. The 2010 plan may not define a preexisting condition more restrictively than a condition for which medical advice was given or treatment was recommended by or received from a physician within six months before the effective date of coverage.

e. Sickness same as accident. A 2010 plan shall not indemnify against losses resulting from sickness on a different basis than losses resulting from accidents.

f. Automatic change of cost sharing. A 2010 plan shall provide that benefits designed to cover cost-sharing amounts under Medicare will be changed automatically to coincide with any changes in the applicable Medicare deductible, copayment, or coinsurance amounts. Premiums may be modified to correspond with such changes.

g. Termination of coverage of spouse. No 2010 plan shall provide for termination of coverage of a spouse solely because of the occurrence of an event specified for termination of coverage of the named insured or group member, other than the nonpayment of premium.

h. Guaranteed renewability. Each 2010 plan shall be guaranteed renewable.

(1) The issuer shall not cancel or nonrenew the policy or certificate solely on the ground of health status of the covered individual.

(2) The issuer shall not cancel or nonrenew the 2010 plan for any reason other than nonpayment of premium or material misrepresentation.

(3) If a group 2010 plan is terminated by the group policyholder and is not replaced as provided under subparagraph 37.8(1)*"h"*(5), the issuer shall offer covered individuals a conversion opportunity to an individual 2010 plan which, at the option of the covered individual, either:

1. Provides for continuation of the benefits contained in the group 2010 plan; or

2. Provides for benefits that otherwise meet the requirements of this subrule.

(4) If a covered individual under a group 2010 plan terminates membership in the group, the issuer shall:

1. Offer the covered individual the conversion opportunity described in subparagraph 37.8(1)*"h"*(3); or

2. At the option of the group policyholder, offer the covered individual continuation of coverage under the group 2010 plan.

(5) If a group 2010 plan is replaced by another group Medicare supplement policy purchased by the same group policyholder, the issuer of the replacement group Medicare supplement policy shall offer coverage under the replacement group Medicare supplement policy to all covered individuals of the replaced group 2010 plan on the effective date of termination of the replaced group 2010 plan. Coverage under the replacement group Medicare supplement policy shall not result in any exclusion for any covered individual's preexisting conditions that would have been covered under the replaced group 2010 plan.

i. Termination involving continuous loss. Termination of a 2010 plan policy or certificate shall be without prejudice to any continuous loss which commenced while the policy or certificate was in force, but the extension of benefits beyond the period during which the policy or certificate was in force may be conditioned upon the continuous total disability of the covered individual, limited to the duration of the policy or certificate benefit period, if any, or payment of the maximum benefits. Receipt of Medicare Part D benefits will not be considered in determining a continuous loss.

j. Suspension for Title XIX coverage.

(1) A 2010 plan shall provide that benefits and premiums under the policy or certificate shall be suspended at the request of the covered individual for the period (not to exceed 24 months) in which the covered individual has applied for and is determined to be entitled to medical assistance under Title XIX of the Social Security Act, but only if the covered individual notifies the issuer of the policy or certificate within 90 days after the date the covered individual becomes entitled to assistance.

(2) If such suspension occurs and if the covered individual loses entitlement to medical assistance, the policy or certificate shall be automatically reinstituted effective as of the date of termination of entitlement if the covered individual provides notice of loss of entitlement within 90 days after the date of loss and pays the premium attributable to the period, effective as of the date of termination of entitlement.

(3) Each 2010 plan shall provide that benefits and premiums under the 2010 plan shall be suspended (for any period that may be provided by federal regulation) at the request of the covered individual if the covered individual is entitled to benefits under Section 226(b) of the Social Security Act and is covered under a group health plan as defined in Section 1862(b)(1)(A)(v) of the Social Security Act. If suspension occurs and if the covered individual loses coverage under the group health plan, the 2010 plan policy or certificate shall be automatically reinstituted effective as of the date of loss of coverage if the covered individual provides notice to the issuer of loss of coverage within 90 days after the date of the loss and pays the premium attributable to the period, effective as of the date of termination of such entitlement.

(4) Reinstitution of coverage as described in subparagraphs 37.8(1)*"j"*(2) and (3):

1. Shall not provide for any waiting period with respect to treatment of preexisting conditions;

2. Shall provide for resumption of coverage that is substantially equivalent to coverage in effect before the date of suspension; and

3. Shall provide for classification of premiums on terms at least as favorable to the covered individual as the premium classification terms that would have applied to the covered individual had the coverage not been suspended.

37.8(2) *Standards for basic core benefits common to 2010 standardized Medicare supplement benefit Plans A, B, C, D, F, F with high deductible, G, M, and N (2010 basic core benefits).*

a. Availability of basic core benefits required. Every issuer of 2010 plans shall make available to each prospective covered individual a 2010 plan including only the following 2010 basic core benefits. An issuer may make available to a prospective covered individual any of the issuer's other Medicare supplement benefit plans in addition to the 2010 plan of basic core benefits, but not in lieu thereof.

b. When issuer must make certain plans available. If an issuer makes available any of the additional benefits described in subrule 37.8(3) or offers standardized benefit Plans K or L (as described in paragraphs 37.8(4)*"h"* and *"i"*), then the issuer shall make available to each prospective covered individual, in addition to a policy form or certificate form with only the 2010 plan basic core benefits as set forth in paragraph 37.8(2)*"c,"* a policy form or certificate form containing either standardized

benefit Plan C (as described in paragraph 37.8(4)*"c"*) or a standardized benefit Plan F (as described in paragraph 37.8(4)*"e"*).

c. *2010 plan basic core benefits.* The 2010 plan basic core benefits shall include the following:

(1) Hospitalization days 61 through 90: coverage of Part A Medicare-eligible expenses for hospitalization, to the extent not covered by Medicare, from the sixty-first day through the ninetieth day in any Medicare benefit period;

(2) Hospitalization for reserve days: coverage of Part A Medicare-eligible expenses incurred for hospitalization to the extent not covered by Medicare for each Medicare lifetime inpatient reserve day used;

(3) Hospitalization for additional 365 days: upon exhaustion of the Medicare hospital inpatient coverage, including the lifetime reserve days, coverage of 100 percent of the Medicare Part A eligible expenses for hospitalization paid at the applicable PPS rate, or other appropriate Medicare standard of payment, subject to a lifetime maximum benefit of an additional 365 days. Medicare requires that the provider shall accept the issuer's payment as payment in full and that the provider may not bill the covered individual for any balance;

(4) Blood: coverage under Medicare Parts A and B for the reasonable cost of the first three pints of blood (or equivalent quantities of packed red blood cells, as defined under federal regulations) unless replaced in accordance with federal regulations;

(5) Coinsurance: coverage for the coinsurance amount or, in the case of hospital outpatient department services paid under a PPS, the copayment amount of Medicare-eligible expenses under Part B regardless of hospital confinement, subject to the Medicare Part B deductible; and

(6) Hospice care: coverage of cost sharing for all Part A Medicare-eligible hospice care and respite care expenses.

37.8(3) *Standards for 2010 plan additional benefits.* The following additional benefits shall be included in 2010 plan Plans B, C, D, F, F with high deductible, G, M, and N as provided by subrule 37.8(4):

a. Medicare Part A deductible: coverage for 100 percent of the Medicare Part A inpatient hospital deductible amount per benefit period;

b. Medicare Part A deductible: coverage for 50 percent of the Medicare Part A inpatient hospital deductible amount per benefit period;

c. Skilled nursing facility care: coverage for the actual billed charges up to the coinsurance amount from the twenty-first day through the one hundredth day in a Medicare benefit period for post-hospital skilled nursing facility care eligible under Medicare Part A;

d. Medicare Part B deductible: coverage for 100 percent of the Medicare Part B deductible amount per calendar year regardless of hospital confinement;

e. One hundred percent of the Medicare Part B excess charges: coverage for all of the difference between the actual Medicare Part B charges as billed, not to exceed any charge limitation established by the Medicare program or state law, and the Medicare-approved Part B charge; and

f. Medically necessary emergency care in a foreign country: coverage to the extent not covered by Medicare for 80 percent of the billed charges for Medicare-eligible expenses for medically necessary emergency hospital, physician and medical care received in a foreign country, which care would have been covered by Medicare if provided in the United States and which care began during the first 60 consecutive days of each trip outside the United States, subject to a calendar year deductible of $250 and a lifetime maximum benefit of $50,000. For purposes of this benefit, "emergency care" shall mean care needed immediately because of an injury or an illness of sudden and unexpected onset.

37.8(4) *Elements required in standardized 2010 Medicare supplement benefit plans.* The 2010 plans shall include the benefits, as described for each plan, as follows:

a. Plan A shall include only the following: the basic core benefits as set forth in subrule 37.8(2).

b. Plan B shall include only the following: the basic core benefits as set forth in subrule 37.8(2), plus 100 percent of the Medicare Part A deductible as defined in paragraph 37.8(3)*"a."*

c. Plan C shall include only the following: the basic core benefits as set forth in subrule 37.8(2), plus 100 percent of the Medicare Part A deductible, skilled nursing facility care, 100 percent of the

Medicare Part B deductible, and medically necessary emergency care in a foreign country as defined in paragraphs 37.8(3)*"a," "c," "d,"* and *"f,"* respectively.

d. Plan D shall include only the following: the basic core benefits as set forth in subrule 37.8(2), plus 100 percent of the Medicare Part A deductible, skilled nursing facility care, and medically necessary emergency care in a foreign country as defined in paragraphs 37.8(3)*"a," "c,"* and *"f,"* respectively.

e. Plan F shall include only the following: the basic core benefits as set forth in subrule 37.8(2), plus 100 percent of the Medicare Part A deductible, skilled nursing facility care, 100 percent of the Medicare Part B deductible, 100 percent of the Medicare Part B excess charges, and medically necessary emergency care in a foreign country as defined in paragraphs 37.8(3)*"a," "c," "d," "e,"* and *"f,"* respectively.

f. Plan F with high deductible.

(1) Plan F with high deductible shall include only the following:

1. One hundred percent of covered expenses following the payment of the annual deductible set forth in subparagraph 37.8(4)*"f"*(2).

2. The basic core benefits as set forth in subrule 37.8(2), plus 100 percent of the Medicare Part A deductible, skilled nursing facility care, 100 percent of the Medicare Part B deductible, 100 percent of the Medicare Part B excess charges, and medically necessary emergency care in a foreign country as defined in paragraphs 37.8(3)*"a," "c," "d," "e,"* and *"f,"* respectively.

(2) The annual deductible in Plan F with high deductible shall consist of out-of-pocket expenses, other than premiums, for services covered by (regular) Plan F, and shall be in addition to any other specific benefit deductibles. The basis for the deductible shall be $1,500 and shall be adjusted annually from 1999 by the Secretary to reflect the change in the consumer price index for all urban consumers for the 12-month period ending with August of the preceding year, and rounded to the nearest multiple of $10.

g. Plan G shall include only the following: the core benefits as set forth in subrule 37.8(2), plus 100 percent of the Medicare Part A deductible, skilled nursing facility care, 100 percent of the Medicare Part B excess charges, and medically necessary emergency care in a foreign country as defined in paragraphs 37.8(3)*"a," "c," "e,"* and *"f,"* respectively.

h. Plan K is mandated by the MMA and shall include only the following:

(1) Medicare Part A hospital coinsurance from the sixty-first day through the ninetieth day: coverage of 100 percent of the Part A hospital coinsurance amount for each day used from the sixty-first day through the ninetieth day in any Medicare benefit period;

(2) Medicare Part A hospital coinsurance from the ninety-first day through the one hundred fiftieth day: coverage of 100 percent of the Part A hospital coinsurance amount for each Medicare lifetime inpatient reserve day used from the ninety-first day through the one hundred fiftieth day in any Medicare benefit period;

(3) Medicare Part A hospitalization after lifetime reserve days are exhausted: upon exhaustion of the Medicare hospital inpatient coverage, including the lifetime reserve days, coverage of 100 percent of the Medicare Part A eligible expenses for hospitalization paid at the applicable PPS rate, or other appropriate Medicare standard of payment, subject to a lifetime maximum benefit of an additional 365 days. The provider shall accept the issuer's payment as payment in full and may not bill the covered individual for any balance;

(4) Medicare Part A deductible: coverage for 50 percent of the Medicare Part A inpatient hospital deductible amount per benefit period until the out-of-pocket limitation is met as described in subparagraph 37.8(4)*"h"*(10);

(5) Skilled nursing facility care: coverage for 50 percent of the coinsurance amount for each day used from the twenty-first day through the one hundredth day in a Medicare benefit period for post-hospital skilled nursing facility care eligible under Medicare Part A until the out-of-pocket limitation is met as described in subparagraph 37.8(4)*"h"*(10);

(6) Hospice care: coverage for 50 percent of cost sharing for all Medicare Part A eligible expenses and respite care until the out-of-pocket limitation is met as described in subparagraph 37.8(4)*"h"*(10);

(7) Blood: coverage for 50 percent, under Medicare Part A or B, of the reasonable cost of the first three pints of blood (or equivalent quantities of packed red blood cells, as defined under federal regulations) unless replaced in accordance with federal regulations until the out-of-pocket limitation is met as described in subparagraph 37.8(4)*"h"*(10);

(8) Medicare Part B cost sharing: except for coverage provided in subparagraph 37.8(4)*"h"*(9), coverage for 50 percent of the cost sharing otherwise applicable under Medicare Part B after the covered individual pays the Part B deductible until the out-of-pocket limitation is met as described in subparagraph 37.8(4)*"h"*(10);

(9) Medicare Part B preventive services: coverage of 100 percent of the cost sharing for Medicare Part B preventive services after the covered individual pays the Medicare Part B deductible; and

(10) Cost sharing after out-of-pocket limits reached: coverage of 100 percent of all cost sharing under Medicare Parts A and B for the balance of the calendar year after the individual has reached the out-of-pocket limitation on annual expenditures under Medicare Parts A and B of $4,000 in 2006, indexed each year by the appropriate inflation adjustment specified by the Secretary.

i. Plan L is mandated by the MMA and shall include only the following:

(1) The benefits described in subparagraphs 37.8(4)*"h"*(1), (2), (3) and (9);

(2) The benefits described in subparagraphs 37.8(4)*"h"*(4), (5), (6), (7) and (8), but substituting 75 percent for 50 percent; and

(3) The benefit described in subparagraph 37.8(4)*"h"*(10), but substituting $2,000 for $4,000.

j. Plan M shall include only the following: the basic core benefits as set forth in subrule 37.8(2), plus 50 percent of the Medicare Part A deductible, skilled nursing facility care, and medically necessary emergency care in a foreign country as defined in paragraphs 37.8(3)*"b,""c,"* and *"f,"* respectively.

k. Plan N shall include only the following: the basic core benefits as set forth in subrule 37.8(2), plus 100 percent of the Medicare Part A deductible, skilled nursing facility care, and medically necessary emergency care in a foreign country as defined in paragraphs 37.8(3)*"a,""c,"* and *"f,"* respectively, with copayments in the following amounts:

(1) The lesser of $20 or the Medicare Part B coinsurance or copayment for each covered provider office visit (including visits to medical specialists); and

(2) The lesser of $50 or the Medicare Part B coinsurance or copayment for each covered emergency room visit; however, this copayment shall be waived if the covered individual is admitted to any hospital and the emergency visit is subsequently covered as a Medicare Part A expense.

37.8(5) *New or innovative benefits.* An issuer may, with the prior approval of the commissioner, offer policies or certificates with new or innovative benefits, in addition to the standardized benefits provided in a policy or certificate that otherwise complies with the applicable standards. The new or innovative benefits shall include only benefits that are appropriate to Medicare supplement insurance, are new or innovative, are not otherwise available, and are cost-effective. Approval of new or innovative benefits must not adversely impact the goal of Medicare supplement simplification. New or innovative benefits shall not include an outpatient prescription drug benefit. New or innovative benefits shall not be used to change or reduce benefits, including a change of any cost-sharing provision, in any standardized plan.

[**ARC 4394C**, IAB 4/10/19, effective 5/15/19]

191—37.9(514D) Standard Medicare supplement benefit plans for 2020 standardized Medicare supplement benefit plan policies or certificates issued for delivery to individuals newly eligible for Medicare on or after January 1, 2020. The Medicare Access and CHIP Reauthorization Act of 2015 (MACRA) requires that the following standards are applicable to all Medicare supplement policies or certificates delivered or issued for delivery in this state to individuals newly eligible for Medicare on or after January 1, 2020. No policy or certificate that provides coverage of the Medicare Part B deductible may be advertised, solicited, delivered or issued for delivery in this state as a Medicare supplement policy or certificate to individuals newly eligible for Medicare on or after January 1, 2020. All policies must comply with the following benefit standards. Benefit plan standards applicable to Medicare supplement

policies and certificates issued to individuals eligible for Medicare before January 1, 2020, remain subject to the requirements of rules 191—37.6(514D), 191—37.7(514D) and 191—37.8(514D).

37.9(1) *Benefit requirements.* The standards and requirements of rule 191—37.8(514D) shall apply to all Medicare supplement policies or certificates delivered or issued for delivery to individuals newly eligible for Medicare on or after January 1, 2020, with the following exceptions:

a. Plan C is redesignated as Plan D and shall provide the benefits contained in paragraph 37.8(4)*"c"* but shall not provide coverage for 100 percent or any portion of the Medicare Part B deductible.

b. Plan F is redesignated as Plan G and shall provide the benefits contained in paragraph 37.8(4)*"e"* but shall not provide coverage for 100 percent or any portion of the Medicare Part B deductible.

c. Plans C, F, and F with high deductible may not be offered to individuals newly eligible for Medicare on or after January 1, 2020.

d. Plan F with high deductible is redesignated as Plan G with high deductible and shall provide the benefits contained in paragraph 37.8(4)*"f,"* but shall not provide coverage for 100 percent or any portion of the Medicare Part B deductible; provided further that the Medicare Part B deductible paid by the covered individual shall be considered an out-of-pocket expense in meeting the annual high deductible.

e. The reference to Plan C or F contained in paragraph 37.8(2)*"b"* is deemed a reference to Plan D or G for purposes of this rule.

37.9(2) *Applicability to certain newly eligible individuals.* This rule applies only to individuals who are newly eligible for Medicare on or after January 1, 2020, by reason of:

a. Attaining age 65 on or after January 1, 2020; or

b. Entitlement to benefits under Medicare Part A pursuant to Section 226(b) or 226A of the Social Security Act, or who are deemed to be eligible for benefits under Section 226(a) of the Social Security Act on or after January 1, 2020.

37.9(3) *Guaranteed issue for eligible persons.* For purposes of rule 191—37.36(514D), in the case of any individual newly eligible for Medicare on or after January 1, 2020, any reference to a Medicare supplement Plan C or F (including Plan F with high deductible) shall be deemed to be a reference to Medicare supplement Plan D or G (including Plan G with high deductible), respectively, that meets the requirements of this rule.

37.9(4) *Offer of redesignated plans to individuals other than newly eligible.* On or after January 1, 2020, the standardized benefit plans described in paragraph 37.9(1)*"d"* may be offered to any individual who was eligible for Medicare prior to January 1, 2020, in addition to the standardized plans described in subrule 37.8(4).

[**ARC 4394C**, IAB 4/10/19, effective 5/15/19]

191—37.10 to **37.19** Reserved.

191—37.20(514D) Medicare Select policies and certificates.

37.20(1) *Applicability of this rule.*

a. Rule 191—37.20(514D) shall apply to Medicare Select policies and certificates, as defined in this rule.

b. No policy or certificate may be advertised as a Medicare Select policy or certificate unless it meets the requirements of this rule.

37.20(2) *Definitions.* For the purposes of this rule, in addition to the definitions of Iowa Code section 514D.2, and of rules 191—37.3(514D) and 191—37.4(514D), the following definitions shall apply:

"Complaint" means any dissatisfaction expressed by a covered individual concerning a Medicare Select issuer or a Medicare Select network provider.

"Grievance" means dissatisfaction expressed in writing by a covered individual under a Medicare Select policy or certificate with the administration, claims practices, or provision of services concerning a Medicare Select issuer or its Medicare Select network providers.

"Medicare Select issuer" means an issuer offering, or seeking to offer, a Medicare Select policy or certificate.

"Medicare Select network provider" means a provider of health care, or a group of providers of health care, which has entered into a written agreement with a Medicare Select issuer to provide benefits insured under a Medicare Select policy or certificate.

"Medicare Select policy" means a Medicare supplement individual policy that contains a restricted network provision; *"Medicare Select certificate"* means an individual's certificate of coverage under a group Medicare supplement policy that contains restricted network provisions; and *"Medicare Select policy or certificate"* means either a Medicare Select policy or a Medicare Select certificate.

"Restricted network provision" means any provision in a Medicare Select policy or certificate which conditions the payment of benefits, in whole or in part, on the use of Medicare Select network providers belonging to a network specified by the Medicare Select policy or certificate.

"Service area" means the geographic area, approved by the commissioner as part of the Medicare Select issuer's plan of operation, within which the Medicare Select issuer is authorized to offer a Medicare Select policy or certificate.

37.20(3) *Authorization to offer Medicare Select policies or certificates.* The commissioner may authorize an issuer to offer a Medicare Select policy or certificate, pursuant to this rule and Section 4358 of the Omnibus Budget Reconciliation Act (OBRA) of 1990, if the commissioner finds, upon review and approval of the plan of operation filed in accordance with subrule 37.20(5), that the issuer has satisfied all of the requirements of this chapter.

37.20(4) *Prohibition against offering Medicare Select policies or certificates without approved plan of operation.* A Medicare Select issuer shall not issue a Medicare Select policy or certificate in this state until its plan of operation has been approved by the commissioner, and the commissioner has authorized the issuer to offer Medicare Select policies or certificates, pursuant to subrule 37.20(3).

37.20(5) *Medicare Select issuer shall file a proposed plan of operation.* An issuer shall file a proposed plan of operation with the commissioner in a format prescribed by the commissioner and receive approval of the proposed plan from the commissioner prior to offering Medicare Select policies or certificates. The plan of operation shall contain at a minimum all of the information required by paragraphs 37.20(5)*"a"* through *"g"* as follows:

a. Evidence that all services covered under the Medicare Select policies or certificates that are subject to restricted network provisions are available and accessible through Medicare Select network providers, including a demonstration that the issuer has met all of the conditions in subparagraphs 37.20(5)*"a"*(1) through (5) as follows:

(1) Such services can be provided by Medicare Select network providers with reasonable promptness with respect to geographic location, hours of operation and after-hours care. The hours of operation and availability of after-hours care shall reflect usual practice in the local area. Geographic availability shall reflect the usual travel times within the community.

(2) The number of Medicare Select network providers in the service area is sufficient, with respect to current and expected covered individuals, either:

1. To adequately deliver all services that are subject to a restricted network provision; or
2. To make appropriate referrals.

(3) There are written agreements with Medicare Select network providers describing specific responsibilities.

(4) Emergency care is available 24 hours per day and seven days per week.

(5) In the case of covered services that are subject to a restricted network provision and are provided on a prepaid basis, there are written agreements with Medicare Select network providers prohibiting such Medicare Select network providers from billing or otherwise seeking reimbursement from or recourse against any covered individual under a Medicare Select policy or certificate. This paragraph shall not apply to supplemental charges or coinsurance amounts as stated in the Medicare Select policy or certificate.

b. A statement or map providing a clear description of the service area.

c. A description of the grievance procedure to be utilized, that is compliant with subrule 37.20(11).

d. A description of the quality assurance program, including:

(1) The formal organizational structure;

(2) The written criteria for selection, retention and removal of Medicare Select network providers; and

(3) The procedures for evaluating quality of care provided by Medicare Select network providers, and the process to initiate corrective action when warranted.

e. A list and description, by specialty, of the Medicare Select network providers.

f. Copies of the written information proposed to be used by the Medicare Select issuer to comply with subrule 37.20(9).

g. Any other information requested by the commissioner.

37.20(6) *Filing of changes and updates to Medicare Select issuer's plan of operations.*

a. A Medicare Select issuer shall file any proposed changes to the plan of operation, except for changes to the list of Medicare Select network providers, with the commissioner prior to implementing such changes. Such changes shall be considered approved by the commissioner after 30 days unless specifically disapproved.

b. An updated list of Medicare Select network providers shall be filed with the commissioner at least quarterly.

37.20(7) *Use of restricted network provision prohibited under certain circumstances.* A Medicare Select policy or certificate issuer shall not apply a restricted network provision to limit a payment amount for covered services provided by providers that are not restricted network providers if:

a. The services are for symptoms requiring emergency care or are immediately required for an unforeseen illness, injury or a condition; and

b. It is not reasonable to obtain such services through a Medicare Select network provider.

37.20(8) *Full coverage for services required under certain circumstances.* A Medicare Select policy or certificate shall provide payment for full coverage under the Medicare Select policy for covered services that are not available through Medicare Select network providers.

37.20(9) *Content of required disclosure.* A Medicare Select issuer shall make full and fair disclosure in writing of the provisions, restrictions, and limitations of the Medicare Select policy or certificate to each applicant. This disclosure shall include at a minimum all of the information described in paragraphs 37.20(9)*"a"* through *"g"* as follows:

a. An outline of coverage sufficient to permit the applicant to compare the coverage and premiums of the Medicare Select policy or certificate with:

(1) Other Medicare supplement policies or certificates offered by the Medicare Select issuer; and

(2) Other Medicare Select policies or certificates.

b. A description (including address, telephone number and hours of operation) of the Medicare Select network providers, including primary care physicians, specialty physicians, hospitals and other providers.

c. A description of the restricted network provisions, including payments for coinsurance and deductibles when providers other than Medicare Select network providers are utilized. Except to the extent specified in the Medicare Select policy or certificate, expenses incurred when using out-of-network providers do not count toward the out-of-pocket annual limit contained in Medicare Select Plans K and L.

d. A description of coverage for emergency and urgently needed care and other out-of-service area coverage.

e. A description of limitations on referrals to Medicare Select network providers and to other providers.

f. A description of the covered individual's rights to purchase any other Medicare supplement policy or certificate otherwise offered by the Medicare Select issuer.

g. A description of the Medicare Select issuer's quality assurance program and grievance procedure.

37.20(10) *Acknowledgment.* Prior to the sale of a Medicare Select policy or certificate, a Medicare Select issuer shall obtain from the applicant a signed and dated form stating that the applicant has received

the information provided pursuant to subrule 37.20(9) and that the applicant understands the restrictions of the Medicare Select policy or certificate.

37.20(11) *Complaint and grievance procedures.* A Medicare Select issuer shall have and use procedures for hearing complaints and resolving written grievances from the covered individuals. Such procedures shall be aimed at mutual agreement for settlement and may include arbitration procedures.

a. The grievance procedure shall be described in the Medicare Select policy or certificate and in the outline of coverage.

b. At the time the Medicare Select policy or certificate is issued, the Medicare Select issuer shall provide detailed information to the covered individual describing how a grievance may be registered with the Medicare Select issuer.

c. The Medicare Select issuer shall consider grievances in a timely manner and shall transmit them to appropriate decision makers who have authority to fully investigate the issue and take corrective action.

d. If a grievance is found to be valid, corrective action shall be taken promptly.

e. All concerned parties shall be notified by the Medicare Select issuer about the results of a grievance.

f. The Medicare Select issuer shall report no later than each March 31 to the commissioner regarding its grievance procedure. The report shall be in a format prescribed by the commissioner and shall contain the number of grievances filed in the prior calendar year and a summary of the subject, nature and resolution of such grievances.

37.20(12) *Opportunity to purchase another policy at time of purchase.* At the time of initial purchase, a Medicare Select issuer shall make available to each applicant for a Medicare Select policy or certificate the opportunity to purchase any Medicare supplement policy or certificate otherwise offered by the Medicare Select issuer.

37.20(13) *Opportunity to purchase another policy after issue.*

a. At the request of a covered individual under a Medicare Select policy or certificate, a Medicare Select issuer shall make available to the covered individual the opportunity to purchase a Medicare supplement policy or certificate offered by the Medicare Select issuer which has comparable or lesser benefits and which does not contain a restricted network provision. The Medicare Select issuer shall make such policies or certificates available without requiring evidence of insurability after the Medicare Select policy or certificate has been in force for six months.

b. For the purposes of this subrule, a Medicare supplement policy or certificate will be considered to have comparable or lesser benefits unless it contains one or more significant benefits not included in the Medicare Select policy or certificate being replaced. For the purposes of this paragraph, a significant benefit means coverage for the Medicare Part A deductible, coverage for at-home recovery services or coverage for Medicare Part B excess charges.

37.20(14) *Continuation of coverage.* Medicare Select policies and certificates shall provide for continuation of coverage in the event the Secretary determines that Medicare Select policies and certificates issued pursuant to this rule should be discontinued due to either the failure of the Medicare Select program to be reauthorized under law or the substantial amendment of the Medicare Select program.

a. Each Medicare Select issuer shall make available to each insured individual under a Medicare Select policy or certificate the opportunity to purchase any Medicare supplement policy or certificate offered by the Medicare Select issuer which has comparable or lesser benefits and which does not contain a restricted network provision. The Medicare Select issuer shall make such policies and certificates available without requiring evidence of insurability.

b. For the purposes of this subrule, a Medicare supplement policy or certificate will be considered to have comparable or lesser benefits unless it contains one or more significant benefits not included in the Medicare Select policy or certificate being replaced. For the purposes of this paragraph, a significant benefit means coverage for the Medicare Part A deductible, coverage for at-home recovery services or coverage for Medicare Part B excess charges.

37.20(15) *Compliance with data requests.* A Medicare Select issuer shall comply with reasonable requests for data made by state or federal agencies, including the U.S. Department of Health and Human Services, for the purpose of evaluating the Medicare Select program.
[**ARC 4394C**, IAB 4/10/19, effective 5/15/19]

191—37.21(514D) Open enrollment.

37.21(1) *Denial of policy for health reason prohibited.* No issuer shall deny or condition the issuance or effectiveness of any Medicare supplement policy or certificate available for sale in this state, or discriminate in the pricing of such a Medicare supplement policy or certificate, because of the health status, claims experience, receipt of health care, or medical condition of an applicant in the case of an application for a Medicare supplement policy or certificate that is submitted prior to or during the six-month period beginning with the first day of the first month in which an individual is both 65 years of age or older and is enrolled for benefits under Medicare Part B. Each Medicare supplement policy and certificate currently available from an issuer shall be made available to all applicants who qualify under this subrule without regard to age.

37.21(2) *When preexisting condition exclusion cannot be applied.*

a. Definition of "continuous period of creditable coverage." For purposes of this subrule, "continuous period of creditable coverage" means the period during which a covered individual was covered by creditable coverage, if during the period of the coverage the covered individual had no breaks in coverage greater than 63 days.

b. No preexisting condition exclusion. If an applicant under subrule 37.21(1) submits an application during the time period referenced in subrule 37.21(1) and, as of the date of application, has had a continuous period of creditable coverage of at least six months, the issuer shall not exclude benefits based on a preexisting condition.

c. Reduced time of preexisting condition exclusion. If the applicant qualifies under subrule 37.21(1) and submits an application during the time period referenced in subrule 37.21(1) and, as of the date of application, has had a continuous period of creditable coverage that is less than six months, the Medicare Select issuer shall reduce the period of any preexisting condition exclusion by the aggregate of the period of creditable coverage applicable to the applicant as of the enrollment date. The Secretary shall specify the manner of the reduction under this subrule.

37.21(3) *When benefits can be excluded because of preexisting condition.* Subrule 37.21(1) shall not be construed, except as provided in rule 191—37.33(514D) or 191—37.36(514D), as preventing the exclusion of benefits under a policy, during the first six months, based on a preexisting condition for which the covered individual received treatment or was otherwise diagnosed during the six months before the coverage became effective.
[**ARC 4394C**, IAB 4/10/19, effective 5/15/19]

191—37.22(514D) Standards for claims payment.

37.22(1) *Compliance with OBRA.* An issuer shall comply with Section 1882(c)(3) of the Social Security Act (as enacted by Section 4081(b)(2)(C) of the Omnibus Budget Reconciliation Act of 1987 (OBRA) 1987, Pub. L. No. 100-203) by:

a. Accepting a notice from an issuer on dually assigned claims submitted by participating providers and suppliers as a claim for benefits in place of any other claim form otherwise required and making a payment determination on the basis of the information contained in that notice;

b. Notifying the participating provider or supplier and the beneficiary of the payment determination;

c. Paying the participating provider or supplier directly;

d. Furnishing, at the time of enrollment, each covered individual with a card listing the policy name, number and a central mailing address to which notices from an issuer may be sent;

e. Paying user fees for claim notices that are transmitted electronically or otherwise; and

f. Providing to the Secretary, at least annually, the issuer's central mailing address to which all claims may be sent by other issuers.

37.22(2) *Certification of compliance with OBRA.* Compliance with the requirements set forth in 37.22(1) shall be certified on the Medicare supplement insurance experience reporting form.
[**ARC 4394C**, IAB 4/10/19, effective 5/15/19]

191—37.23(514D) Loss ratio standards and refund or credit of premium.

37.23(1) *Definitions.* For the purposes of this rule:

"Health care expenses" means expenses of health maintenance organizations associated with the delivery of health care services, which expenses are analogous to incurred losses of issuers.

"Type" means one of the following: an individual policy, a group policy, an individual Medicare Select policy, or a group Medicare Select policy.

37.23(2) *Loss ratio standards.*

a. Calculations.

(1) A Medicare supplement policy form or certificate form shall not be delivered or issued for delivery unless the Medicare supplement policy form or certificate form can be expected, as estimated for the entire period for which rates are computed to provide coverage, to return to covered individuals one of the following amounts in the form of aggregate benefits (not including anticipated refunds or credits) provided under the policy form or certificate form:

1. At least 75 percent of the aggregate amount of premiums earned in the case of group Medicare supplement policies, or

2. At least 65 percent of the aggregate amount of premiums earned in the case of individual Medicare supplement policies.

(2) The percentages in subparagraph 37.23(2)*"a"*(1) are to be calculated on the basis of incurred claims experience or incurred health care expenses where coverage is provided by a health maintenance organization on a service rather than reimbursement basis and earned premiums for such period and in accordance with accepted actuarial principles and practices.

(3) For purposes of subparagraph 37.23(2)*"a"*(2), "incurred health care expenses where coverage is provided by a health maintenance organization" shall not include:

1. Home office and overhead costs;
2. Advertising costs;
3. Commissions and other acquisition costs;
4. Taxes;
5. Capital costs;
6. Administrative costs; and
7. Claims processing costs.

b. Filing demonstration of compliance. All filings of rates and rating schedules shall demonstrate that expected claims in relation to premiums comply with the requirements of this rule when combined with actual experience to date. Filings of rate revisions shall also demonstrate that the anticipated loss ratio over the entire future period for which the revised rates are computed to provide coverage can be expected to meet the appropriate loss ratio standards.

c. Certain direct sales. For purposes of applying paragraph 37.23(2)*"a"* only, policies issued as a result of solicitations of individuals through the mails or by mass media advertising (including both print and broadcast advertising) shall be deemed to be individual policies.

d. Prestandardized plans. For all policies issued prior to January 1, 1992, expected claims in relation to premiums shall meet:

(1) The originally filed anticipated loss ratio when combined with the actual experience from inception;

(2) The appropriate loss ratio requirement from paragraphs "1" and "2" of subparagraph 37.23(1)*"a"*(1) when combined with actual experience beginning with January 1, 1996, to date; and

(3) The appropriate loss ratio requirement from paragraphs "1" and "2" of subparagraph 37.23(1)*"a"*(1) over the entire future period for which rates are computed to provide coverage.

37.23(3) *Refund or credit calculation.*

a. An issuer shall collect and file with the commissioner by May 31 of each year the data contained in the reporting form contained in Appendix A for each type in a standardized Medicare supplement benefit plan (SMSBP).

b. If, on the basis of the experience as reported, the benchmark ratio since inception (Appendix A, ratio 1) exceeds the adjusted experience ratio since inception (Appendix A, ratio 3), then a refund or credit calculation is required. The refund calculation shall be done on a statewide basis for each type in an SMSBP. For purposes of the refund or credit calculation, experience on SMSBP policies issued within the reporting year shall be excluded.

c. For purposes of this rule, for SMSBP policies or certificates issued prior to January 1, 1992, the issuer shall make the refund or credit calculation separately for all individual SMSBP policies (including all group SMSBP policies subject to an individual loss ratio standard when issued) combined and all other group SMSBP policies combined for experience after January 1, 1996. The first report shall be due May 31, 1998.

d. A refund or credit shall be made only when the benchmark loss ratio exceeds the adjusted experience loss ratio and the amount to be refunded or credited exceeds a de minimis level. Such refund shall include interest from the end of the calendar year to the date of the refund or credit at a rate specified by the Secretary, but in no event shall it be less than the average rate of interest for 13-week Treasury notes. A refund or credit against premiums due shall be made by September 30 following the experience year upon which the refund or credit is based.

37.23(4) *Annual filing of premium rates.* An issuer of Medicare supplement policies and certificates issued before or after the effective date of January 1, 1992, in this state shall file annually its rates, rating schedule and supporting documentation including ratios of incurred losses to earned premiums by SMSBP policy duration for approval by the commissioner in accordance with the filing requirements and procedures prescribed by the commissioner.

a. The supporting documentation shall also demonstrate in accordance with actuarial standards of practice using reasonable assumptions that the appropriate loss ratio standards can be expected to be met over the entire period for which rates are computed.

(1) Such demonstration shall exclude active life reserves.

(2) An expected third-year loss ratio which is greater than or equal to the applicable percentage shall be demonstrated for SMSBP policies or certificates in force less than three years.

b. As soon as practicable, but prior to the effective date of enhancements in Medicare benefits, every issuer of Medicare supplement policies or certificates in this state shall file with the commissioner, in accordance with the applicable filing procedures of this state, the following:

(1) Such supporting documents as necessary to justify that the adjustments are appropriate.

1. Appropriate premium adjustments shall be those which:

- Are necessary to produce loss ratios as anticipated for the current premium for the applicable SMSBP policies or certificates;
- Are necessary to produce an expected loss ratio under such SMSBP policies or certificates as will conform with minimum loss ratio standards for SMSBP policies or certificates; and
- Are expected to result in a loss ratio at least as great as that originally anticipated in the rates used to produce current premiums by the issuer for such SMSBP policies or certificates.

2. No premium adjustment which would modify the loss ratio experience under the SMSBP policy other than the adjustments described herein shall be made with respect to an SMSBP policy at any time other than upon its renewal date or anniversary date.

3. If an issuer fails to make premium adjustments acceptable to the commissioner, the commissioner may order premium adjustments, refunds or premium credits deemed necessary to achieve the loss ratio required by this rule.

(2) Any appropriate riders, endorsements or policy forms needed to accomplish the SMSBP policy or certificate modifications necessary to eliminate benefit duplications with Medicare. Such riders, endorsements or policy forms shall provide a clear description of the Medicare supplement benefits provided by the SMSBP policy or certificate.

37.23(5) *Public hearings.* The commissioner may conduct a public hearing to gather information concerning a request by an issuer for an increase in a rate for an SMSBP policy form or certificate form issued before or after the effective date of January 1, 1992, if the experience of the form for the previous reporting period is not in compliance with the applicable loss ratio standard. The determination of compliance is to be made without consideration of any refund or credit for such reporting period. Public notice of such hearing shall be furnished in a manner deemed appropriate by the commissioner.
[**ARC 4394C**, IAB 4/10/19, effective 5/15/19]

191—37.24(514D) Filing and approval of policies and certificates and premium rates.

37.24(1) *Definition.* For the purposes of this rule:

"Type" means one of the following: an individual policy, a group policy, an individual Medicare Select policy, or a group Medicare Select policy.

37.24(2) *Form filing and approval required.* An issuer shall not deliver or issue for delivery a policy or certificate to a resident of this state unless the SMSBP policy form or certificate form has been filed pursuant to rule 191—20.1(505,509,514A,515,515A,515F) and approved by the commissioner.

37.24(3) *MMA requirements to be filed with state of issue.* An issuer shall file any riders or amendments to SMSBP policy or certificate forms to delete outpatient prescription drug benefits as required by the MMA only with the commissioner in the state in which the policy or certificate was issued.

37.24(4) *Rate filing and approval required.* An issuer shall not use or change premium rates for a Medicare supplement policy or certificate unless the rates, rating schedule and supporting documentation have been filed with and approved by the commissioner in accordance with the filing requirements and procedures prescribed by the commissioner.

37.24(5) *One form per type.*

a. Except as provided in paragraph 37.24(5)*"b,"* an issuer shall not file for approval more than one form of a policy or certificate of each type for each SMSBP.

b. An issuer may offer, with the approval of the commissioner, up to four additional policy forms or certificate forms of the same type for the same SMSBP, one for each of the following cases:

(1) The inclusion of new or innovative benefits;

(2) The addition of either direct response or producer marketing methods;

(3) The addition of either guaranteed issue or underwritten coverage;

(4) The offering of coverage to individuals eligible for Medicare by reason of disability.

37.24(6) *Forms to be kept available once approved.*

a. Except as provided in subparagraph 37.24(6)*"a"*(1), an issuer shall continue to make available for purchase any SMSBP policy form or certificate form issued after January 1, 1992, that has been approved by the commissioner. An SMSBP policy form or certificate form shall not be considered to be available for purchase unless the issuer has actively offered it for sale in the previous 12 months.

(1) An issuer may discontinue the availability of an SMSBP policy form or certificate form if the issuer provides to the commissioner in writing its decision at least 30 days prior to discontinuing the availability of the form of the SMSBP policy or certificate. After receipt of the notice by the commissioner, the issuer shall no longer offer for sale the SMSBP policy form or certificate form in this state.

(2) An issuer that discontinues the availability of an SMSBP policy form or certificate form pursuant to subparagraph 37.24(6)*"a"*(1) shall not file for approval of a new SMSBP policy form or certificate form of the same type for the same SMSBP as the discontinued form for a period of five years after the issuer provides notice to the commissioner of the discontinuance. The period of discontinuance may be reduced if the commissioner determines that a shorter period is appropriate.

b. The sale or other transfer of Medicare supplement business to another issuer shall be considered a discontinuance for the purposes of this subrule.

c. A change in the rating structure or methodology shall be considered a discontinuance under paragraph 37.24(6)*"a"* unless the issuer complies with the following requirements:

(1) The issuer provides an actuarial memorandum, in a form and manner prescribed by the commissioner, describing the manner in which the revised rating methodology and resultant rates differ from the existing rating methodology and resultant rates.

(2) The issuer does not subsequently put into effect a change of rates or rating factors that would cause the percentage differential between the discontinued and subsequent rates as described in the actuarial memorandum to change. The commissioner may approve a change to the differential which is in the public interest.

37.24(7) *Experience under forms of same type to be combined for calculations.*

a. Except as provided in paragraph 37.24(7)*"b,"* the experience under all SMSBP policy forms or certificate forms of the same type in an SMSBP shall be combined for purposes of the refund or credit calculation prescribed in rule 191—37.23(514D).

b. Forms assumed under an assumption reinsurance agreement shall not be combined with the experience of other policy or certificate forms for purposes of the refund or credit calculation.

[**ARC 4394C**, IAB 4/10/19, effective 5/15/19]

191—37.25(514D) Permitted compensation arrangements.

37.25(1) *Definition of "compensation."* For purposes of this rule:

"Compensation" includes pecuniary or nonpecuniary remuneration of any kind relating to the sale or renewal of the Medicare supplement or Medicare Select policy or certificate including, but not limited to, bonuses, gifts, prizes, awards and finder's fees.

37.25(2) *Compensation to producer for sales.* An issuer or other entity may provide a commission or other compensation to a producer or other representative for the sale of a Medicare supplement policy or certificate only if the first-year commission or other first-year compensation is no more than 200 percent of the commission or other compensation paid for selling or servicing the Medicare supplement policy or certificate in the second year or period.

37.25(3) *Compensation to producer for renewals.* The commission or other compensation provided in subsequent (renewal) years must be the same as that provided in the second year or period and must be provided for no fewer than five renewal years.

37.25(4) *Compensation for renewals involving replacement.* No issuer or other entity shall provide compensation to its producers and no producer shall receive compensation greater than the renewal compensation payable by the replacing issuer on renewal Medicare supplement policies or certificates if an existing Medicare supplement policy or certificate is replaced.

[**ARC 4394C**, IAB 4/10/19, effective 5/15/19]

191—37.26(514D) Required notice regarding policies or certificates which are not Medicare supplement policies or certificates.

37.26(1) *Issuer required to disclose that a policy is not a Medicare supplement policy.* An issuer of any accident and sickness insurance policy or certificate issued for delivery in this state to a person eligible for Medicare shall notify the insured under the policy that the policy is not a Medicare supplement policy or certificate, if the policy or certificate is not a Medicare supplement policy or certificate.

a. The notice shall either be printed or attached to the first page of the outline of coverage delivered to the insured under the accident and sickness policy or, if no outline of coverage is delivered, to the first page of the policy or certificate delivered to the insured.

b. The notice shall be in no less than 12-point type and shall contain the following language:

"THIS [POLICY OR CERTIFICATE] IS NOT A MEDICARE SUPPLEMENT [POLICY OR CONTRACT]. If you are eligible for Medicare, review the [insert name of most recent version of *2019 Choosing a Medigap Policy: Guide to Health Insurance for People with Medicare*, issued by Centers for Medicare and Medicaid Services] available from the company."

c. The notice requirement of this subrule 37.26(1) shall not apply to an accident and sickness insurance policy or certificate that is a Medicare supplement policy or certificate, a policy issued pursuant to a contract under Section 1876 of the federal Social Security Act (42 U.S.C. Section 1395 et seq.), a disability income policy, or any other policy excepted by rule 191—37.2(514D).

37.26(2) *Issuer required to disclose extent of duplication of Medicare.* When providing an application to persons eligible for Medicare for the health insurance policies or certificates described in subrule 37.26(1), except for policies or certificates excluded by paragraph 37.26(1)*"c,"* issuers shall disclose the extent to which a policy duplicates Medicare. The disclosure shall use the applicable statement in Appendix B and shall be provided as a part of, or together with, the application for the policy or certificate.
[**ARC 4394C**, IAB 4/10/19, effective 5/15/19]

191—37.27(514D) Requirements for application forms and replacement coverage.

37.27(1) *Application to include Appendix C.* Application forms for Medicare supplement policies or certificates shall include in the outline of coverage the "statements and questions for application forms related to duplicate or replacement coverage" set forth in Appendix C, in the order prescribed in Appendix C, designed to elicit the following information, as of the date of the application: whether the applicant currently has a Medicare supplement policy or certificate, a Medicare Advantage policy or certificate, or other Medicaid coverage; whether the applicant has another health insurance policy or certificate in force; or whether the applicant intends a Medicare supplement policy or certificate to replace any other accident and sickness policy or certificate presently in force. An additional page or form containing such questions and statements and the applicant's responses may be used, but it must be signed by the applicant and producer, attached to the application, and kept together with the issuer's records.

37.27(2) *List of policies sold to applicant.* Producers shall list on the form or on an attachment to the form of Appendix C any other health insurance policies they have sold to the applicant, including the following:

a. Policies sold which are still in force.

b. Policies sold in the prior five years which are no longer in force.

37.27(3) *Direct response sales.* In the case of a direct response issuer, a copy of the application or additional page or form, signed by the applicant and acknowledged by the issuer, shall be returned to the applicant by the issuer upon delivery of the policy and shall include the notice regarding replacement of Medicare supplement coverage required of direct response issuers by subrule 37.27(4).

37.27(4) *Required notice regarding replacement.* Upon determining that a sale will involve replacement of Medicare supplement coverage, any issuer, other than a direct response issuer, or its producer, shall furnish the applicant, prior to issuance or delivery of the Medicare supplement policy or certificate, a notice regarding replacement of Medicare supplement coverage. The notice shall be provided in the format described in subrule 37.27(5). One copy of such notice signed by the applicant and the producer, except where the coverage is sold without a producer, shall be provided to the applicant, and an additional signed copy shall be retained by the issuer. A direct response issuer shall deliver to the applicant at the time of the issuance of the policy the notice regarding replacement of Medicare supplement coverage.

37.27(5) *Required format of notice regarding replacement.* The notice required by subrule 37.27(4) for an issuer shall be provided in substantially the form and language of the Notice to Applicant regarding Replacement of Medicare Supplement Insurance or Medicare Advantage, as set forth in Appendix D, in no less than 12-point type. Statements 1 and 2 of the replacement notice of Appendix D (applicable to preexisting conditions) may be deleted by an issuer if the replacement does not involve application of a new preexisting condition limitation.
[**ARC 4394C**, IAB 4/10/19, effective 5/15/19]

191—37.28(514D) Required disclosure provisions.

37.28(1) *General rules.*

a. A Medicare supplement policy or certificate shall include renewal or continuation provisions. The language or specifications of such provisions shall be consistent with the type of Medicare supplement policy issued. Such provisions shall be appropriately captioned and shall appear on the first page of the Medicare supplement policy or certificate, and shall include any reservations by the issuer of the right to change premiums and any automatic renewal premium increases based on the covered individual's age.

b. Except for a rider or an endorsement by which the issuer effectuates a request made in writing by the covered individual, exercises a specifically reserved right under a Medicare supplement policy or certificate, or is required to reduce or eliminate benefits to avoid duplication of Medicare benefits, any rider or endorsement added to a Medicare supplement policy or certificate after the date the policy or certificate is issued, or at reinstatement or renewal, which reduces or eliminates benefits or coverage in the policy or certificate shall require a signed acceptance by the covered individual. After the date of issue of a Medicare supplement policy or certificate, any rider or endorsement which increases benefits or coverage with a concomitant increase in premium during the policy term shall be agreed to in writing signed by the covered individual, unless the benefits are required by the minimum standards for Medicare supplement policies or certificates, or if the increased benefits or coverage is required by law. Where a separate additional premium is charged for benefits provided in connection with a rider or endorsement, such premium charge shall be set forth in the Medicare supplement policy or certificate.

c. Medicare supplement policies or certificates shall not provide for the payment of benefits based on standards described as "usual and customary," "reasonable and customary" or words of similar import.

d. If a Medicare supplement policy or certificate contains any limitations with respect to preexisting conditions, such limitations shall appear as a separate paragraph of the Medicare supplement policy or certificate and be labeled as "Preexisting Condition Limitations."

e. A Medicare supplement policy or certificate shall have a notice prominently printed on the first page of the policy or certificate, or attached thereto, stating in substance that the covered individual shall have the right to return the Medicare supplement policy or certificate within 30 days of its delivery and to have the premium refunded if, after examination of the Medicare supplement policy or certificate, the covered individual is not satisfied for any reason.

f. An issuer of an accident or sickness policy or certificate which provides hospital or medical expense coverage on an expense-incurred or indemnity basis to an individual eligible for Medicare shall provide to any applicant for such policy or certificate the most recent version of *Choosing a Medigap Policy: Guide to Health Insurance for People with Medicare*, issued by Centers for Medicare and Medicaid Services ("guide"), developed jointly by the National Association of Insurance Commissioners and CMS, using the same language, format, type size (no less than 12 point), type-proportional spacing, bold characters and line spacing. Delivery of the guide shall be made whether or not such policy or certificate was advertised, solicited or issued as a Medicare supplement policy or certificate as defined in this chapter. Except in the case of a direct response issuer, delivery of the guide shall be made to the applicant at the time of application and acknowledgment of receipt of the guide shall be obtained by the issuer. A direct response issuer shall deliver the guide to the applicant upon request but not later than at the time the Medicare supplement policy is delivered.

37.28(2) *Notice requirements.*

a. As soon as practicable, but no later than 30 days prior to the annual effective date of any Medicare benefit changes, an issuer shall notify its covered individuals of modifications it has made to Medicare supplement policies or certificates in a format acceptable to the commissioner. The notice shall:

(1) Include a description of revisions to the Medicare program and a description of each modification made to the coverage provided under the Medicare supplement policy or certificate; and

(2) Inform each covered individual as to when any premium adjustment is to be made due to changes in Medicare.

b. The notice of benefit modifications and any premium adjustments shall be in outline form and in clear and simple terms so as to facilitate comprehension.

c. Such notices shall not contain or be accompanied by any solicitation.

37.28(3) *MMA notice requirements.* Issuers shall comply with any notice requirements of the MMA.

37.28(4) *Outline of coverage requirements for Medicare supplement policies.*

a. An issuer shall provide an outline of coverage to any applicant for a Medicare supplement policy or certificate at the time application is presented to the prospective applicant and, except for a direct response policy, shall obtain an acknowledgment of receipt of such outline of coverage from the applicant.

b. If an outline of coverage is provided at the time of application and the Medicare supplement policy or certificate is issued on a basis which would require revision of the outline, the issuer shall provide a substitute outline of coverage properly describing the Medicare supplement policy or certificate to accompany such Medicare supplement policy or certificate when it is delivered to the covered individual, and the substitute outline of coverage shall contain the following statement, in no less than 12-point type, immediately above the issuer's company name:

"NOTICE: Read this outline of coverage carefully. It is not identical to the outline of coverage provided upon application and the coverage originally applied for has not been issued."

c. The outline of coverage provided to an applicant pursuant to this rule shall consist of the following four parts: a cover page; premium information; disclosure pages; and charts displaying the features of each Medicare supplement benefit plan offered by the issuer. The outline of coverage shall be in the language and format prescribed in this rule and in Appendix E in no less than 12-point type. All plans shall be shown on the cover page, and the plans that are offered by the issuer shall be prominently identified. Premium information for plans that are offered by the issuer shall be shown on the cover page or immediately following the cover page and shall be prominently displayed. The premium and mode shall be stated for all plans that are offered to the prospective applicant. All possible premiums for the prospective applicant shall be illustrated.

d. The items in Appendix E shall be included in the outline of coverage in the order prescribed in Appendix E.

[**ARC 4394C**, IAB 4/10/19, effective 5/15/19]

191—37.29 Reserved.

191—37.30(514D) Standards for marketing.

37.30(1) *Requirements for marketing.* An issuer, directly or through its producers, shall:

a. Establish marketing procedures to ensure that any comparison of policies or certificates by its producers will be fair and accurate.

b. Establish marketing procedures to ensure excessive insurance is not sold or issued.

c. Display prominently by type, stamp or other appropriate means, on the first page of the policy or certificate, the following:

"**Notice to buyer: This policy may not cover all of your medical expenses.**"

d. Inquire and otherwise make every reasonable effort to identify whether a prospective covered individual for Medicare supplement policy or certificate already has accident and sickness insurance and the types and amounts of any such insurance.

e. Establish auditable procedures for certifying compliance with this subrule.

f. At solicitation, provide written notice to the prospective covered individual of the name, address, and telephone number of the senior health insurance information program, part of the insurance division. The written notice shall be in a form prescribed by the commissioner.

37.30(2) *Prohibitions in marketing.* In addition to the practices prohibited in Iowa Code chapter 507B, 191—Chapter 15 and other rules promulgated under Iowa Code chapter 507B, and rule 191—37.50(514D), the following acts and practices are prohibited:

a. *Twisting.* Knowingly making any misleading representation or incomplete or fraudulent comparison of any insurance policies or certificates, or of any issuers, for the purpose of inducing, or tending to induce, any person to lapse, forfeit, surrender, terminate, retain, pledge, assign, borrow on, or convert any insurance policy or certificate or to take out a policy or certificate of insurance with another issuer.

b. *High-pressure tactics.* Employing any method of marketing having the effect of or tending to induce the purchase of insurance through force, fright, threat, whether explicit or implied, or undue pressure to purchase or recommend the purchase of insurance.

c. *Cold-lead advertising.* Making use directly or indirectly of any method of marketing which fails to disclose in a conspicuous manner that a purpose of the method of marketing is solicitation of insurance and that contact will be made by an insurance producer or insurance company.

37.30(3) *Prohibited terms in noncompliant policies or certificates.* The terms "Medicare supplement," "Medigap," "Medicare wrap-around" and words of similar import shall not be used unless the policy or certificate is issued in compliance with this chapter.
[**ARC 4394C**, IAB 4/10/19, effective 5/15/19]

191—37.31(514D) Appropriateness of recommended purchase and excessive insurance.

37.31(1) *Appropriateness.* In recommending the purchase or replacement of any Medicare supplement policy or certificate, a producer shall make reasonable efforts to determine the appropriateness of a recommended purchase or replacement.

37.31(2) *No duplication.* Any sale of a Medicare supplement policy or certificate that will provide an individual more than one Medicare supplement policy or certificate is prohibited.

37.31(3) *No Medicare supplement for enrollee in Part C.* An issuer shall not issue a Medicare supplement policy or certificate to an individual enrolled in Medicare Part C unless the effective date of the coverage is after the termination date of the individual's Medicare Part C coverage.
[**ARC 4394C**, IAB 4/10/19, effective 5/15/19]

191—37.32(514D) Reporting of multiple policies.

37.32(1) *Report of in-force Medicare supplement covered individuals.* On or before March 1 of each year, an issuer shall report, using the format of Appendix F, the following information for every covered individual resident of this state for which the issuer has in force more than one Medicare supplement policy or certificate:

a. Policy and certificate number; and

b. Date of issuance.

37.32(2) *Grouping of items.* The items set forth in subrule 37.21(1) must be grouped by covered individual.
[**ARC 4394C**, IAB 4/10/19, effective 5/15/19]

191—37.33(514D) Prohibition against preexisting conditions, waiting periods, elimination periods and probationary periods in replacement policies or certificates.

37.33(1) *Time credited from prior policy or certificate.* If a Medicare supplement policy or certificate replaces another Medicare supplement policy or certificate, the replacing issuer shall waive any time periods applicable to preexisting conditions, waiting periods, elimination periods and probationary periods in the new replacing Medicare supplement policy or certificate to the extent such time was spent under the replaced policy.

37.33(2) *Similar benefits credited from prior policy or certificate.* If a Medicare supplement policy or certificate replaces another Medicare supplement policy or certificate which has been in effect for at least six months, the replacing Medicare supplement policy or certificate shall not provide any time period applicable to preexisting conditions, waiting periods, elimination periods and probationary periods for benefits similar to those contained in the replaced policy or certificate.
[**ARC 4394C**, IAB 4/10/19, effective 5/15/19]

191—37.34(514D) Prohibitions against use of genetic information and against requests for genetic testing. This rule applies to all Medicare supplement policies or certificates with policy years beginning on or after May 21, 2009.

37.34(1) *Definitions.* For the purposes of this rule, the following definitions shall apply:

"Family member" means, with respect to an individual, any other individual who is a first-degree, second-degree, third-degree, or fourth-degree relative of such individual.

"Genetic information" means, with respect to any individual, information about such individual's genetic tests, the genetic tests of family members of such individual, and the manifestation of a disease or disorder in family members of such individual. "Genetic information" includes, with respect to any individual, any request for, or receipt of, genetic services, or participation in clinical research which includes genetic services, by such individual or any family member of such individual. Any reference to genetic information concerning an individual or family member of an individual who is a pregnant

woman includes genetic information of any fetus carried by such pregnant woman or, with respect to an individual or family member utilizing reproductive technology, includes genetic information of any embryo legally held by an individual or family member. The term "genetic information" does not include information about the sex or age of any individual.

"Genetic services" means a genetic test, genetic counseling (including obtaining, interpreting, or assessing genetic information), or genetic education.

"Genetic test" means an analysis of human DNA, RNA, chromosomes, proteins, or metabolites that detects genotypes, mutations, or chromosomal changes. The term "genetic test" does not mean:

1. An analysis of proteins or metabolites that does not detect genotypes, mutations, or chromosomal changes; or

2. An analysis of proteins or metabolites that is directly related to a manifested disease, disorder, or pathological condition that could reasonably be detected by a health care professional with appropriate training and expertise in the field of medicine involved.

"Issuer of a Medicare supplement policy or certificate" means the same as "issuer" as defined in rule 191—37.3(514D) and includes a third-party administrator, or other person acting for or on behalf of such issuer.

"Underwriting purposes" means:

1. Rules for or determination of eligibility (including enrollment and continued eligibility) for benefits under the Medicare supplement policy or certificate;

2. The computation of premium or contribution amounts under the Medicare supplement policy or certificate;

3. The application of any preexisting condition exclusion under the Medicare supplement policy or certificate; and

4. Other activities related to the creation, renewal, or replacement of a contract of health insurance or health benefits.

37.34(2) *Use of genetic information by issuer prohibited.* An issuer of a Medicare supplement policy or certificate:

a. Shall not deny or condition the issuance or effectiveness of the Medicare supplement policy or certificate (including the imposition of any exclusion of benefits under the policy based on a preexisting condition) of an individual on the basis of the genetic information with respect to such individual; and

b. Shall not discriminate in the pricing of the Medicare supplement policy or certificate (including the adjustment of premium rates) of an individual on the basis of the genetic information with respect to such individual.

37.34(3) *What prohibition does not include.* Nothing in subrule 37.34(2) shall be construed to limit the ability of an issuer of a Medicare supplement policy or certificate, to the extent otherwise permitted by law, from:

a. Denying or conditioning the issuance or effectiveness of the Medicare supplement policy or certificate or increasing the premium for a group plan based on the manifestation of a disease or disorder of a covered individual or applicant; or

b. Increasing the premium for any Medicare supplement policy or certificate issued to an individual based on the manifestation of a disease or disorder of another individual who is covered under the Medicare supplement policy. In such case, the manifestation of a disease or disorder in one individual cannot also be used as genetic information about other group members and to further increase the premium for the insured group.

37.34(4) *Issuer prohibited from requiring genetic testing.* An issuer of a Medicare supplement policy or certificate shall not request or require an individual or a family member of such individual to undergo a genetic test.

37.34(5) *Obtaining and using test results to determine payment.* Subrule 37.34(4) shall not be construed to preclude an issuer of a Medicare supplement policy or certificate from obtaining and using the results of a genetic test in making a determination regarding payment (as defined for the purposes of applying the regulations promulgated under Medicare Part C of Title XI and Section 264 of the Health Insurance Portability and Accountability Act of 1996, as may be revised from time to time)

and consistent with subrule 37.34(2). However, for purposes of carrying out this subrule, an issuer of a Medicare supplement policy or certificate may request only the minimum amount of information necessary to accomplish the intended purpose.

37.34(6) *Conditions when issuer may request a genetic test.* Notwithstanding subrule 37.34(4), an issuer of a Medicare supplement policy or certificate may request, but not require, that an individual or a family member of such individual undergo a genetic test if each of the following conditions is met:

a. The request is made pursuant to research that complies with Part 46 of Title 45, Code of Federal Regulations, or equivalent federal regulations, and any applicable state or local law or regulations for the protection of human subjects in research.

b. The issuer of a Medicare supplement policy or certificate clearly indicates to each individual, or in the case of a minor child, to the legal guardian of such child, to whom the request is made that:

(1) Compliance with the request is voluntary; and

(2) Noncompliance will have no effect on enrollment status or premium or contribution amounts.

c. No genetic information collected or acquired under this subrule shall be used for underwriting, determination of eligibility to enroll or maintain enrollment status, premium rates, or the issuance, renewal, or replacement of a Medicare supplement policy or certificate.

d. The issuer of a Medicare supplement policy or certificate notifies the Secretary in writing that the issuer of a Medicare supplement policy or certificate is conducting activities pursuant to the exception provided for under this subrule, including a description of the activities conducted.

e. The issuer of a Medicare supplement policy or certificate complies with such other conditions as the Secretary may by regulation require for activities conducted under this subrule.

37.34(7) *Issuer prohibited from actively obtaining genetic information for underwriting.* An issuer of a Medicare supplement policy or certificate shall not request, require, or purchase genetic information for underwriting purposes.

37.34(8) *Issuer prohibited from actively obtaining genetic information for enrollment.* An issuer of a Medicare supplement policy or certificate shall not request, require, or purchase genetic information with respect to any individual prior to such individual's enrollment under the policy in connection with such enrollment.

37.34(9) *Obtaining information incidentally not a violation.* If an issuer of a Medicare supplement policy or certificate obtains genetic information incidental to the requesting, requiring, or purchasing of other information concerning any individual, such request, requirement, or purchase shall not be considered a violation of subrule 37.34(8) if such request, requirement, or purchase is not in violation of subrule 37.34(7).

[**ARC 4394C**, IAB 4/10/19, effective 5/15/19]

191—37.35(514D) Prohibition against using materials prepared by SHIIP. The Senior Health Insurance Information Program (SHIIP) may prepare a consumer Medicare supplement insurance premium guide and benefits comparison guide. This guide and the SHIIP name or logo shall not be used in the solicitation or sale of health insurance products. Violation of this rule shall be deemed an unfair trade practice under Iowa Code chapter 507B.

[**ARC 4394C**, IAB 4/10/19, effective 5/15/19]

191—37.36(514D) Guaranteed issue for eligible persons.

37.36(1) *Definition of "Medicare Advantage organization."* For purposes of this rule:

"Medicare Advantage organization" means a private company that has a contract with Medicare to provide Medicare Advantage plans and benefits to individuals.

37.36(2) *Guaranteed issue.*

a. Eligible persons for guaranteed issue of a Medicare supplement policy or certificate are those individuals described in subrule 37.36(3) who seek to enroll under the Medicare supplement policy during the period specified in subrule 37.36(4) and who submit evidence of the date of termination, disenrollment, or Medicare Part D enrollment with the application for a Medicare supplement policy or certificate.

b. With respect to eligible individuals for guaranteed issue of a Medicare supplement policy or certificate, an issuer: shall not deny or condition the issuance or effectiveness of a Medicare supplement policy or certificate described in subrule 37.36(6) that is offered by the issuer and is available for issuance to new enrollees; shall not discriminate in the pricing of such Medicare supplement policy or certificate because of health status, claims experience, receipt of health care, or medical condition; and shall not impose an exclusion of benefits based on a preexisting condition under such Medicare supplement policy or certificate.

37.36(3) *Eligible persons.* An eligible person is an individual described in any of the following paragraphs 37.36(3)*"a"* through *"g"*:

a. The individual is enrolled under an employee welfare benefit plan that provides health benefits that supplement benefits under Medicare, and the plan terminates or the plan ceases to provide some or all such supplemental health benefits to the individual (for purposes of this paragraph, "employee welfare benefit plan" means a plan, fund or program of employee benefits as defined in 29 U.S.C. Section 1002 Employee Retirement Income Security Act).

b. The individual is enrolled with a Medicare Advantage organization under a Medicare Advantage plan and any of the following circumstances apply, or the individual is 65 years of age or older and is enrolled with a PACE provider and circumstances exist similar to one of the circumstances described in subparagraphs 37.36(3)*"b"*(1) through (5) that would permit discontinuance of the individual's enrollment with such a provider if such individual were enrolled in a Medicare Advantage plan:

(1) The certification of the Medicare Advantage organization or Medicare Advantage plan has been terminated.

(2) The Medicare Advantage organization has terminated or otherwise discontinued providing the Medicare Advantage plan in the area in which the individual resides.

(3) The individual is no longer eligible to elect the Medicare Advantage plan because of a change in the individual's place of residence or other change in circumstances specified by the Secretary, but not including termination of the individual's enrollment on the basis described in Section 1851(g)(3)(B) of the federal Social Security Act (where the individual has not paid premiums on a timely basis or has engaged in disruptive behavior as specified in standards under Section 1856), or the Medicare Advantage plan is terminated for all individuals within a residence area.

(4) The individual demonstrates, in accordance with guidelines established by the Secretary, that:

1. The Medicare Advantage organization offering the Medicare Advantage plan substantially violated a material provision of the Medicare Advantage organization's contract under this part in relation to the individual, including the failure to provide an enrollee on a timely basis medically necessary care for which benefits are available under the Medicare Advantage plan or the failure to provide such covered care in accordance with applicable quality standards; or

2. The Medicare Advantage organization, or agent, producer or other entity acting on the Medicare Advantage organization's behalf, materially misrepresented the Medicare Advantage plan's provisions in marketing the Medicare Advantage plan to the individual.

(5) The individual meets such other exceptional conditions as the Secretary may provide.

c. The individual is one for whom both subparagraphs 37.36(3)*"c"*(1) and (2) are true:

(1) The individual is enrolled with one of the following organizations:

1. An eligible organization under a contract under Section 1876 of the Social Security Act (Medicare cost);

2. A similar organization operating under demonstration project authority, effective for periods before April 1, 1999;

3. An organization operating under an agreement under Section 1833(a)(1)(A) of the Social Security Act (Health Care Prepayment Plan (HCPP)); or

4. An organization under a Medicare Select policy.

(2) The enrollment ceases under the same circumstances that would permit discontinuance of an individual's election of coverage under paragraph 37.36(3)*"b."*

d. The individual is enrolled under a Medicare supplement policy or certificate, and the enrollment ceases because:

(1) Of the insolvency or rehabilitation of the issuer (pursuant to Iowa Code chapter 507C) or the bankruptcy of the Medicare Advantage organization; or of other involuntary termination of coverage or enrollment under the policy (for purposes of this subparagraph, "bankruptcy" means when a Medicare Advantage organization that is not an issuer has filed, or has had filed against it, a petition for declaration of bankruptcy, and has ceased doing business in the state); or

(2) The issuer of the policy substantially violated a material provision of the policy; or

(3) The issuer, or an agent, producer or other entity acting on the issuer's behalf, materially misrepresented the policy's provisions in marketing the policy to the individual.

e. The individual was enrolled under a Medicare supplement policy or certificate and terminated enrollment and subsequently enrolls, for the first time, with any Medicare Advantage organization under a Medicare Advantage plan, any eligible organization under a contract under Section 1876 of the Social Security Act (Medicare cost), any similar organization operating under demonstration project authority, any PACE provider, or a Medicare Select policy; and the subsequent enrollment under this paragraph 37.36(3)*"e"* was terminated by the enrollee during any period within the first 12 months of such subsequent enrollment (during which the enrollee is permitted to terminate such subsequent enrollment under Section 1851(e) of the federal Social Security Act).

f. The individual, upon first becoming enrolled for benefits under Medicare Part B at age 65 or older, enrolls in a Medicare Advantage plan under Medicare Part C, or with a PACE provider, and disenrolls from the plan or program by no later than 12 months after the effective date of enrollment.

g. The individual enrolls in a Medicare Part D plan during the initial enrollment period and, at the time of enrollment in Medicare Part D, was enrolled under a Medicare supplement policy or certificate that covers outpatient prescription drugs and the individual terminates enrollment in the Medicare supplement policy or certificate and submits evidence of enrollment in Medicare Part D along with the application for a policy described in paragraph 37.36(6)*"e."*

37.36(4) *Guaranteed issue time periods.*

a. In the case of an individual described in paragraph 37.36(3)*"a,"* the guaranteed issue period:

(1) Begins on the later of:

1. The date the individual receives a notice of termination or cessation of some or all supplemental health benefits (or, if a notice is not received, notice that a claim has been denied because of such a termination or cessation); or

2. The date that the applicable coverage terminates or ceases; and

(2) Ends 63 days thereafter.

b. In the case of an individual described in paragraph 37.36(3)*"b,""c,""e"* or *"f"* whose enrollment is terminated involuntarily, the guaranteed issue period begins on the date that the individual receives a notice of termination and ends 63 days after the date the applicable coverage is terminated.

c. In the case of an individual described in subparagraph 37.36(3)*"d"*(1), the guaranteed issue period:

(1) Begins on the earlier of:

1. The date that the individual receives a notice of termination, a notice that the issuer is insolvent or in rehabilitation (pursuant to Iowa Code chapter 507C), or other such similar notice, if any; and

2. The date that the applicable coverage is terminated; and

(2) Ends on the date that is 63 days after the date the coverage is terminated.

d. In the case of an individual described in paragraph 37.36(3)*"b,"*subparagraph 37.36(3)*"d"*(2) or (3), or paragraph 37.36(3)*"e"* or *"f"* who disenrolls voluntarily, the guaranteed issue period begins on the date that is 60 days before the effective date of the disenrollment and ends on the date that is 63 days after the effective date.

e. In the case of an individual described in paragraph 37.36(3)*"g,"* the guaranteed issue period begins on the date the individual receives notice pursuant to Section 1882(v)(2)(B) of the Social Security Act from the Medicare supplement or certificate issuer during the 60-day period immediately preceding

the initial Medicare Part D enrollment period and ends on the date that is 63 days after the effective date of the individual's coverage under Medicare Part D.

f. In the case of an individual described in subrule 37.36(3) but not described in the preceding paragraphs 37.36(4)*"a"* to *"e,"* the guaranteed issue period begins on the effective date of disenrollment and ends on the date that is 63 days after the effective date.

37.36(5) *Extended Medigap access for interrupted trial periods.*

a. In the case of an individual described in subrule 37.36(3) (or deemed to be so described pursuant to this paragraph 37.36(5)*"a"*) whose enrollment with an organization or provider described in paragraph 37.36(3)*"e"* is involuntarily terminated within the first 12 months of enrollment and who, without an intervening enrollment, enrolls with another such organization or provider, the subsequent enrollment shall be deemed to be an initial enrollment as described in paragraph 37.36(3)*"e."*

b. In the case of an individual described in paragraph 37.36(3)*"f"* (or deemed to be so described pursuant to this paragraph 37.36(5)*"b"*) whose enrollment with a plan or in a program described in paragraph 37.36(3)*"f"* is involuntarily terminated within the first 12 months of enrollment and who, without an intervening enrollment, enrolls in another such plan or program, the subsequent enrollment shall be deemed to be an initial enrollment as described in paragraph 37.36(3)*"f."*

c. For purposes of paragraphs 37.36(3)*"e"* and *"f,"* no enrollment of an individual with an organization or provider described in paragraph 37.36(3)*"e,"* or with a plan or in a program described in paragraph 37.36(3)*"f,"* may be deemed to be an initial enrollment under this paragraph 37.36(5)*"c"* after the two-year period beginning on the date on which the individual first enrolled with such an organization, provider, plan or program.

37.36(6) *Products to which eligible persons are entitled.*

a. If an individual meets the requirements of paragraph 37.36(3)*"a,""b,""c,"* or *"d,"* the individual may be issued a Medicare supplement policy or certificate which has a benefit package classified as Plan A, B, C, F (including F with a high deductible), K or L offered by any issuer.

b. The Medicare supplement policy or certificate to which eligible persons are entitled under paragraph 37.36(3)*"e,"* subject to paragraph 37.36(6)*"c,"* is the same Medicare supplement policy or certificate in which the individual was most recently previously enrolled if available from the same issuer, or, if not so available, a policy described in paragraph 37.36(6)*"a."*

c. After December 31, 2005, if the individual was most recently enrolled in a Medicare supplement policy or certificate with an outpatient prescription drug benefit, a Medicare supplement policy or certificate described in this subrule is:

(1) The policy available from the same issuer but modified to remove outpatient prescription drug coverage; or

(2) At the election of the individual, an A, B, C, F (including F with a high deductible), K or L policy that is offered by any issuer.

d. The Medicare supplement policy or certificate to which eligible persons are entitled under paragraph 37.36(3)*"f"* shall include any Medicare supplement policy or certificate offered by any issuer.

e. The Medicare supplement policy or certificate to which eligible persons are entitled under paragraph 37.36(3)*"g"* is a Medicare supplement policy or certificate that has a benefit package classified as Plan A, B, C, F (including F with a high deductible), K or L, and that is offered and is available for issuance to new enrollees by the same issuer that issued the individual's Medicare supplement policy or certificate with outpatient prescription drug coverage.

37.36(7) *Notification of provisions.*

a. At the time of an event described in subrule 37.36(3) because of which an individual loses coverage or benefits due to the termination or change of a contract or agreement, policy, or plan, the organization that terminates or changes the contract or agreement, the issuer terminating or changing the policy, or the administrator of the plan being terminated or changed, respectively, shall notify the individual of the individual's rights under this rule and of the obligations of issuers of Medicare supplement policies or certificates under subrule 37.36(2). Such notice shall be communicated contemporaneously with the notification of termination.

b. At the time of an event described in subrule 37.36(3) because of which an individual ceases enrollment under a contract or agreement, policy, or plan, the organization that offers the contract or agreement, regardless of the basis for the cessation of enrollment, the issuer offering the policy, or the administrator of the plan, respectively, shall notify the individual of the individual's rights under this rule and of the obligations of issuers of Medicare supplement policies or certificates under subrule 37.36(3). Such notice shall be communicated within ten working days of the issuer receiving notification of the disenrollment.

[**ARC 4394C**, IAB 4/10/19, effective 5/15/19]

191—37.37 to **37.49** Reserved.

191—37.50(507B,514D) Medicare supplement advertising.

37.50(1) *Purpose.* The purpose of this rule is to provide prospective purchasers with clear and unambiguous statements in the advertisement of Medicare supplement insurance and to ensure the clear and truthful disclosure of the benefits, limitations and exclusions of policies sold as Medicare supplement insurance. This purpose is intended to be accomplished by the establishment of guidelines and permissible and impermissible standards of conduct in the advertising of Medicare supplement insurance in a manner which prevents unfair, deceptive and misleading advertising and which is conducive to accurate presentation and description to the insurance-buying public through the advertising media and material used by producers and companies.

37.50(2) *Applicability.*

a. This rule shall apply to any "advertisement" of Medicare supplement insurance, as that term is defined in subrule 37.50(3), unless otherwise specified in this rule, that the issuer or producer knows or reasonably should know is intended for presentation, distribution or dissemination in this state when the presentation, distribution or dissemination is made either directly or indirectly by or on behalf of an issuer or producer.

b. The requirements of Iowa Code chapter 507B and 191—Chapter 15 also shall apply to issuers and producers to which this rule 191—37.50(507B,514D) applies, unless specifically exempted therein.

37.50(3) *Definitions.* In addition to the definitions in Iowa Code sections 507B.2 and 514D.2 and rules 191—15.2(507B) and 191—37.3(514D), the following definitions shall apply to this rule 191—37.50(507B,514D). When a term defined in this rule is also defined in Iowa Code section 507B.2 or 514D.2 or rule 191—15.2(507B) or 191—37.3(514D), the definition of the term in this rule shall take precedence.

"Advertisement"

1. Includes the definition of "advertisement" in rule 191—15.2(507B).

2. Includes advertising material included with a Medicare supplement policy or certificate when the Medicare supplement policy or certificate is delivered and the advertising material is used in the solicitation of Medicare supplement policy renewals and reinstatements.

3. Does not include:

- The items excluded in paragraph "2" of the definition of "advertisement" in rule 191—15.2(507B).
- Material to be used solely for the training and education of an issuer's employees, producers, agents or brokers.
- Material used in-house by issuers.
- Communications within an issuer's own organization not intended for dissemination to the public.
- Individual communications of a personal nature with current covered individuals other than material urging the covered individuals to increase or expand coverage.
- Correspondence between a prospective group or blanket policyholder and an issuer in the course of negotiating a group or blanket Medicare supplement policy.
- Court-approved material ordered by a court to be disseminated to covered individuals or group policyholders of Medicare supplement policies.

- A general announcement from a group or blanket Medicare supplement policyholder to eligible individuals on an employment or membership list that a Medicare supplement policy has been written or arranged; provided the announcement clearly indicates that it is preliminary to the issuance of a booklet.

"Certificate" means any certificate issued under a group Medicare supplement policy, which certificate has been delivered or issued for delivery in this state.

"Exception" means any provision in a Medicare supplement policy whereby coverage for a specified hazard is entirely eliminated; it is a statement of a risk not assumed under the Medicare supplement policy or certificate.

"Institutional advertisement" means an advertisement having as its sole purpose the promotion of the reader's, viewer's or listener's interest in the concept of Medicare supplement insurance, or the promotion of the issuer as a seller of Medicare supplement insurance.

"Invitation to contract" means an advertisement that is neither an institutional advertisement nor an invitation to inquire (defined in paragraph 37.50(8)*"d"*).

"Issuer" shall include any entity which is defined as an "issuer" in rule 191—37.3(514D) and is engaged in the advertisement of itself, or of Medicare supplement insurance.

"Lead-generating device" means any communication directed to the public that, regardless of form, content or stated purpose, is intended to result in the compilation or qualification of a list containing names and other personal information to be used to solicit residents of this state for the purchase of Medicare supplement insurance.

"Limitation" means any provision other than an exception or a reduction that restricts coverage under a Medicare supplement policy.

"Medicare supplement insurance" means a group or individual policy of accident and sickness insurance or a contract of hospital and medical service associations or health maintenance organizations that is advertised, marketed or designed primarily as a supplement to reimbursements under Medicare for the hospital, medical, or surgical expenses of persons eligible for Medicare by reason of age.

"Person" means a natural person, association, organization, partnership, trust, group, discretionary group, corporation or any other entity.

"Reduction" means any provision that reduces the amount of the benefit; a risk of loss is assumed but payment upon the occurrence of the loss is limited to some amount or period less than would be otherwise payable had the reduction not been used.

37.50(4) *Form and content of advertisements.*

a. An issuer shall clearly identify its Medicare supplement insurance as an insurance policy or certificate. A Medicare supplement policy or certificate trade name must be followed by the words "Insurance Policy" or similar words clearly identifying the fact that an insurance policy or certificate or health benefits product (in the case of health maintenance organizations, prepaid health plans and other direct service organizations) is being offered.

b. Medicare supplement insurance advertising materials that are reproduced in quantity shall be identified by form numbers or other identifying means. The identification shall be sufficient to distinguish an advertisement from any other advertising materials, policies, applications or other materials used by the issuer.

37.50(5) *Testimonials or endorsements by third parties.* In addition to complying with 191—subrule 15.3(7), when a testimonial refers to benefits received under a Medicare supplement policy or certificate, the issuer shall retain for examination by the commissioner the specific claim data, including claim number, date of loss, and other pertinent information, for a period of four years or until the filing of the next regular report of examination of the issuer, whichever is the longer period of time. The use of testimonials that do not correctly reflect the present practices of the issuer or that are not applicable to the Medicare supplement policy or certificate or benefit being advertised is not permissible.

37.50(6) *Use of statistics; jurisdictional licensing; status of insurer.* Medicare supplement insurance advertisements shall be in compliance with 191—subrule 15.3(5) and with the following:

a. A Medicare supplement insurance advertisement shall specifically identify the Medicare supplement policy or certificate to which statistics relate and, where statistics are given which are

applicable to a different policy or certificate, the advertisement shall state clearly that the data do not relate to the Medicare supplement policy or certificate being advertised.

b. A Medicare supplement insurance advertisement that is intended to be seen or heard beyond the limits of the jurisdiction in which the issuer is licensed shall not imply licensing beyond those limits.

c. A Medicare supplement insurance advertisement shall not create the impression directly or indirectly that the issuer, the issuer's financial condition or status, the issuer's payment of its claims, or the merits, desirability or advisability of the issuer's policy forms or kinds of plans of insurance are approved, endorsed or accredited by any division or agency of this state or of the United States government.

d. A Medicare supplement insurance advertisement shall not imply that approval, endorsement or accreditation of policy forms or advertising has been granted by any division or agency of this state or of the United States government. "Approval" of either policy forms or advertising shall not be used by an issuer to imply or state that a governmental agency has endorsed or recommended the issuer, its policies, its advertising or its financial condition.

37.50(7) *Identity of issuer.* Advertisements shall be in compliance with 191—subrule 15.3(9) and with the following:

a. Advertisements, stationery or envelopes that employ words, letters, initials, symbols or other devices are not permitted if they are so similar to those used by governmental agencies or other issuers that they may lead the public to believe:

(1) The advertised Medicare supplement insurance coverages are somehow provided by or are endorsed by the governmental agencies or the other issuers;

(2) The Medicare supplement insurance advertiser is the same as, is connected with or is endorsed by the governmental agencies or the other issuers.

b. No Medicare supplement insurance advertisement shall use the name of a state or political subdivision thereof in a policy name or description.

c. No Medicare supplement insurance advertisement in the form of envelopes or stationery of any kind may use any name, service mark, slogan, symbol or any device in such a manner that implies that the issuer or the policy advertised, or that any producer who may call upon the consumer in response to the advertisement, is connected with a governmental agency, such as the Social Security Administration.

d. No Medicare supplement insurance advertisement may incorporate the word "Medicare" in the title of the plan or policy being advertised unless, wherever it appears, the word is qualified by language differentiating the plan or policy from Medicare. Such an advertisement, however, shall not use the phrase "_____ Medicare Department of the _____ Insurance Company," or language of similar import.

e. No Medicare supplement insurance advertisement shall be used that fails to include a disclaimer to the effect of "Not connected with or endorsed by the U.S. government or the federal Medicare program."

f. No Medicare supplement insurance advertisement may imply that the reader may lose a right, privilege or benefit under federal, state or local law if the reader fails to respond to the advertisement.

g. No issuer may use, in the trade name of its Medicare supplement insurance policy, any terminology or words so similar to the name of a governmental agency or governmental program as to have the tendency to confuse, deceive or mislead the prospective purchaser.

h. All Medicare supplement insurance advertisements used by producers or solicitors of an issuer shall have prior written approval of the issuer before the advertisements may be used.

i. A producer who makes contact with a consumer as a result of acquiring that consumer's name from a lead-generating device shall disclose that fact in the initial contact with the consumer.

37.50(8) *Introductory, initial or special offers.*

a. Enrollment periods.

(1) An advertisement of an individual Medicare supplement insurance policy shall not directly or by implication represent that a contract or combination of contracts is an introductory, initial or special offer, or that applicants will receive substantial advantages not available at a later date, or that the offer is available only to a specified group of individuals, unless such representation is true. A

Medicare supplement insurance advertisement shall not contain phrases describing an enrollment period as "special," "limited," or similar words or phrases when the issuer uses such enrollment periods as the usual method of advertising Medicare supplement insurance.

(2) An enrollment period during which a particular Medicare supplement insurance product may be purchased on an individual basis shall not be offered within this state unless there has been a lapse of not less than six months between the close of the immediately preceding enrollment period for the same product and the opening of the new enrollment period. The Medicare supplement insurance advertisement shall indicate the date by which the applicant must mail the application, which shall be not fewer than 10 days and not more than 40 days from the date that the enrollment period is advertised for the first time. This rule applies to all advertising media, e.g., mail, newspapers, electronic mail, websites, radio, television, magazines and periodicals, used by any one issuer. This rule is not applicable to solicitations of employees or members of a particular group or association that otherwise would be eligible for group, blanket or franchise insurance. The phrase "any one issuer" in this subparagraph includes all the affiliated companies of a group of insurance companies under common management or control. The phrase "a particular Medicare supplement insurance product" in this subparagraph means an insurance policy that provides benefits substantially different from those contained in any other policy. Different terms of renewability, an increase or decrease in the dollar amounts of benefits, or an increase or decrease in any elimination period or waiting period from those available during an enrollment period for another policy shall not be sufficient to constitute the product's being offered as a different product eligible for concurrent or overlapping enrollment periods.

(3) This rule prohibits any statement or implication to the effect that only a specific number of Medicare supplement policies will be sold, or that a time is fixed for the discontinuance of the sale of the particular Medicare supplement policy advertised because of special advantages available in the policy, unless either representation is true.

b. An advertisement shall not offer a Medicare supplement policy that utilizes a reduced initial premium rate in a manner that overemphasizes the availability and the amount of the initial reduced premium. When an issuer charges an initial premium that differs in amount from the amount of the renewal premium payable on the same mode, the advertisement shall not display the amount of the reduced initial premium either more frequently or more prominently than the renewal premium, and both the initial reduced premium and the renewal premium shall be stated in juxtaposition in each portion of the advertisement where the initial reduced premium appears. The term "juxtaposition" means side by side or immediately above or below.

c. Special awards, such as a "safe driver's award," shall not be used in connection with advertisements of Medicare supplement insurance.

d. An invitation to inquire, which means an advertisement having as its objective the creation of a desire to inquire further about Medicare supplement insurance that is limited to a brief description of coverage, shall contain a provision in the following or substantially similar form:

"This policy has [exclusions] [limitations] [reductions of benefits] [terms under which the policy may be continued in force or discontinued]. For costs and complete details of the coverage, call [or write] your producer or the company [whichever is applicable]."

37.50(9) *Enforcement procedures—certificate of compliance.* Each issuer required to file an annual statement which is now or which hereafter becomes subject to the provisions of this chapter must file with the insurance division, with the issuer's annual statement, a certificate of compliance executed by an authorized officer of the issuer wherein it is stated that, to the best of the authorized officer's knowledge, information and belief, the Medicare supplement insurance advertisements that were disseminated by the issuer during the preceding statement year complied with or were made to comply in all respects with the provisions of this chapter and the laws of this state as implemented and interpreted by this chapter.

37.50(10) *Filing for prior review.* The commissioner may, at the commissioner's discretion, require the filing with the insurance division, for review prior to use, of any Medicare supplement insurance advertising material.

[**ARC 4394C**, IAB 4/10/19, effective 5/15/19]

191—37.51(514D) Severability. If any provisions of this chapter or the application thereof to any person or circumstance is for any reason held to be invalid, the remainder of the chapter and the application of such provision to other persons or circumstances shall not be affected thereby.
[**ARC 4394C**, IAB 4/10/19, effective 5/15/19]

These rules are intended to implement Iowa Code chapters 507B and 514D.

APPENDIX A
MEDICARE SUPPLEMENT REFUND CALCULATION FORM
FOR CALENDAR YEAR _____

TYPE[1]_____ SMSBP[2]_____

For the State of_____ Company Name _____

NAIC Group Code_____ NAIC Company Code_____

Address_____ Person Completing This Exhibit_____

Title_____ Telephone Number_____

Line		(a) Earned Premium[3]	(b) Incurred Claims[4]
1.	Current Year's Experience		
	a. Total (all policy years)		
	b. Current year's issues[5]		
	c. Net (for reporting purposes = 1a – 1b)		
2.	Past Years' Experience (all policy years)		
3.	Total Experience (Net Current Year + Past Year)		

4.	Refunds Last Year (excluding interest)	
5.	Previous Since Inception (excluding interest)	
6.	Refunds Since Inception (excluding interest)	
7.	Benchmark Ratio Since Inception (see worksheet for Ratio 1)	
8.	Experienced Ratio Since Inception (Ratio 2) Total Actual Incurred Claims (line 3, col. b) / Total Earned Prem. (line 3, col. a) – Refunds Since Inception (line 6)	
9.	Life Years Exposed Since Inception If the Experienced Ratio is less than the Benchmark Ratio, and there are more than 500 life years exposure, then proceed to calculation of refund.	
10.	Tolerance Permitted (obtained from credibility table)	

[1] Individual, Group, Individual Medicare Select, or Group Medicare Select only.

[2] "SMSBP" = Standardized Medicare Supplement Benefit Plan – Use "P" for prestandardized Medicare supplement benefit plans.

[3] Includes Modal Loadings and Fees Charged.

[4] Excludes Active Life Reserves.

[5] This is to be used as "Issue Year Earned Premium" for Year 1 of next year's "Worksheet for Calculation of Benchmark Ratios."

Medicare Supplement Credibility Table

Life Years Exposed	
Since Inception	Tolerance
10,000 +	0.0%
5,000 - 9,999	5.0%
2,500 - 4,999	7.5%
1,000 - 2,499	10.0%
500 - 999	15.0%
If less than 500, no credibility.	

MEDICARE SUPPLEMENT REFUND CALCULATION FORM
FOR CALENDAR YEAR _____

TYPE[1] _____ SMSBP[2] _____
For the State of _____ Company Name _____
NAIC Group Code _____ NAIC Company Code _____
Address _____ Person Completing This Exhibit _____
Title _____ Telephone Number _____

11.	Adjustment to Incurred Claims for Credibility Ratio 3 = Ratio 2 + Tolerance	

If Ratio 3 is more than Benchmark Ratio (Ratio 1), a refund or credit to premium is not required. If Ratio 3 is less than the Benchmark Ratio, then proceed.

12.	Adjusted Incurred Claims [Total Earned Premiums (line 3, col. a) – Refunds Since Inception (line 6)] × Ratio 3 (line 11)	
13.	Refund = Total Earned Premiums (line 3, col. a) – Refunds Since Inception (line 6) – [Adjusted Incurred Claims (line 12) / Benchmark Ratio (Ratio 1)]	

If the amount on line 13 is less than .005 times the annualized premium in force as of December 31 of the reporting year, then no refund is made. Otherwise, the amount on line 13 is to be refunded or credited, and a description of the refund or credit against premiums to be used must be attached to this form.

I certify that the above information and calculations are true and accurate to the best of my knowledge and belief.

_____
Signature

_____
Name (Please type.)

_____
Title (Please type.)

_____
Date

[1] Individual, Group, Individual Medicare Select, or Group Medicare Select only.
[2] "SMSBP" = Standardized Medicare Supplement Benefit Plan – Use "P" for prestandardized plans.

REPORTING FORM FOR THE CALCULATION OF
BENCHMARK RATIO SINCE INCEPTION FOR GROUP POLICIES
FOR CALENDAR YEAR _____

TYPE[1] _____ SMSBP[2] _____
For the State of _____ Company Name _____
NAIC Group Code _____ NAIC Company Code _____
Address _____ Person Completing This Exhibit _____
Title _____ Telephone Number _____

(a)[3]	(b)[4]	(c)	(d)	(e)	(f)	(g)	(h)	(i)	(j)	(o)[5]
Year	Earned Premium	Factor	(b) × (c)	Cumulative Loss Ratio	(d) × (e)	Factor	(b) × (g)	Cumulative Loss Ratio	(h) × (i)	Policy Year Loss Ratio
1		2.770		0.507		0.000		0.000		0.46
2		4.175		0.567		0.000		0.000		0.63
3		4.175		0.567		1.194		0.759		0.75
4		4.175		0.567		2.245		0.771		0.77
5		4.175		0.567		3.170		0.782		0.80
6		4.175		0.567		3.998		0.792		0.82
7		4.175		0.567		4.754		0.802		0.84
8		4.175		0.567		5.445		0.811		0.87
9		4.175		0.567		6.075		0.818		0.88
10		4.175		0.567		6.650		0.824		0.88
11		4.175		0.567		7.176		0.828		0.88
12		4.175		0.567		7.655		0.831		0.88
13		4.175		0.567		8.093		0.834		0.89
14		4.175		0.567		8.493		0.837		0.89
15+[6]		4.175		0.567		8.684		0.838		0.89
Total:			(k):		(l):		(m):		(n):	

Benchmark Ratio Since Inception: (l + n)/(k + m): _____

[1] Individual, Group, Individual Medicare Select, or Group Medicare Select only.
[2] "SMSBP" = Standardized Medicare Supplement Benefit Plan – Use "P" for prestandardized Medicare supplement benefit plans.
[3] Year 1 is the current calendar year - 1. Year 2 is the current calendar year - 2 (etc.). (Example: If the current year is 1991, then: Year 1 is 1990; Year 2 is 1989, etc.)
[4] For the calendar year on the appropriate line in column (a), the premium earned during that year for policies issued in that year.
[5] These loss ratios are not explicitly used in computing the benchmark loss ratios. They are the loss ratios, on a policy year basis, which result in the cumulative loss ratios displayed on this worksheet. They are shown here for informational purposes only.
[6] To include the earned premium for all years prior to as well as the 15th year prior to the current year.

REPORTING FORM FOR THE CALCULATION OF
BENCHMARK RATIO SINCE INCEPTION FOR INDIVIDUAL POLICIES
FOR CALENDAR YEAR _____

TYPE[1] _____ SMSBP[2] _____
For the State of _____ Company Name _____
NAIC Group Code _____ NAIC Company Code _____
Address _____ Person Completing This Exhibit _____
Title _____ Telephone Number _____

(a)[3]	(b)[4]	(c)	(d)	(e)	(f)	(g)	(h)	(i)	(j)	(o)[5]
Year	Earned Premium	Factor	(b) × (c)	Cumulative Loss Ratio	(d) × (e)	Factor	(b) × (g)	Cumulative Loss Ratio	(h) × (i)	Policy Year Loss Ratio
1		2.770		0.442		0.000		0.000		0.40
2		4.175		0.493		0.000		0.000		0.55
3		4.175		0.493		1.194		0.659		0.65
4		4.175		0.493		2.245		0.669		0.67
5		4.175		0.493		3.170		0.678		0.69
6		4.175		0.493		3.998		0.686		0.71
7		4.175		0.493		4.754		0.695		0.73
8		4.175		0.493		5.445		0.702		0.75
9		4.175		0.493		6.075		0.708		0.76
10		4.175		0.493		6.650		0.713		0.76
11		4.175		0.493		7.176		0.717		0.76
12		4.175		0.493		7.655		0.720		0.77
13		4.175		0.493		8.093		0.723		0.77
14		4.175		0.493		8.493		0.725		0.77
15+[6]		4.175		0.493		8.684		0.725		0.77
Total:			(k):		(l):		(m):		(n):	

Benchmark Ratio Since Inception: (l + n)/(k + m): _____

[1] Individual, Group, Individual Medicare Select, or Group Medicare Select only.
[2] "SMSBP" = Standardized Medicare Supplement Benefit Plan – Use "P" for prestandardized Medicare supplement benefit plans.
[3] Year 1 is the current calendar year - 1. Year 2 is the current calendar year - 2 (etc.). (Example: If the current year is 1991, then: Year 1 is 1990; Year 2 is 1989, etc.)
[4] For the calendar year on the appropriate line in column (a), the premium earned during that year for policies issued in that year.
[5] These loss ratios are not explicitly used in computing the benchmark loss ratios. They are the loss ratios, on a policy year basis, which result in the cumulative loss ratios displayed on this worksheet. They are shown here for informational purposes.
[6] To include the earned premium for all years prior to as well as the 15th year prior to the current year.

APPENDIX B
DISCLOSURE STATEMENTS
Instructions for Use of the Disclosure Statements for Health Insurance Policies Sold to Medicare Beneficiaries that Duplicate Medicare Benefits

1. Section 1882(d) of the federal Social Security Act [42 U.S.C. 1395ss] prohibits the sale of a health insurance policy (the term policy includes certificate) to a Medicare beneficiary that duplicates Medicare benefits unless it will pay benefits without regard to a beneficiary's other health coverage and it includes the prescribed disclosure statement on or together with the application for the policy.

2. All types of health insurance policies that duplicate Medicare benefits shall include one of the attached disclosure statements, according to the particular policy type involved, on the application or together with the application. The disclosure statement may not significantly or materially vary from the attached statements in terms of language or format (using not less than 12-point type size, type-proportional spacing, bold characters, line spacing, and boxes around text).

3. State and federal law prohibits issuers from selling a Medicare supplement policy or certificate to a person that already has a Medicare supplement policy or certificate except as a replacement policy.

4. Property/casualty and life insurance policies are not considered health insurance.

5. Disability income policies are not considered to provide benefits that duplicate Medicare.

6. Long-term care insurance policies that coordinate with Medicare and other health insurance are not considered to provide benefits that duplicate Medicare.

7. The federal law does not preempt state laws that are more stringent than the federal requirements.

8. The federal law does not preempt existing state form filing requirements.

9. Section 1882 of the federal Social Security Act was amended in Subsection (d)(3)(A) to allow for alternative disclosure statements. The disclosure statements already in Appendix B remain. An issuer may use either disclosure statement with the requisite insurance product. However, issuers should use either the original disclosure statements or the alternative disclosure statements and not use both simultaneously.

[Original disclosure statement for policies that provide benefits for expenses incurred for an accidental injury only.]

IMPORTANT NOTICE TO PERSONS ON MEDICARE
THIS INSURANCE DUPLICATES SOME MEDICARE BENEFITS

This is not Medicare Supplement Insurance

This insurance provides limited benefits, if you meet the policy conditions, for hospital or medical expenses that result from accidental injury. It does not pay your Medicare deductibles or coinsurance and is not a substitute for Medicare Supplement insurance.

This insurance duplicates Medicare benefits when it pays:

- Hospital or medical expenses up to the maximum stated in the policy

Medicare generally pays for most or all of these expenses.

Medicare pays extensive benefits for medically necessary services regardless of the reason you need them. These include:

- Hospitalization
- Physician services
- Outpatient Prescription Drugs if you are enrolled in Medicare Part D
- Other approved items and services

Before You Buy This Insurance

√ Check the coverage in **all** health insurance policies you already have.
√ For more information about Medicare and Medicare Supplement insurance, review the [insert name of most recent version of *2019 Choosing a Medigap Policy: Guide to Health Insurance for People with Medicare*, issued by Centers for Medicare and Medicaid Services], available from the insurance company.
√ For help in understanding your health insurance, contact the Senior Health Insurance Information Program (SHIIP) of the Iowa Insurance Division.

[Original disclosure statement for policies that provide benefits for specified limited services.]

IMPORTANT NOTICE TO PERSONS ON MEDICARE
THIS INSURANCE DUPLICATES SOME MEDICARE BENEFITS

This is not Medicare Supplement Insurance

This insurance provides limited benefits, if you meet the policy conditions, for expenses relating to the specific services listed in the policy. It does not pay your Medicare deductibles or coinsurance and is not a substitute for Medicare Supplement insurance.

This insurance duplicates Medicare benefits when:

- Any of the services covered by the policy are also covered by Medicare

Medicare pays extensive benefits for medically necessary services regardless of the reason you need them. These include:

- Hospitalization
- Physician services
- Outpatient Prescription Drugs if you are enrolled in Medicare Part D
- Other approved items and services

Before You Buy This Insurance

√ Check the coverage in **all** health insurance policies you already have.

√ For more information about Medicare and Medicare Supplement insurance, review the [insert name of most recent version of *2019 Choosing a Medigap Policy: Guide to Health Insurance for People with Medicare*, issued by Centers for Medicare and Medicaid Services], available from the insurance company.

√ For help in understanding your health insurance, contact the Senior Health Insurance Information Program (SHIIP) of the Iowa Insurance Division.

[Original disclosure statement for policies that reimburse expenses incurred for specified diseases or other specified impairments. This includes expense-incurred cancer, specified disease and other types of health insurance policies that limit reimbursement to named medical conditions.]

IMPORTANT NOTICE TO PERSONS ON MEDICARE
THIS INSURANCE DUPLICATES SOME MEDICARE BENEFITS

This is not Medicare Supplement Insurance

This insurance provides limited benefits, if you meet the policy conditions, for hospital or medical expenses only when you are treated for one of the specific diseases or health conditions listed in the policy. It does not pay your Medicare deductibles or coinsurance and is not a substitute for Medicare Supplement insurance.

This insurance duplicates Medicare benefits when it pays:

- Hospital or medical expenses up to the maximum stated in the policy

Medicare generally pays for most or all of these expenses.

Medicare pays extensive benefits for medically necessary services regardless of the reason you need them. These include:

- Hospitalization
- Physician services
- Hospice
- Outpatient Prescription Drugs if you are enrolled in Medicare Part D
- Other approved items and services

Before You Buy This Insurance

√ Check the coverage in **all** health insurance policies you already have.

√ For more information about Medicare and Medicare Supplement insurance, review the [insert name of most recent version of *2019 Choosing a Medigap Policy: Guide to Health Insurance for People with Medicare*, issued by Centers for Medicare and Medicaid Services], available from the insurance company.

√ For help in understanding your health insurance, contact the Senior Health Insurance Information Program (SHIIP) of the Iowa Insurance Division.

[Original disclosure statement for policies that pay fixed dollar amounts for specified diseases or other specified impairments. This includes cancer, specified disease, and other health insurance policies that pay a scheduled benefit or specific payment based on diagnosis of the conditions named in the policy.]

IMPORTANT NOTICE TO PERSONS ON MEDICARE
THIS INSURANCE DUPLICATES SOME MEDICARE BENEFITS

This is not Medicare Supplement Insurance

This insurance pays a fixed amount, regardless of your expenses, if you meet the policy conditions, for one of the specific diseases or health conditions named in the policy. It does not pay your Medicare deductibles or coinsurance and is not a substitute for Medicare Supplement insurance.

This insurance duplicates Medicare benefits because Medicare generally pays for most of the expenses for the diagnosis and treatment of the specific conditions or diagnoses named in the policy.

Medicare pays extensive benefits for medically necessary services regardless of the reason you need them. These include:

- Hospitalization
- Physician services
- Hospice
- Outpatient Prescription Drugs if you are enrolled in Medicare Part D
- Other approved items and services

Before You Buy This Insurance

√ Check the coverage in **all** health insurance policies you already have.

√ For more information about Medicare and Medicare Supplement insurance, review the [insert name of most recent version of *2019 Choosing a Medigap Policy: Guide to Health Insurance for People with Medicare*, issued by Centers for Medicare and Medicaid Services], available from the insurance company.

√ For help in understanding your health insurance, contact the Senior Health Insurance Information Program (SHIIP) of the Iowa Insurance Division.

[Original disclosure statement for indemnity policies and other policies that pay a fixed dollar amount per day, excluding long-term care policies.]

IMPORTANT NOTICE TO PERSONS ON MEDICARE
THIS INSURANCE DUPLICATES SOME MEDICARE BENEFITS

This is not Medicare Supplement Insurance

This insurance pays a fixed dollar amount, regardless of your expenses, for each day you meet the policy conditions. It does not pay your Medicare deductibles or coinsurance and is not a substitute for Medicare Supplement insurance.

This insurance duplicates Medicare benefits when:

- Any expenses or services covered by the policy are also covered by Medicare

Medicare generally pays for most or all of these expenses.

Medicare pays extensive benefits for medically necessary services regardless of the reason you need them. These include:

- Hospitalization
- Physician services
- Outpatient Prescription Drugs if you are enrolled in Medicare Part D
- Hospice
- Other approved items and services

Before You Buy This Insurance

√ Check the coverage in **all** health insurance policies you already have.

√ For more information about Medicare and Medicare Supplement insurance, review the [insert name of most recent version of *2019 Choosing a Medigap Policy: Guide to Health Insurance for People with Medicare*, issued by Centers for Medicare and Medicaid Services], available from the insurance company.

√ For help in understanding your health insurance, contact the Senior Health Insurance Information Program (SHIIP) of the Iowa Insurance Division.

[Original disclosure statement for policies that provide benefits upon both an expense-incurred and fixed indemnity basis.]

IMPORTANT NOTICE TO PERSONS ON MEDICARE
THIS INSURANCE DUPLICATES SOME MEDICARE BENEFITS

This is not Medicare Supplement Insurance

This insurance pays limited reimbursement for expenses if you meet the conditions listed in the policy. It also pays a fixed amount, regardless of your expenses, if you meet other policy conditions. It does not pay your Medicare deductibles or coinsurance and is not a substitute for Medicare Supplement insurance.

This insurance duplicates Medicare benefits when:

- Any expenses or services covered by the policy are also covered by Medicare; or
- It pays the fixed dollar amount stated in the policy and Medicare covers the same event.

Medicare generally pays for most or all of these expenses.

Medicare pays extensive benefits for medically necessary services regardless of the reason you need them. These include:

- Hospitalization
- Physician services
- Hospice care
- Outpatient Prescription Drugs if you are enrolled in Medicare Part D
- Other approved items and services

Before You Buy This Insurance

√ Check the coverage in **all** health insurance policies you already have.

√ For more information about Medicare and Medicare Supplement insurance, review the [insert name of most recent version of *2019 Choosing a Medigap Policy: Guide to Health Insurance for People with Medicare*, issued by Centers for Medicare and Medicaid Services], available from the insurance company.

√ For help in understanding your health insurance, contact the Senior Health Insurance Information Program (SHIIP) of the Iowa Insurance Division.

[Original disclosure statement for other health insurance policies not specifically identified in the preceding statements.]

IMPORTANT NOTICE TO PERSONS ON MEDICARE
THIS INSURANCE DUPLICATES SOME MEDICARE BENEFITS

This is not Medicare Supplement Insurance

This insurance provides limited benefits if you meet the conditions listed in the policy. It does not pay your Medicare deductibles or coinsurance and is not a substitute for Medicare Supplement insurance.

This insurance duplicates Medicare benefits when it pays:

- The benefits stated in the policy and coverage for the same event is provided by Medicare

Medicare generally pays for most or all of these expenses.

Medicare pays extensive benefits for medically necessary services regardless of the reason you need them. These include:

- Hospitalization
- Physician services
- Hospice
- Outpatient Prescription Drugs if you are enrolled in Medicare Part D
- Other approved items and services

Before You Buy This Insurance

√ Check the coverage in **all** health insurance policies you already have.
√ For more information about Medicare and Medicare Supplement insurance, review the [insert name of most recent version of *2019 Choosing a Medigap Policy: Guide to Health Insurance for People with Medicare*, issued by Centers for Medicare and Medicaid Services], available from the insurance company.
√ For help in understanding your health insurance, contact the Senior Health Insurance Information Program (SHIIP) of the Iowa Insurance Division.

[Alternative disclosure statement for policies that provide benefits for expenses incurred for an accidental injury only.]

IMPORTANT NOTICE TO PERSONS ON MEDICARE
THIS IS NOT MEDICARE SUPPLEMENT INSURANCE

Some health care services paid for by Medicare may also trigger the payment of benefits from this policy.

This insurance provides limited benefits, if you meet the policy conditions, for hospital or medical expenses that result from accidental injury. It does not pay your Medicare deductibles or coinsurance and is not a substitute for Medicare Supplement insurance.

Medicare generally pays for most or all of these expenses.

Medicare pays extensive benefits for medically necessary services regardless of the reason you need them. These include:

- Hospitalization
- Physician services
- Outpatient Prescription Drugs if you are enrolled in Medicare Part D
- Other approved items and services

This policy must pay benefits without regard to other health benefit coverage to which you may be entitled under Medicare or other insurance.

Before You Buy This Insurance

√ Check the coverage in **all** health insurance policies you already have.

√ For more information about Medicare and Medicare Supplement insurance, review the [insert name of most recent version of *2019 Choosing a Medigap Policy: Guide to Health Insurance for People with Medicare*, issued by Centers for Medicare and Medicaid Services], available from the insurance company.

√ For help in understanding your health insurance, contact the Senior Health Insurance Information Program (SHIIP) of the Iowa Insurance Division.

[Alternative disclosure statement for policies that provide benefits for specified limited services.]

IMPORTANT NOTICE TO PERSONS ON MEDICARE
THIS IS NOT MEDICARE SUPPLEMENT INSURANCE

Some health care services paid for by Medicare may also trigger the payment of benefits under this policy.

This insurance provides limited benefits, if you meet the policy conditions, for expenses relating to the specific services listed in the policy. It does not pay your Medicare deductibles or coinsurance and is not a substitute for Medicare Supplement insurance.

Medicare pays extensive benefits for medically necessary services regardless of the reason you need them. These include:

- Hospitalization
- Physician services
- Outpatient Prescription Drugs if you are enrolled in Medicare Part D
- Other approved items and services

This policy must pay benefits without regard to other health benefit coverage to which you may be entitled under Medicare or other insurance.

Before You Buy This Insurance

√ Check the coverage in **all** health insurance policies you already have.

√ For more information about Medicare and Medicare Supplement insurance, review the [insert name of most recent version of *2019 Choosing a Medigap Policy: Guide to Health Insurance for People with Medicare*, issued by Centers for Medicare and Medicaid Services], available from the insurance company.

√ For help in understanding your health insurance, contact the Senior Health Insurance Information Program (SHIIP) of the Iowa Insurance Division.

[Alternative disclosure statement for policies that reimburse expenses incurred for specified diseases or other specified impairments. This includes expense-incurred cancer, specified disease and other types of health insurance policies that limit reimbursement to named medical conditions.]

IMPORTANT NOTICE TO PERSONS ON MEDICARE
THIS IS NOT MEDICARE SUPPLEMENT INSURANCE

Some health care services paid for by Medicare may also trigger the payment of benefits from this policy. Medicare generally pays for most or all of these expenses.

This insurance provides limited benefits, if you meet the policy conditions, for hospital or medical expenses only when you are treated for one of the specific diseases or health conditions listed in the policy. It does not pay your Medicare deductibles or coinsurance and is not a substitute for Medicare Supplement insurance.

Medicare generally pays for most or all of these expenses.

Medicare pays extensive benefits for medically necessary services regardless of the reason you need them. These include:

- Hospitalization
- Physician services
- Hospice
- Outpatient Prescription Drugs if you are enrolled in Medicare Part D
- Other approved items and services

This policy must pay benefits without regard to other health benefit coverage to which you may be entitled under Medicare or other insurance.

Before You Buy This Insurance

√ Check the coverage in **all** health insurance policies you already have.

√ For more information about Medicare and Medicare Supplement insurance, review the [insert name of most recent version of *2019 Choosing a Medigap Policy: Guide to Health Insurance for People with Medicare*, issued by Centers for Medicare and Medicaid Services], available from the insurance company.

√ For help in understanding your health insurance, contact the Senior Health Insurance Information Program (SHIIP) of the Iowa Insurance Division.

[Alternative disclosure statement for policies that pay fixed dollar amounts for specified diseases or other specified impairments. This includes cancer, specified disease, and other health insurance policies that pay a scheduled benefit or specific payment based on diagnosis of the conditions named in the policy.]

IMPORTANT NOTICE TO PERSONS ON MEDICARE
THIS IS NOT MEDICARE SUPPLEMENT INSURANCE

Some health care services paid for by Medicare may also trigger the payment of benefits from this policy.

This insurance pays a fixed amount, regardless of your expenses, if you meet the policy conditions, for one of the specific diseases or health conditions named in the policy. It does not pay your Medicare deductibles or coinsurance and is not a substitute for Medicare Supplement insurance.

Medicare pays extensive benefits for medically necessary services regardless of the reason you need them. These include:

- Hospitalization
- Physician services
- Hospice
- Outpatient Prescription Drugs if you are enrolled in Medicare Part D
- Other approved items and services

This policy must pay benefits without regard to other health benefit coverage to which you may be entitled under Medicare or other insurance.

Before You Buy This Insurance

√ Check the coverage in **all** health insurance policies you already have.

√ For more information about Medicare and Medicare Supplement insurance, review the [insert name of most recent version of *2019 Choosing a Medigap Policy: Guide to Health Insurance for People with Medicare*, issued by Centers for Medicare and Medicaid Services], available from the insurance company.

√ For help in understanding your health insurance, contact the Senior Health Insurance Information Program (SHIIP) of the Iowa Insurance Division.

[Alternative disclosure statement for indemnity policies and other policies that pay a fixed dollar amount per day, excluding long-term care policies.]

IMPORTANT NOTICE TO PERSONS ON MEDICARE
THIS IS NOT MEDICARE SUPPLEMENT INSURANCE

Some health care services paid for by Medicare may also trigger the payment of benefits from this policy.

This insurance pays a fixed dollar amount, regardless of your expenses, for each day you meet the policy conditions. It does not pay your Medicare deductibles or coinsurance and is not a substitute for Medicare Supplement insurance.

Medicare generally pays for most or all of these expenses.

Medicare pays extensive benefits for medically necessary services regardless of the reason you need them. These include:

- Hospitalization
- Physician services
- Hospice
- Outpatient Prescription Drugs if you are enrolled in Medicare Part D
- Other approved items and services

This policy must pay benefits without regard to other health benefit coverage to which you may be entitled under Medicare or other insurance.

Before You Buy This Insurance

√ Check the coverage in **all** health insurance policies you already have.

√ For more information about Medicare and Medicare Supplement insurance, review the [insert name of most recent version of *2019 Choosing a Medigap Policy: Guide to Health Insurance for People with Medicare*, issued by Centers for Medicare and Medicaid Services], available from the insurance company.

√ For help in understanding your health insurance, contact the Senior Health Insurance Information Program (SHIIP) of the Iowa Insurance Division.

[Alternative disclosure statement for policies that provide benefits upon both an expense-incurred and fixed indemnity basis.]

IMPORTANT NOTICE TO PERSONS ON MEDICARE
THIS IS NOT MEDICARE SUPPLEMENT INSURANCE

Some health care services paid for by Medicare may also trigger the payment of benefits from this policy.

This insurance pays limited reimbursement for expenses if you meet the conditions listed in the policy. It also pays a fixed amount, regardless of your expenses, if you meet other policy conditions. It does not pay your Medicare deductibles or coinsurance and is not a substitute for Medicare Supplement insurance.

Medicare generally pays for most or all of these expenses.

Medicare pays extensive benefits for medically necessary services regardless of the reason you need them. These include:

- Hospitalization
- Physician services
- Hospice care
- Outpatient Prescription Drugs if you are enrolled in Medicare Part D
- Other approved items and services

This policy must pay benefits without regard to other health benefit coverage to which you may be entitled under Medicare or other insurance.

Before You Buy This Insurance

√ Check the coverage in **all** health insurance policies you already have.

√ For more information about Medicare and Medicare Supplement insurance, review the [insert name of most recent version of *2019 Choosing a Medigap Policy: Guide to Health Insurance for People with Medicare*, issued by Centers for Medicare and Medicaid Services], available from the insurance company.

√ For help in understanding your health insurance, contact the Senior Health Insurance Information Program (SHIIP) of the Iowa Insurance Division.

[Alternative disclosure statement for other health insurance policies not specifically identified in the preceding statements.]

IMPORTANT NOTICE TO PERSONS ON MEDICARE
THIS IS NOT MEDICARE SUPPLEMENT INSURANCE

Some health care services paid for by Medicare may also trigger the payment of benefits from this policy.

This insurance provides limited benefits if you meet the conditions listed in the policy. It does not pay your Medicare deductibles or coinsurance and is not a substitute for Medicare Supplement insurance.

Medicare generally pays for most or all of these expenses.

Medicare pays extensive benefits for medically necessary services regardless of the reason you need them. These include:

- Hospitalization
- Physician services
- Hospice
- Outpatient Prescription Drugs if you are enrolled in Medicare Part D
- Other approved items and services

This policy must pay benefits without regard to other health benefit coverage to which you may be entitled under Medicare or other insurance.

Before You Buy This Insurance

√ Check the coverage in all health insurance policies you already have.

√ For more information about Medicare and Medicare Supplement insurance, review the [insert name of most recent version of *2019 Choosing a Medigap Policy: Guide to Health Insurance for People with Medicare*, issued by Centers for Medicare and Medicaid Services], available from the insurance company.

√ For help in understanding your health insurance, contact the Senior Health Insurance Information Program (SHIIP) of the Iowa Insurance Division.

APPENDIX C
STATEMENTS AND QUESTIONS FOR APPLICATION FORMS RELATED TO DUPLICATE OR REPLACEMENT COVERAGE

Statements

(1) You do not need more than one Medicare supplement policy.

(2) If you purchase this [policy or certificate], you may want to evaluate your existing health coverage and decide if you need multiple coverages.

(3) You may be eligible for benefits under Medicaid and may not need a Medicare supplement [policy or certificate].

(4) If, after purchasing this [policy or certificate], you become eligible for Medicaid, the benefits and premiums under your Medicare supplement [policy or certificate] can be suspended, if requested, during your entitlement to benefits under Medicaid for 24 months. You must request this suspension within 90 days of becoming eligible for Medicaid. If you are no longer entitled to Medicaid, your suspended Medicare supplement [policy or certificate] (or, if that is no longer available, a substantially equivalent [policy or certificate]) will be reinstituted if requested within 90 days of losing your Medicaid eligibility. If the Medicare supplement [policy or certificate] provided coverage for outpatient prescription drugs and you enrolled in Medicare Part D while your [policy or certificate] was suspended, the reinstituted [policy or certificate] will not have outpatient prescription drug coverage, but will otherwise be substantially equivalent to your coverage before the date of the suspension.

(5) If you are eligible for and have enrolled in a Medicare supplement [policy or certificate] by reason of disability and you later become covered by an employer or union-based group health plan, the benefits and premiums under your Medicare supplement [policy or certificate] can be suspended, if requested, while you are covered under the employer or union-based group health plan. If you suspend your Medicare supplement [policy or certificate] under these circumstances, and later lose your employer or union-based group health plan, your suspended Medicare supplement [policy or certificate] (or, if that is no longer available, a substantially equivalent [policy or certificate],) will be reinstituted if requested within 90 days of losing your employer or union-based group health plan. If the Medicare supplement [policy or certificate] provided coverage for outpatient prescription drugs and you enrolled in Medicare Part D while your [policy or certificate] was suspended, the reinstituted [policy or certificate] will not have outpatient prescription drug coverage, but will otherwise be substantially equivalent to your coverage before the date of the suspension.

(6) Counseling services may be available in your state to provide advice concerning your purchase of Medicare supplement insurance and concerning medical assistance through the state Medicaid program, including benefits as a Qualified Medicare Beneficiary (QMB) and a Specified Low-Income Medicare Beneficiary (SLMB).

Questions

If you lost or are losing other health insurance coverage and received a notice from your prior insurance company saying you were eligible for guaranteed issue of a Medicare supplement insurance [policy or certificate], or that you had certain rights to buy such a [policy or certificate], you may be guaranteed acceptance in one or more of our Medicare supplement plans. Please include a copy of the notice from your prior insurance company with your application.

PLEASE ANSWER ALL QUESTIONS.

(Please mark Yes or No below with an "X".)

To the best of your knowledge,

(1) (a) Did you turn age 65 in the last 6 months?

Yes____No____

(b) Did you enroll in Medicare Part B in the last 6 months?

Yes____No____

(c) If yes, what is the effective date? _____

(2) Are you covered for medical assistance through the state Medicaid program?

(NOTE TO APPLICANT: If you are participating in a "Spend-Down Program" and have not met your "Share of Cost," please answer NO to this question.)

Yes____No____

If yes,

(a) Will Medicaid pay your premiums for this Medicare supplement [policy or certificate]?

Yes____No____

(b) Do you receive any benefits from Medicaid OTHER THAN payments toward your Medicare Part B premium?

Yes____No____

(3) (a) If you had coverage from any Medicare plan other than original Medicare within the past 63 days (for example, a Medicare Advantage plan, or a Medicare HMO or PPO), fill in your start and end dates below. If you are still covered under this plan, leave "END" blank.

START __/__/__ END __/__/__

(b) If you are still covered under the Medicare plan, do you intend to replace your current coverage with this new Medicare supplement [policy or certificate]?

Yes____No____

(c) Was this your first time in this type of Medicare plan?

Yes____No____

(d) Did you drop a Medicare supplement policy or certificate to enroll in this plan?

Yes____No____

(4) (a) Do you have another Medicare supplement policy or certificate in force?

Yes____No____

(b) If so, with what company, and what plan do you have [optional for direct mailers]?

_____

(c) If so, do you intend to replace your current Medicare supplement policy or certificate with this [policy or certificate]?

Yes____No____

(5) Have you had coverage under any other health insurance within the past 63 days? (For example, an employer, union, or individual plan)

Yes____No____

(a) If so, with what company and what kind of policy or certificate?

_____

_____

_____

_____

(b) What are your dates of coverage under the other policy or certificate?

START __/__/__ END __/__/__

(If you are still covered under the other policy or certificate, leave "END" blank.)

APPENDIX D

NOTICE TO APPLICANT REGARDING REPLACEMENT OF MEDICARE SUPPLEMENT INSURANCE OR MEDICARE ADVANTAGE

[Insurance company's name and address]

SAVE THIS NOTICE! IT MAY BE IMPORTANT TO YOU IN THE FUTURE.

According to [your application] [information you have furnished], you intend to terminate an existing Medicare supplement policy or certificate or Medicare Advantage policy or certificate and replace it with a policy to be issued by [Company Name] Insurance Company. Your new policy will provide thirty (30) days within which you may decide without cost whether you desire to keep the policy. You should review this new coverage carefully. Compare it with all accident and sickness coverage you now have. If, after due consideration, you find that purchase of this Medicare supplement [policy or certificate] is a wise decision, you should terminate your present Medicare supplement policy or certificate or Medicare Advantage policy or certificate. You should evaluate the need for other accident and sickness coverage you have that may duplicate this policy.

STATEMENT TO APPLICANT BY ISSUER, PRODUCER [BROKER OR OTHER REPRESENTATIVE]:

I have reviewed your current medical or health insurance coverage. To the best of my knowledge, this Medicare supplement policy or certificate will not duplicate your existing Medicare supplement policy or certificate or, if applicable, Medicare Advantage policy or certificate because you intend to terminate your existing Medicare supplement policy or certificate or Medicare Advantage policy or certificate. The replacement [policy or certificate] is being purchased for the following reason (check one):

____ Additional benefits.

____ No change in benefits, but lower premiums.

____ Fewer benefits and lower premiums.

____ My plan has outpatient prescription drug coverage and I am enrolling in Part D.

____ Disenrollment from a Medicare Advantage policy or certificate. Please explain reason for disenrollment. [optional only for direct mailers]

____ Other. (Please specify.)_____

1. **Note:** If the issuer of the Medicare supplement policy or certificate being applied for does not impose, or is otherwise prohibited from imposing, preexisting condition limitations, please skip to statement 2 below. Health conditions which you may presently have (preexisting conditions) may not be immediately or fully covered under the new policy. This could result in denial or delay of a claim for benefits under the new [policy or certificate], whereas a similar claim might have been payable under your present policy or certificate.

2. State law provides that your replacement policy or certificate may not contain new preexisting conditions, waiting periods, elimination periods or probationary periods. The insurance company will waive any time periods applicable to preexisting conditions, waiting periods, elimination periods or probationary periods in the new policy or certificate (or coverage) for similar benefits to the extent such time was spent (depleted) under the original policy or certificate.

3. If you still wish to terminate your present policy or certificate and replace it with new coverage, be certain to truthfully and completely answer all questions on the application concerning your medical and health history. Failure to include all material medical information on an application may provide a basis for the company to deny any future claims and to refund your premium as though your policy or certificate had never been in force. After the application has been completed and before you sign it, review it carefully to be certain that all information has been properly recorded. [If the policy or certificate is guaranteed issue, this paragraph need not appear.]

Do not cancel your present policy or certificate until you have received your new [policy or certificate] and are sure that you want to keep it.

_____
(Signature of Producer, Broker or Other Representative)*
[Typed Name and Address of Issuer, and of Producer or Broker]

_____
(Applicant's Signature)

_____
(Date)
*Signature not required for direct response sales.

APPENDIX E
OUTLINE OF COVERAGE: BENEFIT CHARTS

[Any amount in brackets in this Appendix E shall be changed to coincide with any change in amount made by the Secretary of the U.S. Department of Health and Human Services.]

Benefit Chart of Medicare Supplement Plans Sold for Effective Dates On or After June 1, 2010

This chart shows the benefits included in each of the standardized Medicare Supplement plans. Every company must make Plan "A" available. Some plans may not be available in your state.

Basic Benefits:

- **Hospitalization** – Part A coinsurance plus coverage for 365 additional days after Medicare benefits end.
- **Medical Expenses** – Part B coinsurance (generally 20% of Medicare-approved expenses) or copayments for hospital outpatient services. Plans K, L and N require insureds to pay a portion of Part B coinsurance or copayments.
- **Blood** – First three pints of blood each year.
- **Hospice** – Part A coinsurance.

A	B	C	D	F	F*	G	K	L	M	N
Basic, including 100% Part B coinsurance	Basic, including 100% Part B coinsurance	Basic, including 100% Part B coinsurance	Basic, including 100% Part B coinsurance	Basic, including 100% Part B co-insurance*		Basic, including 100% Part B coinsurance	Hospitalization and preventive care paid at 100%; other basic benefits paid at 50%	Hospitalization and preventive care paid at 100%; other basic benefits paid at 75%	Basic, including 100% Part B coinsurance	Basic, including 100% Part B coinsurance, except up to $20 copayment for office visit, and up to $50 copayment for ER
		Skilled Nursing Facility Coinsurance	Skilled Nursing Facility Coinsurance	Skilled Nursing Facility Coinsurance		Skilled Nursing Facility Coinsurance	50% Skilled Nursing Facility Coinsurance	75% Skilled Nursing Facility Coinsurance	Skilled Nursing Facility Coinsurance	Skilled Nursing Facility Coinsurance
	Part A Deductible	Part A Deductible	Part A Deductible	Part A Deductible		Part A Deductible	50% Part A Deductible	75% Part A Deductible	50% Part A Deductible	Part A Deductible
		Part B Deductible		Part B Deductible						
				Part B Excess (100%)		Part B Excess (100%)				
		Foreign Travel Emergency	Foreign Travel Emergency	Foreign Travel Emergency		Foreign Travel Emergency			Foreign Travel Emergency	Foreign Travel Emergency
							Out-of-pocket limit $[5560]; paid at 100% after limit reached	Out-of-pocket limit $[2780]; paid at 100% after limit reached		

* Plan F also has an option called a high deductible Plan F. This high deductible plan pays the same benefits as Plan F after one has paid a calendar year $[2300] deductible. Benefits from high deductible Plan F will not begin until out-of-pocket expenses exceed $[2300]. Out-of-pocket expenses for this deductible are expenses that would ordinarily be paid by the

policy. These expenses include the Medicare deductibles for Part A and Part B, but do not include the plan's separate foreign travel emergency deductible.

PREMIUM INFORMATION [Boldface Type]

We, [insert issuer's name], can only raise your premium if we raise the premium for all policies like yours in this state. [If the premium is based on the increasing age of the insured individual, include information specifying when premiums will change.]

READ YOUR POLICY VERY CAREFULLY [Boldface Type]

This is only an outline describing your policy's most important features. The policy is your insurance contract. You must read the policy itself to understand all of the rights and duties of both you and your insurance company.

RIGHT TO RETURN POLICY [Boldface Type]

If you find that you are not satisfied with your policy, you may return it to [insert issuer's address]. If you send the policy back to us within 30 days after you receive it, we will treat the policy as if it had never been issued and return all of your payments.

POLICY REPLACEMENT [Boldface Type]

If you are replacing another health insurance policy, do NOT cancel it until you have actually received your new policy and are sure you want to keep it.

NOTICE [Boldface Type]

This policy may not fully cover all of your medical costs.

[for producers:]
Neither [insert company's name] nor its producers are connected with Medicare.

[for direct response:]
[Insert company's name] is not connected with Medicare.

This outline of coverage does not give all the details of Medicare coverage. Contact your local Social Security office or consult "Medicare and You" for more details.

COMPLETE ANSWERS ARE VERY IMPORTANT [Boldface Type]

When you fill out the application for the new policy, be sure to answer truthfully and completely all questions about your medical and health history. The company may cancel your policy and refuse to pay any claims if you leave out or falsify important medical information. [If the policy or certificate is guaranteed issue, this paragraph need not appear.]

Review the application carefully before you sign it. Be certain that all information has been properly recorded.

[Include for each plan prominently identified in the cover page a chart showing the services, Medicare payments, plan payments and insured payments, using the same language, in the same order, using uniform layout and format as shown in the charts below. No more than four plans may be shown on one chart. For purposes of illustration, charts for each plan are included in this Appendix E: Outline of Coverage. An issuer may use additional benefit plan descriptions on these charts pursuant to paragraph 37.8(1)*"c."*]

[Include an explanation of any innovative benefits on the cover page and in the chart, in a manner approved by the commissioner.]

Benefit Chart of Medicare Supplement Plans Sold On or After January 1, 2020

This chart shows the benefits included in each of the standardized Medicare supplement plans. Some plans may not be available. Only applicants first eligible for Medicare before 2020 may purchase Plans C, F, and high deductible F.

Note: A ✓ means 100% of the benefit is paid.

Benefits	Plans Available to All Applicants								Medicare first eligible before 2020 only	
	A	B	D	G[1]	K	L	M	N	C	F[1]
Medicare Part A coinsurance and hospital coverage (up to an additional 365 days after Medicare benefits are used up)	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓
Medicare Part B coinsurance or copayment	✓	✓	✓	✓	50%	75%	✓	✓Copays apply[3]	✓	✓
Blood (first three pints)	✓	✓	✓	✓	50%	75%	✓	✓	✓	✓
Medicare Part A hospice care coinsurance or copayment	✓	✓	✓	✓	50%	75%	✓	✓	✓	✓
Skilled nursing facility coinsurance			✓	✓	50%	75%	✓	✓	✓	✓
Medicare Part A deductible		✓	✓	✓	50%	75%	50%	✓	✓	✓
Medicare Part B deductible									✓	✓
Medicare Part B excess charges				✓						✓
Foreign travel emergency (up to plan limits)			✓	✓			✓	✓	✓	✓
Out-of-pocket limit in [2019][2]					[$5560][2]	[$2780][2]				

[1]Plans F and G also have high deductible options which require first paying the plans' deductibles of [$2300] before the plans begin to pay. Once the plans' deductibles are met, the plans pay 100% of covered services for the rest of the calendar year. High deductible Plan G does not cover the Medicare Part B deductible. However, high deductible Plans F and G count your payments of the Medicare Part B deductible toward meeting the plan deductibles.

[2]Plans K and L pay 100% of covered services for the rest of the calendar year once you meet the out-of-pocket yearly limits.

[3]Plan N pays 100% of the Medicare Part B coinsurance, except for copayments of up to $20 for some office visits and up to $50 copayments for emergency room visits that do not result in inpatient admissions.

PLAN A
MEDICARE (PART A)—HOSPITAL SERVICES—PER BENEFIT PERIOD

* A benefit period begins on the first day you receive service as an inpatient in a hospital and ends after you have been out of the hospital and have not received skilled care in any other facility for 60 days in a row.

SERVICES	MEDICARE PAYS	PLAN PAYS	YOU PAY
HOSPITALIZATION* Semiprivate room and board, general nursing and miscellaneous services and supplies			
First 60 days	All but $[1364]	$0	$[1364] (Part A deductible)
61st through 90th day	All but $[341] a day	$[341] a day	$0
91st day and after:			
—While using 60 lifetime reserve days	All but $[682] a day	$[682] a day	$0
—Once lifetime reserve days are used:			
—Additional 365 days	$0	100% of Medicare eligible expenses	$0**
—Beyond the additional 365 days	$0	$0	All costs
SKILLED NURSING FACILITY CARE* You must meet Medicare's requirements, including having been in a hospital for at least 3 days and entered a Medicare-approved facility within 30 days after leaving the hospital.			
First 20 days	All approved amounts	$0	$0
21st through 100th day	All but $[170.50] a day	$0	Up to $[170.50] a day
101st day and after	$0	$0	All costs
BLOOD			
First 3 pints	$0	3 pints	$0
Additional amounts	100%	$0	$0
HOSPICE CARE You must meet Medicare's requirements, including a doctor's certification of terminal illness.	All but very limited copayment/coinsurance for outpatient drugs and inpatient respite care	Medicare copayment/ coinsurance	$0

** NOTICE: When your Medicare Part A hospital benefits are exhausted, the insurance company stands in the place of Medicare and will pay whatever amount Medicare would have paid for up to an additional 365 days as provided in the policy's basic core benefits ("basic core benefits" are the equivalent of what is provided under Medicare Part A). During this time, the hospital is prohibited from billing you for the balance based on any difference between its billed charges and the amount Medicare would have paid.

PLAN A
MEDICARE (PART B)—MEDICAL SERVICES—PER CALENDAR YEAR

SERVICES	MEDICARE PAYS	PLAN PAYS	YOU PAY
MEDICAL EXPENSES— IN OR OUT OF THE HOSPITAL AND OUTPATIENT HOSPITAL TREATMENT, such as physician's services, inpatient and outpatient medical and surgical services and supplies, physical and speech therapy, diagnostic tests, durable medical equipment			
First $[185] of Medicare-Approved Amounts*	$0	$0	$[185] (Part B deductible)
Remainder of Medicare-Approved Amounts	Generally 80%	Generally 20%	$0
Part B Excess Charges (Above Medicare-Approved Amounts)	$0	$0	All costs
BLOOD			
First 3 pints	$0	All costs	$0
Next $[185] of Medicare-Approved Amounts*	$0	$0	$[185] (Part B deductible)
Remainder of Medicare-Approved Amounts	80%	20%	$0
CLINICAL LABORATORY SERVICES— TESTS FOR DIAGNOSTIC SERVICES	100%	$0	$0

PLAN A
MEDICARE PARTS A & B

SERVICES	MEDICARE PAYS	PLAN PAYS	YOU PAY
HOME HEALTH CARE MEDICARE-APPROVED SERVICES			
—Medically necessary skilled care services and medical supplies	100%	$0	$0
—Durable medical equipment			
First $[185] of Medicare-Approved Amounts*	$0	$0	$[185] (Part B deductible)
Remainder of Medicare-Approved Amounts	80%	20%	$0

* Once you have been billed $[185] of Medicare-approved amounts for covered services, your Medicare Part B deductible will have been met for the calendar year.

MEDICARE PLAN B
MEDICARE PART A—HOSPITAL SERVICES—PER BENEFIT PERIOD

* A benefit period begins on the first day you receive service as an inpatient in a hospital and ends after you have been out of the hospital and have not received skilled care in any other facility for 60 days in a row.

SERVICES	MEDICARE PAYS	PLAN PAYS	YOU PAY
HOSPITALIZATION* Semiprivate room and board, general nursing and miscellaneous services and supplies			
First 60 days	All but $[1364]	$[1364] (Part A deductible)	$0
61st through 90th day	All but $[341] a day	$[341] a day	$0
91st day and after:			
—While using 60 lifetime reserve days	All but $[682] a day	$[682] a day	$0
—Once lifetime reserve days are used:			
—Additional 365 days	$0	100% of Medicare eligible expenses	$0**
—Beyond the additional 365 days	$0	$0	All costs
SKILLED NURSING FACILITY CARE* You must meet Medicare's requirements, including having been in a hospital for at least 3 days and entered a Medicare-approved facility within 30 days after leaving the hospital.			
First 20 days	All approved amounts	$0	$0
21st through 100th day	All but $[170.50] a day	$0	Up to $[170.50] a day
101st day and after	$0	$0	All costs
BLOOD			
First 3 pints	$0	3 pints	$0
Additional amounts	100%	$0	$0
HOSPICE CARE You must meet Medicare's requirements, including a doctor's certification of terminal illness.	All but very limited copayment/ coinsurance for outpatient drugs and inpatient respite care	Medicare copayment/ coinsurance	$0

** NOTICE: When your Medicare Part A hospital benefits are exhausted, the insurance company stands in the place of Medicare and will pay whatever amount Medicare would have paid for up to an additional 365 days as provided in the policy's basic core benefits ("basic core benefits" are the equivalent of what is provided under Medicare Part A). During this time, the hospital is prohibited from billing you for the balance based on any difference between its billed charges and the amount Medicare would have paid.

PLAN B
MEDICARE (PART B)—MEDICAL SERVICES—PER CALENDAR YEAR

SERVICES	MEDICARE PAYS	PLAN PAYS	YOU PAY
MEDICAL EXPENSES— IN OR OUT OF THE HOSPITAL AND OUTPATIENT HOSPITAL TREATMENT, such as physician's services, inpatient and outpatient medical and surgical services and supplies, physical and speech therapy, diagnostic tests, durable medical equipment			
First $[185] of Medicare-Approved Amounts*	$0	$0	$[185] (Part B deductible)
Remainder of Medicare-Approved Amounts	Generally 80%	Generally 20%	$0
Part B Excess Charges (Above Medicare-Approved Amounts)	$0	$0	All costs
BLOOD			
First 3 pints	$0	All costs	$0
Next $[185] of Medicare-Approved Amounts*	$0	$0	$[185] (Part B deductible)
Remainder of Medicare-Approved Amounts	80%	20%	$0
CLINICAL LABORATORY SERVICES— TESTS FOR DIAGNOSTIC SERVICES	100%	$0	$0

PLAN B
PARTS A & B

SERVICES	MEDICARE PAYS	PLAN PAYS	YOU PAY
HOME HEALTH CARE MEDICARE-APPROVED SERVICES			
—Medically necessary skilled care services and medical supplies	100%	$0	$0
—Durable medical equipment			
First $[185] of Medicare-Approved Amounts*	$0	$0	$[185] (Part B deductible)
Remainder of Medicare-Approved Amounts	80%	20%	$0

* Once you have been billed $[185] of Medicare-approved amounts for covered services, your Part B deductible will have been met for the calendar year.

PLAN C
MEDICARE (PART A)—HOSPITAL SERVICES—PER BENEFIT PERIOD

SERVICES	MEDICARE PAYS	PLAN PAYS	YOU PAY
HOSPITALIZATION* Semiprivate room and board, general nursing and miscellaneous services and supplies			
First 60 days	All but $[1364]	$[1364] (Part A deductible)	$0
61st through 90th day	All but $[341] a day	$[341] a day	$0
91st day and after:			
—While using 60 lifetime reserve days	All but $[682] a day	$[682] a day	$0
—Once lifetime reserve days are used:			
—Additional 365 days	$0	100% of Medicare eligible expenses	$0**
—Beyond the additional 365 days	$0	$0	All costs
SKILLED NURSING FACILITY CARE* You must meet Medicare's requirements, including having been in a hospital for at least 3 days and entered a Medicare-approved facility within 30 days after leaving the hospital.			
First 20 days	All approved amounts	$0	$0
21st through 100th day	All but $[170.50] a day	Up to $[170.50] a day	$0
101st day and after	$0	$0	All costs
BLOOD			
First 3 pints	$0	3 pints	$0
Additional amounts	100%	$0	$0
HOSPICE CARE You must meet Medicare's requirements, including a doctor's certification of terminal illness.	All but very limited copayment/ coinsurance for outpatient drugs and inpatient respite care	Medicare copayment/ coinsurance	$0

* A benefit period begins on the first day you receive service as an inpatient in a hospital and ends after you have been out of the hospital and have not received skilled care in any other facility for 60 days in a row.

** NOTICE: When your Medicare Part A hospital benefits are exhausted, the insurance company stands in the place of Medicare and will pay whatever amount Medicare would have paid for up to an additional 365 days as provided in the policy's basic core benefits ("basic core benefits" are the equivalent of what is provided under Medicare Part A). During this time, the hospital is prohibited from billing you for the balance based on any difference between its billed charges and the amount Medicare would have paid.

PLAN C
MEDICARE (PART B)—MEDICAL SERVICES—PER CALENDAR YEAR

SERVICES	MEDICARE PAYS	PLAN PAYS	YOU PAY
MEDICAL EXPENSES— IN OR OUT OF THE HOSPITAL AND OUTPATIENT HOSPITAL TREATMENT, such as physician's services, inpatient and outpatient medical and surgical services and supplies, physical and speech therapy, diagnostic tests, durable medical equipment			
First $[185] of Medicare-Approved Amounts*	$0	$[185] (Part B deductible)	$0
Remainder of Medicare-Approved Amounts	Generally 80%	Generally 20%	$0
Part B Excess Charges (Above Medicare-Approved Amounts)	$0	$0	All costs
BLOOD			
First 3 pints	$0	All costs	$0
Next $[185] of Medicare-Approved Amounts*	$0	$[185] (Part B deductible)	$0
Remainder of Medicare-Approved Amounts	80%	20%	$0
CLINICAL LABORATORY SERVICES— TESTS FOR DIAGNOSTIC SERVICES	100%	$0	$0

PLAN C
PARTS A & B

SERVICES	MEDICARE PAYS	PLAN PAYS	YOU PAY
HOME HEALTH CARE MEDICARE-APPROVED SERVICES			
—Medically necessary skilled care services and medical supplies	100%	$0	$0
—Durable medical equipment			
First $[185] of Medicare-Approved Amounts*	$0	$[185] (Part B deductible)	$0
Remainder of Medicare-Approved Amounts*	80%	20%	$0

* Once you have been billed $[185] of Medicare-approved amounts for covered services, your Part B deductible will have been met for the calendar year.

PLAN C
OTHER BENEFITS—NOT COVERED BY MEDICARE

SERVICES	MEDICARE PAYS	PLAN PAYS	YOU PAY
FOREIGN TRAVEL—NOT COVERED BY MEDICARE Medically necessary emergency care services beginning during the first 60 days of each trip outside the USA			
First $250 each calendar year	$0	$0	$250
Remainder of charges	$0	80% to a lifetime maximum benefit of $50,000	20% and amounts over the $50,000 lifetime maximum

PLAN D
MEDICARE (PART A)—HOSPITAL SERVICES—PER BENEFIT PERIOD

SERVICES	MEDICARE PAYS	PLAN PAYS	YOU PAY
HOSPITALIZATION* Semiprivate room and board, general nursing and miscellaneous services and supplies			
First 60 days	All but $[1364]	$[1364] (Part A deductible)	$0
61st through 90th day	All but $[341] a day	$[341] a day	$0
91st day and after:			
—While using 60 lifetime reserve days	All but $[682] a day	$[682] a day	$0
—Once lifetime reserve days are used:			
—Additional 365 days	$0	100% of Medicare eligible expenses	$0**
—Beyond the additional 365 days	$0	$0	All costs
SKILLED NURSING FACILITY CARE* You must meet Medicare's requirements, including having been in a hospital for at least 3 days and entered a Medicare-approved facility within 30 days after leaving the hospital.			
First 20 days	All approved amounts	$0	$0
21st through 100th day	All but $[170.50] a day	Up to $[170.50] a day	$0
101st day and after	$0	$0	All costs
BLOOD			
First 3 pints	$0	3 pints	$0
Additional amounts	100%	$0	$0
HOSPICE CARE You must meet Medicare's requirements, including a doctor's certification of terminal illness.	All but very limited copayment/ coinsurance for outpatient drugs and inpatient respite care	Medicare copayment/ coinsurance	$0

* A benefit period begins on the first day you receive service as an inpatient in a hospital and ends after you have been out of the hospital and have not received skilled care in any other facility for 60 days in a row.

** NOTICE: When your Medicare Part A hospital benefits are exhausted, the insurance company stands in the place of Medicare and will pay whatever amount Medicare would have paid for up to an additional 365 days as provided in the policy's basic core benefits ("basic core benefits" are the equivalent of what is provided under Medicare Part A). During this time, the hospital is prohibited from billing you for the balance based on any difference between its billed charges and the amount Medicare would have paid.

PLAN D
MEDICARE (PART B)—MEDICAL SERVICES—PER CALENDAR YEAR

SERVICES	MEDICARE PAYS	PLAN PAYS	YOU PAY
MEDICAL EXPENSES— IN OR OUT OF THE HOSPITAL AND OUTPATIENT HOSPITAL TREATMENT, such as physician's services, inpatient and outpatient medical and surgical services and supplies, physical and speech therapy, diagnostic tests, durable medical equipment			
First $[185] of Medicare-Approved Amounts*	$0	$0	$[185] (Part B deductible)
Remainder of Medicare-Approved Amounts	Generally 80%	Generally 20%	$0
Part B Excess Charges (Above Medicare-Approved Amounts)	$0	$0	All costs
BLOOD			
First 3 pints	$0	All costs	$0
Next $[185] of Medicare-Approved Amounts*	$0	$0	$[185] (Part B deductible)
Remainder of Medicare-Approved Amounts	80%	20%	$0
CLINICAL LABORATORY SERVICES— TESTS FOR DIAGNOSTIC SERVICES	100%	$0	$0

PLAN D
PARTS A & B

SERVICES	MEDICARE PAYS	PLAN PAYS	YOU PAY
HOME HEALTH CARE MEDICARE-APPROVED SERVICES			
—Medically necessary skilled care services and medical supplies	100%	$0	$0
—Durable medical equipment			
First $[185] of Medicare-Approved Amounts*	$0	$0	$[185] (Part B deductible)
Remainder of Medicare-Approved Amounts	80%	20%	$0

* Once you have been billed $[185] of Medicare-approved amounts for covered services, your Part B deductible will have been met for the calendar year.

PLAN D
OTHER BENEFITS—NOT COVERED BY MEDICARE

SERVICES	MEDICARE PAYS	PLAN PAYS	YOU PAY
FOREIGN TRAVEL—NOT COVERED BY MEDICARE Medically necessary emergency care services beginning during the first 60 days of each trip outside the USA			
First $250 each calendar year	$0	$0	$250
Remainder of charges	$0	80% to a lifetime maximum benefit of $50,000	20% and amounts over the $50,000 lifetime maximum

PLAN F or HIGH DEDUCTIBLE PLAN F
MEDICARE (PART A)—HOSPITAL SERVICES—PER BENEFIT PERIOD

SERVICES	MEDICARE PAYS	[AFTER YOU PAY $[2300] DEDUCTIBLE,**] PLAN PAYS	[IN ADDITION TO $[2300] DEDUCTIBLE,**] YOU PAY
HOSPITALIZATION* Semiprivate room and board, general nursing and miscellaneous services and supplies			
First 60 days	All but $[1364]	$[1364] (Part A deductible)	$0
61st through 90th day	All but $[341] a day	$[341] a day	$0
91st day and after:			
—While using 60 lifetime reserve days	All but $[682] a day	$[682] a day	$0
—Once lifetime reserve days are used:			
—Additional 365 days	$0	100% of Medicare eligible expenses	$0***
—Beyond the additional 365 days	$0	$0	All costs
SKILLED NURSING FACILITY CARE* You must meet Medicare's requirements, including having been in a hospital for at least 3 days and entered a Medicare-approved facility within 30 days after leaving the hospital.			
First 20 days	All approved amounts	$0	$0
21st through 100th day	All but $[170.50] a day	Up to $[170.50] a day	$0
101st day and after	$0	$0	All costs
BLOOD			
First 3 pints	$0	3 pints	$0
Additional amounts	100%	$0	$0
HOSPICE CARE You must meet Medicare's requirements, including a doctor's certification of terminal illness.	All but very limited copayment/ coinsurance for outpatient drugs and inpatient respite care	Medicare copayment/ coinsurance	$0

* A benefit period begins on the first day you receive service as an inpatient in a hospital and ends after you have been out of the hospital and have not received skilled care in any other facility for 60 days in a row.

[** This high deductible plan pays the same benefits as Plan F after you have paid a calendar year $[2300] deductible. Benefits from the high deductible Plan F will not begin until out-of-pocket expenses are $[2300]. Out-of-pocket expenses for this deductible are expenses that would ordinarily be paid by the policy. This includes the Medicare deductibles for Part A and Part B, but does not include the plan's separate foreign travel emergency deductible.]

*** NOTICE: When your Medicare Part A hospital benefits are exhausted, the insurance company stands in the place of Medicare and will pay whatever amount Medicare would have paid for up to an additional 365 days as provided in the policy's basic core ("basic core benefits" are the equivalent of what is provided under Medicare Part A). During this time, the hospital is prohibited from billing you for the balance based on any difference between its billed charges and the amount Medicare would have paid.

PLAN F or HIGH DEDUCTIBLE PLAN F
MEDICARE (PART B)—MEDICAL SERVICES—PER CALENDAR YEAR

SERVICES	MEDICARE PAYS	[AFTER YOU PAY $[2300] DEDUCTIBLE,**] PLAN PAYS	[IN ADDITION TO $[2300] DEDUCTIBLE,**] YOU PAY
MEDICAL EXPENSES— IN OR OUT OF THE HOSPITAL AND OUTPATIENT HOSPITAL TREATMENT, such as physician's services, inpatient and outpatient medical and surgical services and supplies, physical and speech therapy, diagnostic tests, durable medical equipment			
First $[185] of Medicare-Approved Amounts*	$0	$[185] (Part B deductible)	$0
Remainder of Medicare-Approved Amounts	Generally 80%	Generally 20%	$0
Part B Excess Charges (Above Medicare-Approved Amounts)	$0	100%	$0
BLOOD			
First 3 pints	$0	All costs	$0
Next $[185] of Medicare-Approved Amounts*	$0	$[185] (Part B deductible)	$0
Remainder of Medicare-Approved Amounts	80%	20%	$0
CLINICAL LABORATORY SERVICES— TESTS FOR DIAGNOSTIC SERVICES	100%	$0	$0

* Once you have been billed $[185] of Medicare-approved amounts for covered services, your Part B deductible will have been met for the calendar year.

[** This high deductible plan pays the same benefits as Plan F after you have paid a calendar year $[2300] deductible. Benefits from the high deductible Plan F will not begin until out-of-pocket expenses are $[2300]. Out-of-pocket expenses for this deductible are expenses that would ordinarily be paid by the policy. This includes the Medicare deductibles for Part A and Part B, but does not include the plan's separate foreign travel emergency deductible.]

PLAN F or HIGH DEDUCTIBLE PLAN F
PARTS A & B

SERVICES	MEDICARE PAYS	[AFTER YOU PAY $[2300] DEDUCTIBLE,**] PLAN PAYS	[IN ADDITION TO $[2300] DEDUCTIBLE,**] YOU PAY
HOME HEALTH CARE MEDICARE-APPROVED SERVICES			
—Medically necessary skilled care services and medical supplies	100%	$0	$0
—Durable medical equipment			
First $[185] of Medicare-Approved Amounts*	$0	$[185] (Part B deductible)	$0
Remainder of Medicare-Approved Amounts	80%	20%	$0

PLAN F or HIGH DEDUCTIBLE PLAN F
OTHER BENEFITS—NOT COVERED BY MEDICARE

SERVICES	MEDICARE PAYS	[AFTER YOU PAY $[2300] DEDUCTIBLE,**] PLAN PAYS	[IN ADDITION TO $[2300] DEDUCTIBLE,**] YOU PAY
FOREIGN TRAVEL—NOT COVERED BY MEDICARE Medically necessary emergency care services beginning during the first 60 days of each trip outside the USA			
First $250 each calendar year	$0	$0	$250
Remainder of charges	$0	80% to a lifetime maximum benefit of $50,000	20% and amounts over the $50,000 lifetime maximum

* Once you have been billed $[185] of Medicare-approved amounts for covered services, your Part B deductible will have been met for the calendar year.

[** This high deductible plan pays the same benefits as Plan F after you have paid a calendar year $[2300] deductible. Benefits from the high deductible Plan F will not begin until out-of-pocket expenses are $[2300]. Out-of-pocket expenses for this deductible are expenses that would ordinarily be paid by the policy. This includes the Medicare deductibles for Part A and Part B, but does not include the plan's separate foreign travel emergency deductible.]

PLAN G or HIGH DEDUCTIBLE PLAN G
MEDICARE (PART A)—HOSPITAL SERVICES—PER BENEFIT PERIOD

SERVICES	MEDICARE PAYS	[AFTER YOU PAY $[2300] DEDUCTIBLE,**] PLAN PAYS	[IN ADDITION TO $[2300] DEDUCTIBLE,**] YOU PAY
HOSPITALIZATION* Semiprivate room and board, general nursing and miscellaneous services and supplies			
First 60 days	All but $[1364]	$[1364] (Part A deductible)	$0
61st through 90th day	All but $[341] a day	$[341] a day	$0
91st day and after:			
—While using 60 lifetime reserve days	All but $[682] a day	$[682] a day	$0
—Once lifetime reserve days are used:			
—Additional 365 days	$0	100% of Medicare eligible expenses	$0***
—Beyond the additional 365 days	$0	$0	All costs
SKILLED NURSING FACILITY CARE* You must meet Medicare's requirements, including having been in a hospital for at least 3 days and entered a Medicare-approved facility within 30 days after leaving the hospital.			
First 20 days	All approved amounts	$0	$0
21st through 100th day	All but $[170.50] a day	Up to $[170.50] a day	$0
101st day and after	$0	$0	All costs
BLOOD			
First 3 pints	$0	3 pints	$0
Additional amounts	100%	$0	$0
HOSPICE CARE You must meet Medicare's requirements, including a doctor's certification of terminal illness.	All but very limited copayment/ coinsurance for outpatient drugs and inpatient respite care	Medicare copayment/ coinsurance	$0

* A benefit period begins on the first day you receive service as an inpatient in a hospital and ends after you have been out of the hospital and have not received skilled care in any other facility for 60 days in a row.

[** This high deductible plan pays the same benefits as Plan G after you have paid a calendar year [$2300] deductible. Benefits from the high deductible Plan G will not begin until out-of-pocket expenses are [$2300]. Out-of-pocket expenses for this deductible include expenses for the Medicare Part B deductible, and expenses that would ordinarily be paid by the policy. This does not include the plan's separate foreign travel emergency deductible.]

*** NOTICE: When your Medicare Part A hospital benefits are exhausted, the issuer stands in the place of Medicare and will pay whatever amount Medicare would have paid for up to an additional 365 days as provided in the policy's basic core benefits ("basic core benefits" are the equivalent of what is provided under Medicare Part A). During this time, the hospital is prohibited from billing you for the balance based on any difference between its billed charges and the amount Medicare would have paid.

PLAN G or HIGH DEDUCTIBLE PLAN G
MEDICARE (PART B)—MEDICAL SERVICES—PER CALENDAR YEAR

SERVICES	MEDICARE PAYS	[AFTER YOU PAY $[2300] DEDUCTIBLE,**] PLAN PAYS	[IN ADDITION TO $[2300] DEDUCTIBLE,**] YOU PAY
MEDICAL EXPENSES— IN OR OUT OF THE HOSPITAL AND OUTPATIENT HOSPITAL TREATMENT, such as physician's services, inpatient and outpatient medical and surgical services and supplies, physical and speech therapy, diagnostic tests, durable medical equipment			
First $[185] of Medicare-Approved Amounts*	$0	$0	$[185] (Unless Part B deductible has been met)
Remainder of Medicare-Approved Amounts	Generally 80%	Generally 20%	$0
Part B Excess Charges (Above Medicare-Approved Amounts)	$0	100%	0%
BLOOD			
First 3 pints	$0	All costs	$0
Next $[185] of Medicare-Approved Amounts*	$0	$0	$[185] (Unless Part B deductible has been met)
Remainder of Medicare-Approved Amounts	80%	20%	$0
CLINICAL LABORATORY SERVICES— TESTS FOR DIAGNOSTIC SERVICES	100%	$0	$0

* Once you have been billed $[185] of Medicare-approved amounts for covered services, your Part B deductible will have been met for the calendar year.

[**This high deductible plan pays the same benefits as Plan G after you have paid a calendar year $[2300] deductible. Benefits from the high deductible Plan G will not begin until out-of-pocket expenses are $[2300]. Out-of-pocket expenses for this deductible include expenses for the Medicare Part B deductible, and expenses that would ordinarily be paid by the policy. This does not include the plan's separate foreign travel emergency deductible.]

PLAN G or HIGH DEDUCTIBLE PLAN G
PARTS A & B

SERVICES	MEDICARE PAYS	[AFTER YOU PAY $[2300] DEDUCTIBLE,**] PLAN PAYS	[IN ADDITION TO $[2300] DEDUCTIBLE,**] YOU PAY
HOME HEALTH CARE MEDICARE-APPROVED SERVICES			
—Medically necessary skilled care services and medical supplies	100%	$0	$0
—Durable medical equipment			
First $[185] of Medicare-Approved Amounts*	$0	$0	$[185] (Unless Part B deductible has been met)
Remainder of Medicare-Approved Amounts	80%	20%	$0

PLAN G or HIGH DEDUCTIBLE PLAN G
OTHER BENEFITS—NOT COVERED BY MEDICARE

SERVICES	MEDICARE PAYS	[AFTER YOU PAY $[2300] DEDUCTIBLE,**] PLAN PAYS	[IN ADDITION TO $[2300] DEDUCTIBLE,**] YOU PAY
FOREIGN TRAVEL—NOT COVERED BY MEDICARE Medically necessary emergency care services beginning during the first 60 days of each trip outside the USA			
First $250 each calendar year	$0	$0	$250
Remainder of charges	$0	80% to a lifetime maximum benefit of $50,000	20% and amounts over the $50,000 lifetime maximum

* Once you have been billed $[185] of Medicare-approved amounts for covered services, your Part B deductible will have been met for the calendar year.

[**This high deductible plan pays the same benefits as Plan G after you have paid a calendar year $[2300] deductible. Benefits from the high deductible Plan G will not begin until out-of-pocket expenses are $[2300]. Out-of-pocket expenses for this deductible include expenses for the Medicare Part B deductible, and expenses that would ordinarily be paid by the policy. This does not include the plan's separate foreign travel emergency deductible.]

PLAN K

MEDICARE (PART A)—HOSPITAL SERVICES—PER BENEFIT PERIOD

SERVICES	MEDICARE PAYS	PLAN PAYS	YOU PAY*
HOSPITALIZATION** Semiprivate room and board, general nursing and miscellaneous services and supplies			
First 60 days	All but $[1364]	$[682] (50% of Part A deductible)	$[682] (50% of Part A deductible)♦
61st through 90th day	All but $[341] a day	$[341] a day	$0
91st day and after:			
—While using 60 lifetime reserve days	All but $[682] a day	$[682] a day	$0
—Once lifetime reserve days are used:			
—Additional 365 days	$0	100% of Medicare eligible expenses	$0***
—Beyond the additional 365 days	$0	$0	All costs
SKILLED NURSING FACILITY CARE** You must meet Medicare's requirements, including having been in a hospital for at least 3 days and entered a Medicare-approved facility within 30 days after leaving the hospital.			
First 20 days	All approved amounts	$0	$0
21st through 100th day	All but $[170.50] a day	Up to $[85.25] a day	Up to $[85.25] a day♦
101st day and after	$0	$0	All costs
BLOOD			
First 3 pints	$0	50%	50%♦
Additional amounts	100%	$0	$0
HOSPICE CARE You must meet Medicare's requirements, including a doctor's certification of terminal illness.	All but very limited copayment/ coinsurance for outpatient drugs and inpatient respite care	50% of copayment/ coinsurance	50% of Medicare copayment/ coinsurance♦

* You will pay half the cost sharing of some covered services until you reach the annual out-of-pocket maximum of $[5560] each calendar year. The amounts that count toward your annual limit are noted with diamonds (♦) in the chart above. Once you reach the annual maximum, the plan pays 100% of your Medicare copayment and coinsurance for the rest of the calendar year. **However, this limit does NOT include charges from your provider that exceed Medicare-approved amounts (these are called "Excess Charges"), and you will be responsible for paying this difference in the amount charged by your provider and the amount paid by Medicare for the item or service.**

** A benefit period begins on the first day you receive service as an inpatient in a hospital and ends after you have been out of the hospital and have not received skilled care in any other facility for 60 days in a row.

*** NOTICE: When your Medicare Part A hospital benefits are exhausted, the insurance company stands in the place of Medicare and will pay whatever amount Medicare would have paid for up to an additional 365 days as provided in the policy's basic core benefits ("basic core benefits" are the equivalent of what is provided under Medicare Part A). During this time, the hospital is prohibited from billing you for the balance based on any difference between its billed charges and the amount Medicare would have paid.

PLAN K
MEDICARE (PART B)—MEDICAL SERVICES—PER CALENDAR YEAR

SERVICES	MEDICARE PAYS	PLAN PAYS	YOU PAY*
MEDICAL EXPENSES— IN OR OUT OF THE HOSPITAL AND OUTPATIENT HOSPITAL TREATMENT, such as physician's services, inpatient and outpatient medical and surgical services and supplies, physical and speech therapy, diagnostic tests, durable medical equipment			
First $[185] of Medicare-Approved Amounts****	$0	$0	$[185] (Part B deductible)****♦
Preventive Benefits for Medicare-Covered Services	Generally 80% or more of Medicare-Approved Amounts	Remainder of Medicare-Approved Amounts	All costs above Medicare-Approved Amounts
Remainder of Medicare-Approved Amounts	Generally 80%	Generally 10%	Generally 10%♦
Part B Excess Charges (Above Medicare-Approved Amounts)	$0	$0	All costs (and they do not count toward annual out-of-pocket limit of $[5560])*
BLOOD			
First 3 pints	$0	50%	50%♦
Next $[185] of Medicare-Approved Amounts****	$0	$0	$[185] (Part B deductible)****♦
Remainder of Medicare-Approved Amounts	Generally 80%	Generally 10%	Generally 10%♦
CLINICAL LABORATORY SERVICES— TESTS FOR DIAGNOSTIC SERVICES	100%	$0	$0

* You will pay half the cost sharing of some covered services until you reach the annual out-of-pocket maximum of $[5560] each calendar year. The amounts that count toward your annual limit are noted with diamonds (♦) in the chart above. Once you reach the annual maximum, the plan pays 100% of your Medicare copayment and coinsurance for the rest of the calendar year. **However, this limit does NOT include charges from your provider that exceed Medicare-approved amounts (these are called "Excess Charges"), and you will be responsible for paying this difference in the amount charged by your provider and the amount paid by Medicare for the item or service.**

**** Once you have been billed $[185] of Medicare-approved amounts for covered services, your Part B deductible will have been met for the calendar year.

PLAN K
PARTS A & B

SERVICES	MEDICARE PAYS	PLAN PAYS	YOU PAY*
HOME HEALTH CARE MEDICARE-APPROVED SERVICES			
—Medically necessary skilled care services and medical supplies	100%	$0	$0
—Durable medical equipment			
First $[185] of Medicare-Approved Amounts*****	$0	$0	$[185] (Part B deductible)♦
Remainder of Medicare-Approved Amounts	80%	10%	10%♦

Medicare benefits are subject to change. Please consult the latest [*Choosing a Medigap Policy: Guide to Health Insurance for People with Medicare*, issued by Centers for Medicare and Medicaid Services].

* You will pay half the cost sharing of some covered services until you reach the annual out-of-pocket maximum of $[5560] each calendar year. The amounts that count toward your annual limit are noted with diamonds (♦) in the chart above. Once you reach the annual maximum, the plan pays 100% of your Medicare copayment and coinsurance for the rest of the calendar year. **However, this limit does NOT include charges from your provider that exceed Medicare-approved amounts (these are called "Excess Charges"), and you will be responsible for paying this difference in the amount charged by your provider and the amount paid by Medicare for the item or service.**

***** This plan limits your annual out-of-pocket payments for Medicare-approved amounts to $[5560] per year. **However, this limit does NOT include charges from your provider that exceed Medicare-approved amounts (these are called "Excess Charges"), and you will be responsible for paying this difference in the amount charged by your provider and the amount paid by Medicare for the item or service.**

PLAN L
MEDICARE (PART A)—HOSPITAL SERVICES—PER BENEFIT PERIOD

SERVICES	MEDICARE PAYS	PLAN PAYS	YOU PAY*
HOSPITALIZATION** Semiprivate room and board, general nursing and miscellaneous services and supplies			
First 60 days	All but $[1364]	$[1023] (75% of Part A deductible)	$[341] (25% of Part A deductible)♦
61st through 90th day	All but $[341] a day	$[341] a day	$0
91st day and after:			
—While using 60 lifetime reserve days	All but $[682] a day	$[682] a day	$0
—Once lifetime reserve days are used:			
—Additional 365 days	$0	100% of Medicare eligible expenses	$0***
—Beyond the additional 365 days	$0	$0	All costs
SKILLED NURSING FACILITY CARE** You must meet Medicare's requirements, including having been in a hospital for at least 3 days and entered a Medicare-approved facility within 30 days after leaving the hospital.			
First 20 days	All approved amounts	$0	$0
21st through 100th day	All but $[170.50] a day	Up to $[127.88] a day (75% of Part A Coinsurance)	Up to $[42.63] a day (25% of Part A Coinsurance)♦
101st day and after	$0	$0	All costs
BLOOD			
First 3 pints	$0	75%	25%♦
Additional amounts	100%	$0	$0
HOSPICE CARE You must meet Medicare's requirements, including a doctor's certification of terminal illness.	All but very limited copayment/ coinsurance for outpatient drugs and inpatient respite care	75% of copayment/ coinsurance	25% of copayment/ coinsurance♦

* You will pay one-fourth of the cost sharing of some covered services until you reach the annual out-of-pocket limit of $[2780] each calendar year. The amounts that count toward your annual limit are noted with diamonds (♦) in the chart above. Once you reach the annual limit, the plan pays 100% of your Medicare copayment and coinsurance for the rest of the calendar year. **However, this limit does NOT include charges from your provider that exceed Medicare-approved amounts (these are called "Excess Charges"), and you will be responsible for paying this difference in the amount charged by your provider and the amount paid by Medicare for the item or service.**

** A benefit period begins on the first day you receive service as an inpatient in a hospital and ends after you have been out of the hospital and have not received skilled care in any other facility for 60 days in a row.

*** NOTICE: When your Medicare Part A hospital benefits are exhausted, the insurance company stands in the place of Medicare and will pay whatever amount Medicare would have paid for up to an additional 365 days as provided in the policy's basic core benefits ("basic core benefits" are the equivalent of what is provided under Medicare Part A). During this time, the hospital is prohibited from billing you for the balance based on any difference between its billed charges and the amount Medicare would have paid.

PLAN L
MEDICARE (PART B)—MEDICAL SERVICES—PER CALENDAR YEAR

SERVICES	MEDICARE PAYS	PLAN PAYS	YOU PAY*
MEDICAL EXPENSES— IN OR OUT OF THE HOSPITAL AND OUTPATIENT HOSPITAL TREATMENT, such as physician's services, inpatient and outpatient medical and surgical services and supplies, physical and speech therapy, diagnostic tests, durable medical equipment			
First $[185] of Medicare-Approved Amounts****	$0	$0	$[185] (Part B deductible)****♦
Preventive Benefits for Medicare-Covered Services	Generally 75% or more of Medicare-Approved Amounts	Remainder of Medicare-Approved Amounts	All costs above Medicare-Approved Amounts
Remainder of Medicare-Approved Amounts	Generally 80%	Generally 15%	Generally 5%♦
Part B Excess Charges (Above Medicare-Approved Amounts)	$0	$0	All costs (and they do not count toward annual out-of-pocket limit of $[2780])*
BLOOD			
First 3 pints	$0	75%	25%♦
Next $[185] of Medicare-Approved Amounts****	$0	$0	$[185] (Part B deductible)♦
Remainder of Medicare-Approved Amounts	Generally 80%	Generally 15%	Generally 5%♦
CLINICAL LABORATORY SERVICES— TESTS FOR DIAGNOSTIC SERVICES	100%	$0	$0

* You will pay one-fourth of the cost sharing of some covered services until you reach the annual out-of-pocket limit of $[2780] each calendar year. The amounts that count toward your annual limit are noted with diamonds (♦) in the chart above. Once you reach the annual limit, the plan pays 100% of your Medicare copayment and coinsurance for the rest of the calendar year. **However, this limit does NOT include charges from your provider that exceed Medicare-approved amounts (these are called "Excess Charges"), and you will be responsible for paying this difference in the amount charged by your provider and the amount paid by Medicare for the item or service.**

**** Once you have been billed $[185] of Medicare-approved amounts for covered services (which are noted with an asterisk), your Part B deductible will have been met for the calendar year.

PLAN L
PARTS A & B

SERVICES	MEDICARE PAYS	PLAN PAYS	YOU PAY*
HOME HEALTH CARE MEDICARE-APPROVED SERVICES			
—Medically necessary skilled care services and medical supplies	100%	$0	$0
—Durable medical equipment First $[185] of Medicare-Approved Amounts****	$0	$0	$[185] (Part B deductible)♦
Remainder of Medicare-Approved Amounts	80%	15%	5%♦

Medicare benefits are subject to change. Please consult the latest [*Choosing a Medigap Policy: Guide to Health Insurance for People with Medicare*, issued by Centers for Medicare and Medicaid Services].

* You will pay one-fourth of the cost sharing of some covered services until you reach the annual out-of-pocket limit of $[2780] each calendar year. The amounts that count toward your annual limit are noted with diamonds (♦) in the chart above. Once you reach the annual limit, the plan pays 100% of your Medicare copayment and coinsurance for the rest of the calendar year. **However, this limit does NOT include charges from your provider that exceed Medicare-approved amounts (these are called "Excess Charges"), and you will be responsible for paying this difference in the amount charged by your provider and the amount paid by Medicare for the item or service.**

**** Once you have been billed $[185] of Medicare-approved amounts for covered services (which are noted with an asterisk), your Part B deductible will have been met for the calendar year.

PLAN M
MEDICARE (PART A)—HOSPITAL SERVICES—PER BENEFIT PERIOD

SERVICES	MEDICARE PAYS	PLAN PAYS	YOU PAY
HOSPITALIZATION* Semiprivate room and board, general nursing and miscellaneous services and supplies			
First 60 days	All but $[1364]	$[682] (50% of Part A deductible)	$[682] (50% of Part A deductible)
61st through 90th day	All but $[341] a day	$[341] a day	$0
91st day and after:			
—While using 60 lifetime reserve days	All but $[682] a day	$[682] a day	$0
—Once lifetime reserve days are used:			
—Additional 365 days	$0	100% of Medicare eligible expenses	$0**
—Beyond the additional 365 days	$0	$0	All costs
SKILLED NURSING FACILITY CARE* You must meet Medicare's requirements, including having been in a hospital for at least 3 days and entered a Medicare-approved facility within 30 days after leaving the hospital.			
First 20 days	All approved amounts	$0	$0
21st through 100th day	All but $[170.50] a day	Up to $[170.50] a day	$0
101st day and after	$0	$0	All costs
BLOOD			
First 3 pints	$0	3 pints	$0
Additional amounts	100%	$0	$0
HOSPICE CARE You must meet Medicare's requirements, including a doctor's certification of terminal illness.	All but very limited copayment/ coinsurance for outpatient drugs and inpatient respite care	Medicare copayment/ coinsurance	$0

* A benefit period begins on the first day you receive service as an inpatient in a hospital and ends after you have been out of the hospital and have not received skilled care in any other facility for 60 days in a row.

** NOTICE: When your Medicare Part A hospital benefits are exhausted, the insurance company stands in the place of Medicare and will pay whatever amount Medicare would have paid for up to an additional 365 days as provided in the policy's basic core benefits ("basic core benefits" are the equivalent of what is provided under Medicare Part A). During this time, the hospital is prohibited from billing you for the balance based on any difference between its billed charges and the amount Medicare would have paid.

PLAN M
MEDICARE (PART B)—MEDICAL SERVICES—PER CALENDAR YEAR

SERVICES	MEDICARE PAYS	PLAN PAYS	YOU PAY
MEDICAL EXPENSES— IN OR OUT OF THE HOSPITAL AND OUTPATIENT HOSPITAL TREATMENT, such as physician's services, inpatient and outpatient medical and surgical services and supplies, physical and speech therapy, diagnostic tests, durable medical equipment			
First $[185] of Medicare-Approved Amounts*	$0	$0	$[185] (Part B deductible)
Remainder of Medicare-Approved Amounts	Generally 80%	Generally 20%	0%
Part B Excess Charges (Above Medicare-Approved Amounts)	$0	$0	All costs
BLOOD			
First 3 pints	$0	All costs	$0
Next $[185] of Medicare-Approved Amounts*	$0	$0	$[185] (Part B deductible)
Remainder of Medicare-Approved Amounts	80%	20%	$0
CLINICAL LABORATORY SERVICES— TESTS FOR DIAGNOSTIC SERVICES	100%	$0	$0

* Once you have been billed $[185] of Medicare-approved amounts for covered services, your Part B deductible will have been met for the calendar year.

PLAN M
PARTS A & B

SERVICES	MEDICARE PAYS	PLAN PAYS	YOU PAY
HOME HEALTH CARE MEDICARE-APPROVED SERVICES			
—Medically necessary skilled care services and medical supplies	100%	$0	$0
—Durable medical equipment First $[185] of Medicare-Approved Amounts*	$0	$0	$[185] (Part B deductible)
Remainder of Medicare-Approved Amounts	80%	20%	$0

* Once you have been billed $[185] of Medicare-approved amounts for covered services, your Part B deductible will have been met for the calendar year.

PLAN M
OTHER BENEFITS—NOT COVERED BY MEDICARE

SERVICES	MEDICARE PAYS	PLAN PAYS	YOU PAY
FOREIGN TRAVEL—NOT COVERED BY MEDICARE Medically necessary emergency care services beginning during the first 60 days of each trip outside the USA			
First $250 each calendar year	$0	$0	$250
Remainder of charges	$0	80% to a lifetime maximum benefit of $50,000	20% and amounts over the $50,000 lifetime maximum

PLAN N
MEDICARE (PART A)—HOSPITAL SERVICES—PER BENEFIT PERIOD

SERVICES	MEDICARE PAYS	PLAN PAYS	YOU PAY
HOSPITALIZATION* Semiprivate room and board, general nursing and miscellaneous services and supplies			
First 60 days	All but $[1364]	$[1364] (Part A deductible)	$0
61st through 90th day	All but $[341] a day	$[341] a day	$0
91st day and after:			
—While using 60 lifetime reserve days	All but $[682] a day	$[682] a day	$0
—Once lifetime reserve days are used:			
—Additional 365 days	$0	100% of Medicare eligible expenses	$0**
—Beyond the additional 365 days	$0	$0	All costs
SKILLED NURSING FACILITY CARE* You must meet Medicare's requirements, including having been in a hospital for at least 3 days and entered a Medicare-approved facility within 30 days after leaving the hospital.			
First 20 days	All approved amounts	$0	$0
21st through 100th day	All but $[170.50] a day	Up to $[170.50] a day	$0**
101st day and after	$0	$0	All costs
BLOOD			
First 3 pints	$0	3 pints	$0
Additional amounts	100%	$0	$0
HOSPICE CARE You must meet Medicare's requirements, including a doctor's certification of terminal illness.	All but very limited copayment/ coinsurance for outpatient drugs and inpatient respite care	Medicare copayment/ coinsurance	$0

* A benefit period begins on the first day you receive service as an inpatient in a hospital and ends after you have been out of the hospital and have not received skilled care in any other facility for 60 days in a row.

** NOTICE: When your Medicare Part A hospital benefits are exhausted, the insurance company stands in the place of Medicare and will pay whatever amount Medicare would have paid for up to an additional 365 days as provided in the policy's basic core benefits ("basic core benefits" are the equivalent of what is provided under Medicare Part A). During this time, the hospital is prohibited from billing you for the balance based on any difference between its billed charges and the amount Medicare would have paid.

PLAN N
MEDICARE (PART B)—MEDICAL SERVICES—PER CALENDAR YEAR

SERVICES	MEDICARE PAYS	PLAN PAYS	YOU PAY
MEDICAL EXPENSES— IN OR OUT OF THE HOSPITAL AND OUTPATIENT HOSPITAL TREATMENT, such as physician's services, inpatient and outpatient medical and surgical services and supplies, physical and speech therapy, diagnostic tests, durable medical equipment			
First $[185] of Medicare-Approved Amounts*	$0	$0	$[185] (Part B deductible)
Remainder of Medicare-Approved Amounts	Generally 80%	Balance, other than up to $[20] per office visit and up to $[50] per emergency room visit. The copayment of up to $[50] is waived if the insured individual is admitted to any hospital and the emergency visit is covered as a Medicare Part A expense.	Up to $[20] per office visit and up to $[50] per emergency room visit. The copayment of up to $[50] is waived if the insured individual is admitted to any hospital and the emergency visit is covered as a Medicare Part A expense.
Part B Excess Charges (Above Medicare-Approved Amounts)	$0	$0	All costs
BLOOD			
First 3 pints	$0	All costs	$0
Next $[185] of Medicare-Approved Amounts*	$0	$0	$[185] (Part B deductible)
Remainder of Medicare-Approved Amounts	80%	20%	$0
CLINICAL LABORATORY SERVICES— TESTS FOR DIAGNOSTIC SERVICES	100%	$0	$0

* Once you have been billed $[185] of Medicare-approved amounts for covered services, your Part B deductible will have been met for the calendar year.

PLAN N
PARTS A & B

SERVICES	MEDICARE PAYS	PLAN PAYS	YOU PAY
HOME HEALTH CARE MEDICARE-APPROVED SERVICES			
—Medically necessary skilled care services and medical supplies	100%	$0	$0
—Durable medical equipment First $[185] of Medicare-Approved Amounts*	$0	$0	$[185] (Part B deductible)
Remainder of Medicare-Approved Amounts	80%	20%	$0

* Once you have been billed $[185] of Medicare-approved amounts for covered services, your Part B deductible will have been met for the calendar year.

PLAN N
OTHER BENEFITS—NOT COVERED BY MEDICARE

SERVICES	MEDICARE PAYS	PLAN PAYS	YOU PAY
FOREIGN TRAVEL—NOT COVERED BY MEDICARE Medically necessary emergency care services beginning during the first 60 days of each trip outside the USA			
First $250 each calendar year	$0	$0	$250
Remainder of charges	$0	80% to a lifetime maximum benefit of $50,000	20% and amounts over the $50,000 lifetime maximum

APPENDIX F
FORM FOR REPORTING
MEDICARE SUPPLEMENT POLICIES OR CERTIFICATES
Pursuant to Iowa Administrative Code rule 191—37.32(514D)

Company Name: _____

Address: _____

_____

Phone Number: _____

Due March 1, annually

The purpose of this form is to report the following information on each resident of this state who has in force more than one Medicare supplement policy or certificate. The information is to be grouped by covered individual.

Policy and Certificate #	Date of Issuance

_____
Signature

_____
Name and Title (please type)

_____
Date

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TITLE VIII
MEDICAL ASSISTANCE

CHAPTER 73
MANAGED CARE

PREAMBLE

This chapter provides that most Iowa medical assistance program benefits will be provided through managed care. Notwithstanding any provisions of 441—Chapters 74 through 91, program benefits shall be provided through managed care as provided in this chapter. The program benefits provided through managed care will be paid for by managed care organizations participating in the program pursuant to this chapter, subject to the conditions, procedures, and payment rates or methodologies established by the managed care organization, consistent with this chapter and with the contract between the department and the managed care organization.

Implementation of managed care pursuant to this chapter is subject to approval by the Secretary of the United States Department of Health and Human Services (Secretary) of any Iowa state plan amendments and any waivers of the requirements of Title XIX of the Social Security Act that are required to allow for federal funding.

This chapter shall be construed to comply with all requirements for federal funding under Title XIX of the Social Security Act or under the terms of any applicable waiver granted by the Secretary. To the extent this chapter is inconsistent with any applicable federal funding requirement under Title XIX or the terms of any applicable waiver, the requirements under Title XIX or the terms of the waiver shall prevail.

441—73.1(249A) Definitions.

"Behavioral health services" means mental health and substance use disorder treatment services.

"Capitated payment" means a monthly payment to the contractor on behalf of each enrollee for the provision of health services under the contract. Payment is made regardless of whether the enrollee receives services during the month.

"Choice counseling" means the provision of unbiased information on managed care plans or provider options and answers to related questions and access to personalized assistance to help members understand the materials provided by the managed care organizations or the state, to answer questions about each of the options available, and to facilitate enrollment with a managed care organization.

"Claim" means a formal request for payment for benefits received or services rendered.

"Clean claim" means a claim that has no defect or impropriety (including any lack of required substantiating documentation) or particular circumstance requiring special treatment that prevents timely payment of the claim. "Clean claim" does not include a claim from a provider that is under investigation for fraud or abuse or a claim under review for medical necessity.

"CMS" means the Centers for Medicare and Medicaid Services, a division of the U.S. Department of Health and Human Services.

"Code of Federal Regulations (CFR)" means the codification of the general and permanent rules published in the Federal Register by the executive departments and agencies of the federal government.

"Community-based case management" means a collaborative process of planning, facilitation, and advocacy for options and services to meet a member's needs through communication and available resources to promote high-quality, cost-effective outcomes.

"Contract" means a contract between the department and a managed care organization. These contracts shall meet all applicable requirements of state and federal law, including the requirements of the Code of Federal Regulations, Title 42 CFR 434 as amended to October 16, 2015.

"Covered services" means physical health, behavioral health and long-term care services set forth in rule 441—73.5(249A).

"Department" means the Iowa department of human services.

"Discharge planning" means the process, which begins at admission, of determining an enrollee's continued need for treatment services and of developing a plan to address ongoing needs.

"Emergency medical condition" means a physical or behavioral condition manifesting itself by acute symptoms of sufficient severity (including severe pain) that a prudent layperson who possesses an average knowledge of health and medicine could reasonably expect the absence of immediate medical attention to result in the following:

1. Placing the health of the individual (or, with respect to a pregnant woman, the health of the woman or her unborn child) in serious jeopardy;
2. Serious impairment to bodily functions; or
3. Serious dysfunction of any bodily organ or part.

"Emergency services" means covered inpatient and outpatient services that are both furnished by a provider that is qualified to furnish these services and needed to evaluate or stabilize an emergency medical condition.

"EMTALA" means the Emergency Medical Treatment and Active Labor Act.

"Enrollee" means a HAWK-I, Iowa Health and Wellness Plan or Medicaid member who is eligible for managed care organization enrollment and has been enrolled with a managed care organization as defined in subrule 73.3(2).

"Enrollment broker" means the entity the department uses to enroll persons in a managed care organization. The enrollment broker must be conflict free and meet all applicable requirements of state and federal law, including 42 CFR 438.10 as amended to October 16, 2015.

"HAWK-I program" means the healthy and well kids in Iowa program as set forth in 441—Chapter 86, the Iowa program to provide health care coverage for uninsured children of eligible families as authorized by Title XXI of the federal Social Security Act.

"Health maintenance organization" means a public or private organization which is licensed as a managed care organization or prepaid health plan under insurance division rules set forth in 191—Chapter 40.

"HIPP" means the health insurance premium payment program.

"Home- and community-based services (HCBS)" means services that are provided as an alternative to long-term care institutional services in a nursing facility or an intermediate care facility for persons with an intellectual disability (ICF/ID) or to delay or prevent placement in a nursing facility or ICF/ID.

"Incident reporting" means the reporting of critical events or incidents deemed sufficiently serious to warrant near-term review and follow-up by an appropriate authority. Such incidents may include but are not limited to:

1. Abuse and neglect;
2. The unauthorized use of restraint, seclusion or restrictive interventions;
3. Serious injuries that require medical intervention or result in hospitalization, or both;
4. Criminal victimization;
5. Death;
6. Financial exploitation;
7. Medication errors; and
8. Other incidents or events that involve harm or risk of harm to a participant.

"Insolvency" means a financial condition that exists when an entity is unable to pay its debts as they become due in the usual course of business or when the liabilities of the entity exceed its assets.

"Iowa Health and Wellness Plan" means the medical assistance program set forth in 441—Chapter 74.

"Level of care" means an evaluation to determine and establish an individual's need for the level of care provided in a hospital, a nursing facility, or an ICF/ID within the near future.

"Long-term care (LTC)" or *"long-term services and supports (LTSS)"* means the services of a nursing facility (NF), an intermediate care facility for persons with an intellectual disability (ICF/ID), state resource centers or services funded through Section 1915(c) home- and community-based services waivers, Section 1915(i) state plan home- and community-based habilitation program and the PACE program.

"Managed care organization (MCO)" means an entity that (1) is under contract with the department to provide services to Medicaid recipients and (2) meets the definition of "health maintenance organization" in Iowa Code section 514B.1.

"Mandatory enrollment" means mandatory participation in a managed care organization as specified in subrule 73.3(2).

"Medical loss ratio (MLR)" means the percentage of capitation payments that is used to pay medical expenses.

"Medically necessary services" means those covered services that are, under the terms and conditions of the contract, determined through contractor utilization management to be:

1. Appropriate and necessary for the symptoms, diagnosis or treatment of the condition of the member;
2. Provided for the diagnosis or direct care and treatment of the condition of the member to enable the member to make reasonable progress in treatment;
3. Within standards of professional practice and given at the appropriate time and in the appropriate setting;
4. Not primarily for the convenience of the member, the member's physician or other provider; and
5. The most appropriate level of covered services that can safely be provided.

"Medical records" means all medical, behavioral health, and long-term care histories; records, reports and summaries; diagnoses; prognoses; record of treatment and medication ordered and given; X-ray and radiology interpretations; physical therapy charts and notes; lab reports; other individualized medical, behavioral health, and long-term care documentation in written or electronic format; and analyses of such information.

"Member" means any person determined by the department to be eligible for the HAWK-I program, the Iowa Health and Wellness Plan, or the Medicaid program.

"Money Follows the Person (MFP) Rebalancing Demonstration Grant" means a federal grant that will assist Iowa in transitioning individuals from a nursing facility or ICF/ID into the community and in rebalancing long-term care expenditures.

"Needs-based eligibility" means an evaluation to determine and establish an individual's need for habilitation services.

"Network" or *"provider network"* means a group of participating health care providers (both individual and group practitioners) linked through contractual arrangements to the contractor to supply a range of health care services.

"Out-of-network provider" means any provider that is not directly or indirectly employed by or does not have a provider agreement with the contractor or any of its subcontractors pursuant to the contract between the department and the contractor.

"PACE" means the program for all-inclusive care for the elderly.

"Participating providers" means the providers of covered physical health, behavioral health and long-term care services that have contracted with a managed care organization.

"PMIC" means a psychiatric medical institution for children.

"Prior authorization" means the process of obtaining prior approval as to the appropriateness of a service or medication. Prior authorization does not guarantee coverage.

"Warm transfer" means a telecommunications mechanism in which the person answering the call facilitates transfer to a third party, announces the caller and issue and remains engaged as necessary to provide assistance.

[**ARC 2358C**, IAB 1/6/16, effective 1/1/16]

441—73.2(249A) Contracts with a managed care organization.

73.2(1) The department may enter into a contract with a managed care organization licensed under the provisions of insurance division rules set forth in 191—Chapter 40 for the scope of services as defined in rule 441—73.6(249A).

73.2(2) The department shall determine that the managed care organization meets the following requirements:

a. The managed care organization shall make available the services it provides to enrollees as established in the contract.

b. The managed care organization shall provide satisfaction to the department against the risk of insolvency and ensure that neither Medicaid members nor the state shall be responsible for the managed care organization's debts if the managed care organization becomes insolvent. The managed care organization shall comply with insurance division provisions set forth in rule 191—40.12(514B) regarding net worth and rule 191—40.14(514B) containing reporting requirements.

c. The managed care organization shall attain and maintain accreditation by the National Committee on Quality Assurance (NCQA) or URAC (formerly known as the Utilization Review Accreditation Commission).

73.2(3) If not already accredited, the managed care organization must demonstrate it has initiated the accreditation process as of the contract effective date and must achieve accreditation at the earliest date allowed by NCQA or URAC. Prior to the contract effective date, the managed care organization must be licensed and in good standing in the state of Iowa as a health maintenance organization in accordance with insurance division rules set forth in 191—Chapter 40.

73.2(4) The contract shall meet the following minimum requirements. The contract shall:

a. Be in writing.

b. Specify the duration of the contract period.

c. List the services which must be covered.

d. Describe service access and provide access information.

e. List conditions for nonrenewal, termination, suspension, and modification.

f. Specify the method and rate of reimbursement.

g. Provide for disclosure of ownership and subcontracted relationships.

h. Specify that all subcontracts shall be in writing, shall comply with the provisions of the contract between the department and the managed care organization, and shall include any general requirements of the contract that are appropriate to the service or activity covered by the subcontract.

i. Specify appeal and grievance rights.

j. Specify all operational and service delivery expectations.

k. Specify reporting requirements.

l. Specify requirements for utilization management and quality improvement.

m. Specify requirements for program integrity.

n. Specify termination requirements and assessment of penalties.

[**ARC 2358C**, IAB 1/6/16, effective 1/1/16]

441—73.3(249A) Enrollment.

73.3(1) *Enrollment area.* The coverage area for enrollment shall be statewide.

73.3(2) *Members subject to enrollment.* All HAWK-I program and Iowa Health and Wellness Plan members shall be subject to mandatory enrollment in a managed care organization. All Medicaid members, with the exception of the following, shall be subject to mandatory enrollment in a managed care organization:

a. Members who are medically needy as defined at 441—subrule 75.1(35).

b. Individuals eligible only for emergency medical services because the individuals do not meet citizenship or alienage requirements, pursuant to 441—subrule 75.11(4).

c. Persons who are currently presumptively eligible as defined in 441—subrules 75.1(30), 75.1(40), and 75.1(44).

d. Persons eligible for the program of all-inclusive care for the elderly (PACE) who voluntarily elect PACE coverage as defined in 441—subrule 88.24(1).

e. Persons enrolled in the health insurance premium payment program (HIPP) pursuant to rule 441—75.21(249A).

f. Persons eligible only for the Medicare savings program as defined in rules 441—75.1(249A) and 441—76.1(249A).

g. American Indian and Alaska Native populations who are exempt from mandatory enrollment pursuant to 42 CFR 438.50(d)(2) but who may enroll voluntarily.

73.3(3) *Enrollment process.* The department shall notify members who must be enrolled in a managed care organization of enrollment and the effective date of enrollment. The department will implement an enrollment process in accordance with federal funding requirements, including 42 CFR 438 as amended to October 16, 2015.

a. General. Members may receive managed care organization choice counseling from the enrollment broker. The enrollment broker will provide information about individual managed care organization benefit structures, services and network providers, as well as information about other Medicaid programs as requested by the Medicaid member to assist the member in making an informed selection.

b. Tentative assignment. Members shall be tentatively assigned to a managed care organization and offered the opportunity to choose from the available managed care organizations within a time frame specified in the tentative assignment letter.

c. Request to change enrollment.

(1) A member shall have a minimum of ten days from the date of the tentative assignment letter to request enrollment with a different managed care organization. The request may be made on a form designated by the department, in writing, or by telephone call to the enrollment broker's toll-free member telephone line. Changes are subject to the effective date provisions of subrule 73.3(4).

(2) An enrollee may, within 90 days of initial enrollment, request to change enrollment from one managed care organization and enroll in another managed care organization. The request may be made on a form designated by the department, in writing, or by telephone call to the enrollment broker's toll-free member telephone line. Changes are subject to the effective date provisions of subrule 73.3(4).

d. Ongoing enrollment. Enrollees shall remain enrolled with the chosen managed care organization for a total of 12 months.

e. Enrollment cycle. Prior to the end of the enrollee's annual enrollment period, the enrollee shall be notified of the option to maintain enrollment with the current managed care organization or to enroll with a different managed care organization.

73.3(4) *Effective date of enrollment.* The effective date of enrollment shall be no later than the first day of the second month beginning after the date on which the managed care organization receives the designated managed health care choice form or written or verbal request.

73.3(5) *Benefit reimbursement prior to enrollment.*

a. Prior to the effective date of managed care enrollment, except as provided in paragraph 73.3(5)*"b,"* the Medicaid program shall reimburse providers for covered program benefits pursuant to 441—Chapters 74 to 91, as applicable for eligible members.

b. The managed care organization shall be responsible for covering newly retroactive Medicaid eligibility periods, prior to the effective date of enrollment, in the following cases:

(1) Babies born to Medicaid-enrolled women who are retroactively eligible to the month of birth; and

(2) Children enrolled in the HAWK-I program retroactive to the date of application. For purposes of this requirement, a retroactive Medicaid eligibility period is defined as a period of time up to three months prior to the Medicaid determination month.

[**ARC 2358C**, IAB 1/6/16, effective 1/1/16]

441—73.4(249A) Disenrollment process.

73.4(1) *Enrollee-requested disenrollment.* An enrollee may request disenrollment with a managed care organization as follows:

a. During the first 90 days following the date of the enrollee's initial enrollment with the managed care organization, the enrollee may request disenrollment, for any reason, in writing or by a telephone call to the enrollment broker's toll-free member telephone line.

b. After the 90 days following the date of the enrollee's enrollment with the managed care organization, when an enrollee is requesting disenrollment due to good cause, the enrollee member shall first make a verbal or written filing of the issue through the managed care organization's grievance system. If the member does not experience resolution, the managed care organization shall direct the member to the enrollment broker. The enrolled member may request disenrollment in writing or by a telephone call to the enrollment broker's toll-free member telephone line and must request a good-cause change for enrollment. Good-cause changes include the following:

(1) The managed care organization does not, because of moral or religious objections, cover the service the member seeks.

(2) The member needs related services to be performed at the same time; not all related services are available within the network; and the member's primary care provider or another provider determines that receiving the services separately would subject the member to unnecessary risk.

(3) Other reasons, including but not limited to poor quality of care, lack of access to services covered under the contract, lack of access to providers experienced in dealing with the member's health care needs, or eligibility and choice to participate in a program not available in managed care (for example, PACE).

c. The final decision for disenrollment shall be determined by the department.

73.4(2) *Disenrollment by department.* Disenrollment will occur when:

a. The contract between the department and the managed care organization is terminated.

b. The enrollee becomes ineligible for Medicaid, the HAWK-I program or the Iowa Health and Wellness Plan. If the enrollee becomes ineligible and is later reinstated to these programs, enrollment in the managed care organization will also be reinstated.

c. The enrollee transfers to an eligibility group excluded from managed care organization enrollment. See definition of "enrollee" in rule 441—73.1(249A).

d. The department has determined that participation in the HIPP program as described in rule 441—75.21(249A) is more cost-effective than enrollment in managed health care.

e. Death of the enrollee.

f. The enrollee has changed residence to another state.

73.4(3) *Managed care organization-requested disenrollment.* A managed care organization shall not disenroll an enrollee or encourage an enrollee to disenroll for any reason, including the enrollee's health care needs or change in health care status or because of the enrollee's utilization of medical services, diminished capacity, or uncooperative or disruptive behavior resulting from the enrollee's special needs (except when the enrollee's continued enrollment seriously impairs the managed care organization's ability to furnish services to either this particular enrollee or other enrollees). In instances where the exception applies, the managed care organization shall provide evidence to the department that continued enrollment of an enrollee seriously impairs the managed care organization's ability to furnish services to either this particular enrollee or other enrollees. The managed care organization shall have methods by which the department is assured that disenrollment is not requested for another reason.

73.4(4) *Disenrollment effective date.* The effective date of a department-approved disenrollment shall be no later than the first day of the second calendar month beginning after the month in which: (1) the enrollee requests disenrollment pursuant to subrule 73.4(1); (2) the department notifies the enrollee and managed care organization of disenrollment pursuant to subrule 73.4(2); or (3) the managed care organization requests disenrollment pursuant to subrule 73.4(3). The enrollee shall remain enrolled in the managed care organization and the managed care organization will be responsible for services covered under the contract until the effective date of disenrollment unless the enrollee is in an inpatient setting at the time of disenrollment. If the enrollee is in an inpatient setting at the time of disenrollment, the managed care organization shall be responsible for the inpatient services for 60 days or until the enrollee is discharged.

[**ARC 2358C**, IAB 1/6/16, effective 1/1/16]

441—73.5(249A) Covered services.

73.5(1) *Required services.* A managed care organization shall provide:

a. For enrollees other than Iowa Health and Wellness Plan enrollees and HAWK-I program enrollees, services as set forth in 441—Chapters 78, 81, 82, 83, 84, 85, and 87, with the exception of the following:

(1) Area education agency services.
(2) Dental services not provided in an outpatient hospital setting.
(3) Infant and toddler program services.
(4) Local education agency services.
(5) State of Iowa Veterans Home services.
(6) Money Follows the Person Grant-funded services.

b. Services as set forth in 441—Chapter 74 for Iowa Health and Wellness Plan enrollees.

c. Services as set forth in 441—Chapter 86 for HAWK-I program enrollees.

73.5(2) *Community-based case management service.* The managed care organization is required to provide services that meet requirements specified in the contract and in 441—subrule 90.5(1).

73.5(3) *Health home services.* The managed care organization is required to provide services that meet the requirements specified in 441—subrule 78.53(1) and as specified in the contract.

73.5(4) *Value-added services.* A managed care organization may develop optional services and supports to address the needs of enrollees. These services and supports shall be implemented only after approval by the department.

[**ARC 2358C**, IAB 1/6/16, effective 1/1/16]

441—73.6(249A) Amount, duration and scope of services.

73.6(1) The managed care organization shall provide, at a minimum, all benefits and services deemed medically necessary that are covered under the contract with the agency. In accordance with federal funding requirements, including 42 CFR 438.210(a)(3) as amended to October 16, 2015, the managed care organization shall furnish covered services in an amount, duration and scope reasonably expected to achieve the purpose for which the services are furnished. The managed care organization may not arbitrarily deny or reduce the amount, duration and scope of a required service solely because of diagnosis, type of illness, or condition of the enrollee. With the exception of court-ordered services, the managed care organization shall require as a condition of payment managed care organization approval of admissions to a nursing facility, an intermediate care facility for persons with an intellectual disability, psychiatric medical institutions for children, and a mental health institute. Managed care organizations shall also require managed care organization approval of out-of-state placements as a condition of payment.

73.6(2) The managed care organization may place appropriate limits on services on the basis of medical necessity criteria for the purpose of utilization management, provided the services can reasonably be expected to achieve their purpose in accordance with the contract. The managed care organization shall not:

a. Avoid costs for services covered in the contract by referring members to publicly supported health care resources.

b. Deny reimbursement of covered services based on the presence of a preexisting condition.

73.6(3) The managed care organization shall allow each enrollee to choose a health professional, to the extent possible and appropriate, within the managed care organization's provider network. The managed care organization shall ensure compliance with the Americans with Disabilities Act (ADA) in the delivery and approval of all services.

[**ARC 2358C**, IAB 1/6/16, effective 1/1/16]

441—73.7(249A) Emergency services.

73.7(1) Emergency services shall be available 24 hours a day, 7 days a week.

73.7(2) In accordance with federal funding requirements, including 42 CFR 438.114 as amended to October 16, 2015, the managed care organization shall:

a. Cover emergency services without the need for prior authorization and may not limit reimbursement to network providers.

b. Cover and pay for emergency services regardless of whether the provider that furnishes the services has a contract with the managed care organization.

c. Pay noncontracted providers for emergency services the amount that would have been paid if the service had been provided under the state's fee-for-service Medicaid program.

d. Cover the medical screening examination, as defined by EMTALA, provided to a member who presents to an emergency department with an emergency medical condition.

73.7(3) The managed care organization shall not deny payment for:

a. Treatment obtained when an enrollee has an emergency medical condition, including cases in which the absence of immediate medical attention would result in placing the health of the enrollee in serious jeopardy, serious impairment to bodily functions, or serious dysfunction of any bodily organ or part.

b. Treatment obtained when a representative of the managed care organization instructs the enrollee to seek emergency medical services.

[**ARC 2358C**, IAB 1/6/16, effective 1/1/16]

441—73.8(249A) Access to service.

73.8(1) The managed care organization shall ensure enrollees have access to services as specified in the contract. In general, the managed care organization shall provide available, accessible, and adequate numbers of institutional facilities, service locations, and service sites and professional, allied, and paramedical personnel for the provision of covered services, including all emergency services, on a 24-hours-a-day, 7-days-a-week basis. At a minimum, access to services shall comply with the standards described in the contract. For areas of the state where provider availability is insufficient to meet these standards, for example, in health professional shortage areas and medically underserved areas, the access standards shall meet the usual and customary standards for the community. Exceptions to the requirements contained in this rule shall be justified and documented to the state on the basis of community standards. All other services not specified in this rule shall meet the usual and customary standards for the community.

73.8(2) Choice of providers. An enrollee shall use the managed care organization's provider network unless the managed care organization has authorized a referral to a nonparticipating provider for provision of a service or treatment plan or as specified for provision of emergency services set forth in rule 441—73.7(249A). In accordance with federal funding requirements, including 42 CFR 431.51(b)(2) as amended to October 16, 2015, the managed care organization shall allow enrollees freedom of choice of providers of any department-enrolled family planning service provider including those providers who are not in the managed care organization's network.

73.8(3) Continuity of care. The managed care organization shall have policies and procedures that provide for the continuity of care of treatment to ensure that a new enrollee's existing services are honored as required in the contract.

73.8(4) Adequate service referral support and after-hours call-in coverage. The managed care organization shall ensure enrollee access to service information and medical coverage 24 hours a day, 7 days a week, 365 days a year.

a. *Member helpline.* The managed care organization shall maintain a dedicated toll-free member services helpline as established in the contract to handle a variety of member inquiries and to provide warm transfer of enrollees to outside entities, such as provider offices, and to internal managed care organization departments, such as to care coordinators.

b. *Nurse call line.* The managed care organization shall operate a toll-free nurse call line that provides nurse triage telephone services for members to receive medical advice 24 hours a day, 7 days a week from trained medical professionals.

73.8(5) An enrollee's primary care provider shall be responsible for providing preventative and primary health care to the enrollee; for initiating referrals for specialist care, where appropriate; and for maintaining the continuity of patient care. Primary care providers may be physicians, advanced

registered nurse practitioners, or physician assistants, licensed and practicing in accordance with state law.
[**ARC 2358C**, IAB 1/6/16, effective 1/1/16; **ARC 4392C**, IAB 4/10/19, effective 6/1/19]

441—73.9(249A) Incident reporting. The managed care organization shall develop and implement a critical incident reporting and management system for participating providers in accordance with the department requirements for reporting incidents for Section 1915(c) HCBS Waivers, the Section 1915(i) Habilitation Program, and as required for licensure of programs through the department of inspections and appeals. The managed care organization shall develop and implement policies and procedures, subject to department review and approval, to:

1. Address and respond to incidents;
2. Report incidents to the appropriate entities in accordance with required time frames; and
3. Track and analyze incidents.

[**ARC 2358C**, IAB 1/6/16, effective 1/1/16]

441—73.10(249A) Discharge planning. The managed care organization shall establish policies and procedures, subject to approval by the department, that protect an individual from involuntary discharge that may lead to placement in an inappropriate or more restrictive setting. The managed care organization shall facilitate a seamless transition whenever a member transitions between facilities or residences.
[**ARC 2358C**, IAB 1/6/16, effective 1/1/16]

441—73.11(249A) Level of care assessment and annual reviews. The managed care organization shall establish policies and procedures to ensure the implementation of level of care and needs-based eligibility assessments and reassessments as required in the contract and consistent with the department's level of care and needs-based eligibility assessment process and the requirements provided in 441—Chapters 75, 78, 81, 82, 83, and 85. Waiver level of care determinations must be consistent with those made for the appropriate institutional level of care under the state plan.

73.11(1) Initial level of care assessment. Managed care organizations are responsible for conducting level of care and needs-based eligibility assessments for a current enrollee who requires a level of care or a needs-based eligibility assessment. The managed care organization shall perform the assessment using department-approved assessment tools. The results of the assessment shall be submitted to the IME medical services unit for determination of level of care or needs-based eligibility.

73.11(2) Annual continued stay reviews, continued care reviews and redeterminations. When an enrollee requires a continued stay review, a continued care review or a redetermination, the managed care organization shall use department-approved assessment tools. If the managed care organization becomes aware that the enrollee's functional or medical status has changed in a way that may affect the enrollee's level of care or needs-based eligibility, the managed care organization shall submit the assessment findings to the IME medical services unit for determination of level of care or needs-based eligibility.

73.11(3) At any time, if the managed care organization becomes aware that the enrollee's functional or medical status has changed in a way that may affect level of care or needs-based eligibility, the managed care organization shall conduct a level of care or needs-based assessment using the department-approved tools and submit the assessment to the IME medical services unit for determination of level of care or needs-based eligibility.
[**ARC 2358C**, IAB 1/6/16, effective 1/1/16]

441—73.12(249A) Appeal of managed care organization actions. The managed care organization shall have written appeal policies and procedures for an enrollee, or an enrollee's authorized representative, to appeal a managed care organization action. The policies must address contractual requirements and federal funding requirements, including 42 CFR 438.400(b) as amended to October 16, 2015.

73.12(1) *Managed care organization appealable actions.* Managed care organization actions that may be appealed include:

a. Denial or limited authorization of a requested service, including the type or level of service.

b. Reduction, suspension, or termination of a previously authorized service.

c. Denial, in whole or in part, of payment of service.

d. Failure to provide services in a timely manner as defined by the department.

e. Failure of the managed care organization to act within the required time frames set forth in federal funding requirements, including 42 CFR 438.408(b) as amended to October 16, 2015.

f. For a resident of a rural area that has only one appropriate provider of a needed service, the denial of an enrollee's request to exercise the enrollee's right to obtain services outside of the MCO's network.

73.12(2) *Appeal process.* The managed care organization appeal process shall be approved by the department and shall:

a. Allow for the appeal request to be submitted in writing or verbally. If the request is submitted verbally, it must be followed up with a written submission.

b. Require acknowledgment of the receipt of a request for an appeal within three working days.

c. Allow for participation by the enrollee and the provider.

d. Provide for resolution of nonexpedited appeals to be concluded within 30 calendar days of receipt of the request unless an extension is requested.

e. Provide for resolution of expedited appeals where the standard time period could seriously jeopardize the member's health or ability to maintain or regain maximum function to be within 72 hours of receipt of the notice pursuant to federal funding requirements, including 42 CFR 438.402 as amended to October 16, 2015.

f. Ensure that the review will be made by qualified professionals who were not involved with the original action.

g. Ensure issuance of a notice of decision for each appeal. These notices shall contain the member's appeal rights with the department and shall contain an adequate explanation of the action taken and the reason for the decision.

[**ARC 2358C**, IAB 1/6/16, effective 1/1/16; **ARC 3667C**, IAB 3/14/18, effective 2/14/18]

441—73.13(249A) Appeal to department. If the enrollee is not satisfied with the final decision rendered by the managed care organization through the managed care organization's appeal process, the enrollee may appeal an action in accordance with the appeal process available to all persons receiving Medicaid-funded services as set forth in 441—Chapter 7.

[**ARC 2358C**, IAB 1/6/16, effective 1/1/16]

441—73.14(249A) Continuation of benefits. The managed care organization shall be required to continue the member's benefits during the appeal in accordance with federal funding requirements, including 42 CFR 438.420 as amended to October 16, 2015.

73.14(1) If the benefits are continued or reinstated while the appeal is pending, the benefits must be continued until one of the following occurs:

a. The enrollee withdraws the appeal request;

b. Ten days pass after the MCO mailed the notice providing the resolution of the appeal against the enrollee, unless the enrollee, within the ten-day time frame, has requested a state fair hearing with continuation of benefits until a state fair hearing decision is reached; or

c. The time period or service limits of a previously authorized service have been met.

73.14(2) If the final resolution of the appeal is adverse to the enrollee, that is, it upholds the managed care organization's action, the managed care organization may recover the cost of the services furnished to the enrollee while the appeal is pending, to the extent that services were furnished solely because of the requirements to maintain benefits during the appeal.

73.14(3) If the managed care organization or state fair hearing officer reverses a decision to deny, limit, or delay services that were not furnished while the appeal was pending, the managed care organization must authorize and provide the disputed services promptly and as expeditiously as the member's health condition requires. If the managed care organization or the state fair hearing officer

reverses a decision to deny authorization of services and the enrollee received the disputed services while the appeal was pending, the managed care organization must pay for these services.
[**ARC 2358C**, IAB 1/6/16, effective 1/1/16]

441—73.15(249A) Grievances. The managed care organization shall have policies and procedures for review of any nonclinical incidents, nonclinical complaints, or nonclinical concerns. Grievances may be communicated verbally or in writing and require that the review be conducted by someone other than the person or persons involved in the grievance. All policies related to the review of grievances shall be approved by the department prior to implementation.
[**ARC 2358C**, IAB 1/6/16, effective 1/1/16]

441—73.16(249A) Written record. All enrollee appeals and grievances shall be logged and reported to the department. The log shall include the status and resolution of all appeals and grievances.
[**ARC 2358C**, IAB 1/6/16, effective 1/1/16]

441—73.17(249A) Information concerning procedures relating to the review of managed care organization decisions and actions. The managed care organization's written procedures for the review of managed care organization decisions and actions shall be provided to each new enrollee, to participating providers in a provider manual, and to nonparticipating providers upon request.
[**ARC 2358C**, IAB 1/6/16, effective 1/1/16]

441—73.18(249A) Records and reports.

73.18(1) *Records system.* The managed care organization shall document and maintain clinical and fiscal records in accordance with federal and state requirements, including rule 441—79.3(249A) and 42 CFR 456 as amended to October 16, 2015, throughout the course of the contract. The records system shall:

a. Identify transactions with or on behalf of each enrollee by the state identification number assigned to the enrollee by the department.

b. Provide a rationale for and documentation of decisions made by the managed care organization, based upon medical necessity.

c. Permit effective professional review for medical audit processes.

d. Facilitate an adequate system for monitoring treatment reimbursed by the managed care organization including follow up of the implementation of discharge plans and referral to other providers.

73.18(2) *Content of individual treatment record.* The managed care organization shall ensure that participating providers maintain an adequate record-keeping system that includes a complete medical or service record for each enrolled member including documentation of all services provided to each enrollee in compliance with the contract and provisions of rule 441—79.3(249A) and pursuant to federal funding requirements, including 42 CFR 456 as amended to October 16, 2015.

73.18(3) *Confidentiality of health care, mental health care, and substance abuse information.* The managed care organization shall protect and maintain the confidentiality of health care, mental health care, and substance abuse information by implementing policies for staff and through contract terms with participating providers. The policies must comply with applicable state and federal laws.
[**ARC 2358C**, IAB 1/6/16, effective 1/1/16]

441—73.19(249A) Audits. The department or its designee and the U.S. Department of Health and Human Services (HHS) may evaluate through inspections or other means the quality, appropriateness, and timeliness of services performed by the managed care organization. The department or HHS may audit and inspect any records of a managed care organization, or the subcontractor of the managed care organization, that pertain to services performed and the determination of amounts paid under the contract. These records will be made available at times, places, and in a manner as authorized representatives of the department, its designee or HHS may request.
[**ARC 2358C**, IAB 1/6/16, effective 1/1/16]

441—73.20(249A) Marketing. Managed care organization marketing activities and materials shall comply with applicable laws and regulations regarding marketing by the managed care organizations and contract terms. The department shall approve all marketing materials, which must comply with federal funding requirements, including 42 CFR 438.10 and 42 CFR 438.104 as amended to October 16, 2015.
[**ARC 2358C**, IAB 1/6/16, effective 1/1/16]

441—73.21(249A) Enrollee education.

73.21(1) *Use of services.* The managed care organization shall provide written information to all enrollees on the use of services the managed care organization is responsible to arrange, monitor, and reimburse. Information must include the array of services covered; how to access covered services; the providers participating; an explanation of the process for the review of managed care organization decisions and actions, including the enrollee's right to a fair hearing under 441—Chapter 7 and how to access that fair hearing process; provision of after-hours and emergency care; procedures for notifying enrollees of a change in benefits or office sites; how to request a change in providers; a statement of consumer rights and responsibilities; out-of-area use of service information; availability of toll-free telephone information and crisis assistance; and the appropriate use of the referral system.

73.21(2) *Outreach to members with special needs.* The managed care organization shall provide enhanced outreach to members with special needs including, but not limited to, persons with psychiatric disabilities, an intellectual disability or other cognitive impairments, illiterate persons, non-English-speaking persons, and persons with visual or hearing impairments.

73.21(3) *Patient rights and responsibilities.* The managed care organization shall have in effect a written statement of patient rights and responsibilities which is available upon request as well as issued to all new enrollees. This statement shall be part of the packet of enrollment information provided to all new enrollees.
[**ARC 2358C**, IAB 1/6/16, effective 1/1/16]

441—73.22(249A) Payment to the managed care organization.

73.22(1) *Capitation rate.* In consideration for all services rendered by a managed care organization under a contract with the department, the managed care organization will receive a payment each month for each enrolled member. The monthly reimbursement may be reduced by amounts withheld for pay-for-performance components of the contract. The withheld amounts will be distributed based on the terms defined in the managed care contract. Additionally, the department will make an allowance for obligations resulting from Section 9010 of the Patient Protection and Affordable Care Act, the health insurance providers fee. This capitation rate, inclusive of the amounts withheld and the health insurance providers fee, represents the total obligation of the department with respect to the costs of medical care and services provided to enrolled members under the contract except as otherwise designated in the contract rate. Pay-for-performance terms will allow for incentive reimbursement if the managed care organization meets metrics defined in the managed care contract.

73.22(2) *Determination of rate.* The actuarially sound capitation rate will be determined according to the terms of federal funding requirements, including 42 CFR 438.6 as amended to October 16, 2015, Actuarial Standards of Practice 49, and other related CMS regulations and generally accepted actuarial principles and practices.

73.22(3) *Third-party liability.* If an enrolled member has health insurance coverage or a responsible party other than the Medicaid program available for payment of medical expenses, it is the right and responsibility of the managed care organization to investigate these third-party resources and attempt to obtain payment. The managed care organization shall retain all funds collected from third-party resources. A complete record of all income from these sources must be maintained and made available to the department on request.

73.22(4) *Medical loss ratio.* The managed care organization shall report the experienced medical loss ratio for each contract rate period. In the event that the medical loss ratio falls below the

department-designated target, the department shall recoup excess capitation paid to the managed care organization.
[**ARC 2358C**, IAB 1/6/16, effective 1/1/16]

441—73.23(249A) Claims payment by the managed care organization.

73.23(1) The managed care organizations shall pay or deny:

a. Ninety percent of all clean claims within 14 calendar days of receipt,

b. Ninety-nine point five percent of all clean claims within 21 calendar days of receipt, and

c. One hundred percent of all claims within 90 calendar days of receipt.

73.23(2) Limits on payment responsibility for services.

a. The managed care organization is not required to reimburse providers for the provision of services that do not meet the criteria of medical necessity.

b. The managed care organization has the right to require prior authorization of covered services and to deny reimbursement to providers that do not comply with such requirements.

c. Payment responsibilities for emergency room services are as provided at rule 441—73.7(249A).

73.23(3) Payment to nonparticipating providers. In reimbursing nonparticipating providers, the managed care organization is obligated to pay 90 percent of the payment to participating providers.
[**ARC 2358C**, IAB 1/6/16, effective 1/1/16]

441—73.24(249A) Quality assurance. The managed care organization shall have in effect an internal quality assurance and performance improvement system that meets the requirements of any or all applicable state and federal laws.
[**ARC 2358C**, IAB 1/6/16, effective 1/1/16]

441—73.25(249A) Certifications and program integrity. The managed care organization shall develop and implement policies, procedures and a mandatory compliance plan to ensure compliance with the contract requirements for certification, program integrity and prohibited affiliations. The managed care organization shall cooperate and collaborate with the department on all program integrity activities. The managed care organization shall comply with state and federal laws pertaining to these requirements, including 42 CFR 438.608 and 42 CFR 455 as amended to October 16, 2015.
[**ARC 2358C**, IAB 1/6/16, effective 1/1/16]

These rules are intended to implement Iowa Code section 249A.4 and 2015 Iowa Acts, Senate File 505, section 12.

[Filed Emergency After Notice ARC 2358C (Notice ARC 2241C, IAB 11/11/15), IAB 1/6/16, effective 1/1/16]

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CHAPTER 176
DEPENDENT ADULT ABUSE

[Prior to 7/1/83, Social Services[770] Ch 156]
[Previously appeared as Ch 156—renumbered IAB 2/29/84]
[Prior to 2/11/87, Human Services[498]]

441—176.1(235B) Definitions.

"Adult abuse" means either:

1. Any of the following as a result of the willful or negligent acts or omissions of a caretaker:

- Physical injury to, or injury which is at variance with the history given of the injury, or unreasonable confinement, unreasonable punishment, or assault of a dependent adult.
- The commission of a sexual offense under Iowa Code chapter 709 or Iowa Code section 726.2 with or against a dependent adult.
- Exploitation of a dependent adult, which means the act or process of taking unfair advantage of a dependent adult or the adult's physical or financial resources for one's own personal or pecuniary profit, without the informed consent of the dependent adult, including theft, by the use of undue influence, harassment, duress, deception, false representation, or false pretenses.
- The deprivation of the minimum food, shelter, clothing, supervision, physical or mental health care, and other care necessary to maintain a dependent adult's life or health.
- Sexual exploitation of a dependent adult by a caretaker. "Sexual exploitation" means any consensual or nonconsensual sexual contact with a dependent adult which includes but is not limited to kissing; touching of the clothed or unclothed inner thigh, breast, groin, buttock, anus, pubes, or genitals; or a sex act, as defined in Iowa Code section 702.17. "Sexual exploitation" includes the transmission, display, taking of electronic images of the unclothed breast, groin, buttock, anus, pubes, or genitals of a dependent adult by a caretaker for a purpose not related to treatment or diagnosis or as part of an ongoing assessment, evaluation or investigation. "Sexual exploitation" does not include touching which is part of a necessary examination, treatment, or care by a caretaker acting within the scope of the practice or employment of the caretaker; the exchange of a brief touch between the dependent adult and a caretaker for the purpose of reassurance, comfort, or casual friendship; or touching between spouses.

2. The deprivation of the minimum food, shelter, clothing, supervision, physical or mental health care, and other care necessary to maintain a dependent adult's life or health as a result of the acts or omissions of the dependent adult.

"Appropriate evaluation or assessment" means that evaluation or assessment reasonably believed by the department to be warranted by the facts and circumstances of the case as reported.

"Assault" means "assault" as defined in Iowa Code section 708.1.

"At-risk adult" means an adult who, because of a significant impairment due to a physical or mental disability or both, is unable to meet essential daily needs without assistance and whose personal health or safety is at risk due to such impairments, the environment, substance abuse problems, a lack of services or social supports, a refusal to accept services, or other risk factors identified through an assessment.

"Caretaker" means a related or nonrelated person who has the responsibility for the protection, care, or custody of a dependent adult as a result of assuming the responsibility voluntarily, by contract, through employment, or by order of the court.

"Collateral sources" means any person or agency who is presently providing, either in a professional or paraprofessional capacity, service to the dependent adult, including, but not limited to, doctors, counselors, and public health nurses.

"Confidentiality" means the withholding of information from any manner of communication, public or private.

"Denial of critical care" exists when the dependent adult's basic needs are denied or ignored to such an extent that there is immediate or potential danger of the dependent adult suffering injury or death, or is a denial of, or a failure to provide the mental health care necessary to adequately treat the dependent adult's serious social maladjustment, or is a gross failure of the caretaker to meet the emotional needs of the dependent adult necessary for normal functioning, or is a failure of the caretaker to provide for the proper supervision of the dependent adult.

"Department" means the department of human services and includes the county and central offices of the department, unless otherwise specified.

"Dependent adult" means a person 18 years of age or older who is unable to protect the person's own interests or unable to adequately perform or obtain services necessary to meet essential human needs, as a result of a physical or mental condition which requires assistance from another.

"Expungement" means the process of destroying dependent adult abuse information.

"Immediate danger to health or safety" means a situation in which death or severe bodily injury could reasonably be expected to occur without intervention.

"Immediately" means within 24 hours when referring to mandatory reporters reporting suspected abuse of a dependent adult.

"Individual employed as an outreach person" means a person who, in the course of employment, makes regular contacts with dependent adults regarding available community resources.

"Informed consent" (as used in Iowa Code paragraph 235B.2(5)*"c"*) means a dependent adult's agreement to allow something to happen that is based on a full disclosure of known facts and circumstances needed to make the decision intelligently, i.e., knowledge of risks involved or alternatives.

"Minimum food, shelter, clothing, supervision, physical and mental health care, and other care" means that food, shelter, clothing, supervision, physical and mental health care, and other care which, if not provided, would constitute denial of critical care.

"Multidisciplinary team" shall mean a membership of individuals who possess knowledge and skills related to the diagnosis, assessment, and disposition of dependent adult abuse cases and who are professionals practicing in the disciplines of medicine, public health, social work, law, law enforcement and other disciplines relative to dependent adults. Members of the team shall include, but are not limited to, persons representing the area agencies on aging, county attorneys, health care providers, and others involved in advocating or providing services for dependent adults.

"Physical injury" means damage to any bodily tissue to the extent that the tissue must undergo a healing process in order to be restored to a sound and healthy condition, or damage to any bodily tissue to the extent that the tissue cannot be restored to a sound and healthy condition, or damage to any bodily tissue which results in the death of the person who has sustained the damage, or physical injury which is at variance with the history given of it.

"Preponderance of evidence" shall mean evidence which is of greater weight or more convincing than the evidence which is offered in opposition to it.

"Proper supervision" means that supervision which a reasonable and prudent person would exercise under similar facts and circumstances, but in no event shall a person place a dependent adult in a situation that may endanger the dependent adult's life or health or cruelly punish or unreasonably confine the dependent adult.

"Registry" means the central registry for dependent adult abuse information established in Iowa Code Supplement section 235B.5.

"Report" means a verbal or written statement, made to the department, which alleges that dependent adult abuse has occurred.

[**ARC 8099B**, IAB 9/9/09, effective 8/13/09; **ARC 9258B**, IAB 12/1/10, effective 2/1/11]

441—176.2(235B) Denial of critical care. The failure on the part of the caretaker or dependent adult to provide for minimum food, shelter, clothing, supervision, physical or mental care, and other care necessary for the dependent adult's health and welfare when financially able to do so or when offered financial and other reasonable means to do so shall constitute denial of critical care to that dependent adult.

441—176.3(235B) Appropriate evaluation. Immediately upon receipt of a dependent adult abuse report the worker shall conduct an intake sufficient to determine whether the allegation constitutes a report of dependent adult abuse.

176.3(1) Dependent adult abuse reports shall be evaluated when all of the following criteria are alleged to be met:

a. The person is a dependent adult.

b. Dependent adult abuse exists as defined in Iowa Code section 235B.2.

c. A caretaker exists in reports of physical injury to or unreasonable confinement or cruel punishment of a dependent adult; commission of a sexual offense; exploitation; and deprivation by another person of food, shelter, clothing, supervision, physical and mental health care and other care necessary to maintain life or health.

176.3(2) Nondependent adult abuse situations. The following are not dependent adult abuse situations:

a. A report of domestic abuse under Iowa Code chapter 236, Domestic Abuse, does not in and of itself constitute a report of dependent adult abuse.

b. Circumstances in which the dependent adult declines medical treatment if the dependent adult holds a belief or is an adherent of a religion whose tenets and practices call for reliance on spiritual means in place of reliance on medical treatment.

c. Circumstances in which the dependent adult's caretaker, acting in accordance with the dependent adult's stated or implied consent, declines medical treatment if the dependent adult holds a belief or is an adherent of a religion whose tenets and practices call for reliance on spiritual means in place of reliance on medical treatment.

d. Withholding and withdrawing of health care from a dependent adult who is terminally ill in the opinion of a licensed physician when the withholding and withdrawing of health care is done at the request of the dependent adult or at the request of the dependent adult's next-of-kin or guardian pursuant to the applicable procedures under Iowa Code chapter 125, 144A, 222, 229, or 633.

e. All persons legally incarcerated in a penal setting, either in a local jail or confined to the custody of the director of the department of corrections.

176.3(3) Reports of dependent adult abuse which are the result of the acts or omissions of the dependent adult shall be collected and maintained in the files of the dependent adult as assessments only and shall not be included on the central registry. The central registry shall be notified as to the disposition of the assessment.

176.3(4) Confirmed, not registered. Reports of physical abuse or denial of critical care by a caretaker that would otherwise be founded reports shall be considered confirmed, not registered reports if the abuse is determined to be minor, isolated, and unlikely to reoccur. These reports shall be assessments and shall not be included on the central abuse registry. The assessment shall be maintained in the local office as directed in subrule 176.13(4).

441—176.4(235B) Reporters. The central registry and county office shall accept reports from mandatory reporters or any other person who believes dependent adult abuse has occurred.

176.4(1) Mandatory reporters shall:

a. Report suspected abuse of a dependent adult within 24 hours of becoming aware of an abusive incident.

b. Make a written report within 48 hours after an oral report.

176.4(2) The reporter may use a form prescribed by the department or may use a form developed by the reporter that meets the requirements of Iowa Code section 235B.3.

[**ARC 4393C**, IAB 4/10/19, effective 6/1/19]

441—176.5(235B) Reporting procedure.

176.5(1) Each report made by someone other than a mandatory reporter may be oral or written.

176.5(2) The report shall be made by telephone or otherwise to the department of human services. When the person making the report has reason to believe that immediate protection for the dependent adult is advisable, that person shall also make an oral report to an appropriate law enforcement agency.

176.5(3) The department of human services shall:

a. Immediately, upon receipt of a report, make an oral report to the registry;

b. Forward a copy of the report to the registry; and

c. Promptly notify the appropriate county attorney of the receipt of any report.

176.5(4) The report shall contain the following information, or as much thereof as the person making the report is able to furnish:

a. The names and home addresses of the dependent adult, appropriate relatives, caretakers, and other persons believed to be responsible for the care of the dependent adult.

b. The dependent adult's present whereabouts if not the same as the address given.

c. The reason the adult is believed to be dependent. Dependency is the first criterion to be considered before beginning an evaluation.

d. The dependent adult's age.

e. The nature and extent of the adult abuse, including evidence of previous adult abuse. The existence of alleged adult abuse is the second criterion to be considered before beginning an evaluation.

f. Information concerning the suspected adult abuse of other dependent adults in the same residence.

g. Other information which the person making the report believes might be helpful in establishing the cause of the abuse or the identity of the person or persons responsible for the abuse, or helpful in providing assistance to the dependent adult.

h. The name and address of the person making the report.

176.5(5) A report shall be accepted whether or not it contains all of the information requested in 176.5(4), and may be made to the department, county attorney, or law enforcement agency. When the report is made to any agency other than the department of human services, that agency shall promptly refer the report to the department.

441—176.6(235B) Duties of the department upon receipt of report.

176.6(1) When a report is received, the department shall promptly commence an appropriate evaluation or assessment, except that the department of inspections and appeals is responsible for the evaluation and disposition of a case of adult abuse in a health care facility, including hospitals as defined in Iowa Code section 135B.1 and facilities as defined in Iowa Code section 135C.1. The department shall forward all reports and other information concerning adult abuse in a health care facility to the department of inspections and appeals on the first working day following the submitting of the report. The department of inspections and appeals shall inform the registry of all actions taken or contemplated concerning the evaluation or disposition of a case of adult abuse in a health care facility. The primary purpose of the evaluation or assessment by the department shall be the protection of the dependent adult named in the report.

176.6(2) The evaluation or assessment shall include all of the following:

a. Identification of the nature, extent, and cause of the adult abuse, if any, to the dependent adult named in the report.

b. The identification of the person or persons responsible for the adult abuse.

c. A determination of whether other dependent adults in the same residence have been subjected to adult abuse.

d. A critical examination of the residential environment of the dependent adult named in the report, and the dependent adult's relationship with caretakers and other adults in the same residence.

e. A critical explanation of all other pertinent matters.

176.6(3) The evaluation or assessment, with the consent of the dependent adult or caretaker, when appropriate, may include a visit to the residence of the dependent adult named in the report and an examination of the dependent adult. If permission to enter the residence and to examine the dependent adult is refused, the district court, upon a showing of probable cause that a dependent adult has been abused, may authorize a person, authorized by the department, to make an evaluation or assessment, to enter the residence of, and to examine the dependent adult.

Upon a showing of probable cause that a dependent adult has been financially exploited, a court may authorize a person, also authorized by the department, to gain access to the financial records of the dependent adult.

176.6(4) County attorneys, law enforcement agencies, multidisciplinary teams as defined in Iowa Code section 235B.1, subsection 1, and social services agencies in the state shall cooperate and assist in

the evaluation or assessment upon the request of the department. County attorneys and appropriate law enforcement agencies shall also take any other lawful action necessary or advisable for the protection of the dependent adult.

176.6(5) Completion of evaluation or assessment report. Upon completion of its evaluation or assessment, the department shall complete a report that describes its findings and includes all actions taken or contemplated.

a. The department shall complete its report within 20 working days of the receipt of the abuse allegations, unless the worker's supervisor grants an extension of time for good cause shown. The worker's supervisor may grant an extension for a maximum of 30 working days. No more than three extensions shall be granted.

b. Upon completion of an evaluation, the department shall enter its report into the dependent adult reporting and evaluation system (DARES).

c. Upon completion of an assessment when the alleged abuse is the result of the acts or omissions of the dependent adult, the department shall place the report in the case file of the dependent adult and enter the information into DARES.

176.6(6) Report to county attorney. The department shall transmit a copy of the report of its evaluation or assessment to the appropriate county attorney. The county attorney shall notify the local office of the department of any actions or contemplated actions with respect to a suspected case of adult abuse.

176.6(7) Based on the evaluation, the department shall complete an assessment of services needed by a dependent adult believed to be the victim of abuse, the dependent adult's family, or a caretaker. The department shall explain that the department does not have independent legal authority to compel the acceptance of protective services. Upon voluntary acceptance of the offer of services, the department shall make referrals or may provide necessary protective services to eligible dependent adults, their family members, and caretakers.

176.6(8) Court action. When, upon completion of the evaluation or assessment or upon referral from the state department of inspections and appeals, the department determines that the best interests of the dependent adult require court action, the department shall initiate action for the appointment of a guardian or conservator, or for admission or commitment to an appropriate institution or facility, pursuant to the applicable procedures under Iowa Code chapter 125, 222, 229, or 633. The department may pursue other remedies provided by law pursuant to the applicable procedures under Iowa Code sections 235B.17, 235B.18, 235B.19, and 235B.20 or any other legal remedy which provides protection to a dependent adult. The appropriate county attorney shall assist the department in the preparation of the necessary papers to initiate the action, and shall appear and represent the department at all district court proceedings.

176.6(9) The department shall assist the district court during all stages of court proceedings involving a suspected case of adult abuse.

176.6(10) In every case involving adult abuse which is substantiated by the department and which results in a judicial proceeding on behalf of the dependent adult, legal counsel shall be appointed by the court to represent the dependent adult in the proceedings. The court may also appoint a guardian ad litem to represent the dependent adult when necessary to protect the dependent adult's best interests. The same attorney may be appointed to serve both as legal counsel and as guardian ad litem. Before legal counsel or a guardian ad litem is appointed pursuant to Iowa Code section 235B.3, subsection 7, paragraph *"c,"* the court shall require the dependent adult and any person legally responsible for the support of the dependent adult to complete under oath a detailed financial statement. If, on the basis of that financial statement, the court deems that the dependent adult or the legally responsible person is able to bear all or a portion of the cost of the legal counsel or guardian ad litem, the court shall so order. In cases where the dependent adult or the legally responsible person is unable to bear the cost of the legal counsel or guardian ad litem, the expense shall be paid by the county.

176.6(11) Notification of licensing authority. Based on information discovered during an evaluation of dependent adult abuse in a program providing care to a dependent adult, the department shall notify

the licensing or accrediting authority for the program, the governing body of the program, and the administrator in charge of the program of any of the following:

a. A violation of program policy noted in the evaluation.

b. An instance in which program policy or lack of program policy may have contributed to the dependent adult abuse.

c. An instance in which general practice in the program appears to differ from the program's policy.

The licensing or accrediting authority, the governing body, and the administrator in charge of the program shall take any lawful action which may be necessary or advisable to protect dependent adults receiving care in the program.

176.6(12) Assessments by other agencies. The department may approve agencies considered capable and appropriate to complete assessments of dependent adults who are suspected of being abused.

a. The department may make a referral to an approved agency to complete an assessment of a dependent adult who is suspected of being abused, in conjunction with a department abuse evaluation or assessment on the dependent adult.

b. The department may use information obtained from the assessment completed by the approved agency in the abuse evaluation or assessment. The department has complete authority in determining the conclusions of the abuse evaluation or assessment.

176.6(13) Referrals to other agencies. During an assessment or evaluation of suspected abuse of a dependent adult, the department shall:

a. Make a referral to the division of labor services of the department of workforce development if an issue is discovered that concerns wages, workplace safety, or labor and employment matters under the jurisdiction of that agency.

b. Make a referral to the civil rights commission if an issue is discovered that involves discrimination under the jurisdiction of that agency.

176.6(14) Assessment of dependency and risk. After the first visit to a dependent adult who is alleged to be abused, the department shall complete an assessment of the adult using a form prescribed by the department. The department shall assess:

a. The adult's dependency,

b. The risk to the adult's health or safety, and

c. The areas in which the adult is either dependent or independent.

176.6(15) Follow-up for at-risk adults. When it has not been possible or necessary to obtain a court order for services to an at-risk adult, the department shall attempt to empower the at-risk adult to agree to accept services and to participate in preparing a safety plan. If the adult refuses to sign a safety plan for an at-risk adult and to accept recommended services, the department shall provide periodic visits.

a. *Purpose.* The purpose of the visits shall be to:

(1) Assess the adult for increased risk or impairment,

(2) Monitor the adult's situation to determine the feasibility of intervening with protective services, and

(3) Empower the adult to accept recommended services and to engage in safety planning.

b. *Exemption.* If it has been determined there is a physical threat to the safety of the department employee who is attempting to visit an at-risk adult, the department shall not attempt a periodic visit unless the physical threat to safety has been removed.

c. *Criteria to continue visits.* Periodic visits shall continue if:

(1) The adult's health or safety has deteriorated somewhat but not to the point that a court order is necessary; or

(2) The adult's health or safety has remained the same and there is a possibility the adult may in the future agree to services and to participating in preparing a safety plan.

d. *Criteria to end visits.* Periodic visits shall be terminated when:

(1) The adult agrees to services and services are arranged; or

(2) The adult's health or safety has deteriorated to the point that the department has requested court action pursuant to subrule 176.6(8); or

(3) The adult's health or safety has not changed six months after the initial report of alleged abuse; there appears no possibility the adult will ever agree to services; and the adult is competent to make decisions.

[**ARC 9258B**, IAB 12/1/10, effective 2/1/11; **ARC 4393C**, IAB 4/10/19, effective 6/1/19]

441—176.7(235B) Appropriate evaluation or assessment.

176.7(1) After receipt of the report alleging dependent adult abuse, the field worker shall make an evaluation or assessment to determine whether the information as reported, other known information, and any information gathered as a result of the worker's contact with collateral sources would tend to corroborate the alleged abuse.

176.7(2) When the information gathered in the evaluation or assessment tends to corroborate, or the worker is uncertain as to whether it repudiates the allegations of the report, the worker shall immediately continue the evaluation or assessment by making a reasonable effort to ensure the safety of the adult. The worker and the worker's supervisor shall determine whether an immediate threat to the physical safety of the adult is believed to exist.

a. If an immediate threat to the physical safety of the adult is believed to exist, the field worker shall make every reasonable effort to examine the adult, as authorized by 176.6(3), within one hour after receipt of the report and shall take any lawful action necessary or advisable for the protection of the adult.

b. When physical safety of the adult is not endangered, the worker shall make every reasonable effort to examine the adult within 24 hours after receipt of the report.

176.7(3) In the event the information gathered in the evaluation or assessment fails to corroborate the allegation of adult abuse, the worker, with approval of the supervisor, may terminate the evaluation or assessment and submit the report required by subrule 176.6(5).

441—176.8(235B) Immunity from liability for reporters. A person participating in good faith in making a report or cooperating or assisting the department in evaluating or assessing a case of dependent adult abuse has immunity from liability, civil or criminal, which might otherwise be incurred or imposed based upon the act of making the report or giving the assistance. The person has the same immunity with respect to participation in good faith in a judicial proceeding resulting from the report or assistance or relating to the subject matter of the report or assistance.

441—176.9(235B) Registry records. Central registry records shall be kept in the name of the dependent adult and cross-referenced in the name of the caretaker.

441—176.10(235B) Adult abuse information disseminated.

176.10(1) *Requests for information.* Written requests for adult abuse information by the subject of a report as defined in subrule 176.10(3), paragraph *"a,"* may be submitted to the county office of the department on the department-prescribed form entitled Request for Child and Dependent Adult Abuse Information.

Oral requests for dependent adult abuse information may be made to the county office or the central registry when the person making the request believes that the information is needed immediately and the person is authorized to access the information, pursuant to the requirements of Iowa Code section 235B.7, subsection 2. If a request is made orally by telephone, a written request shall be filed within 72 hours of the oral request on the department-prescribed form entitled Request for Child and Dependent Adult Abuse Information. When an oral request to the county office to obtain dependent adult abuse information is granted by the central registry, the county shall document the approval to the central registry on the department-prescribed form entitled Request for Child and Dependent Adult Abuse Information.

All other requests for information shall be made to the central registry by mail or fax pursuant to the requirements of Iowa Code section 235B.7.

176.10(2) *Verification of identity.* The county office shall verify the identity of the person making the request on the department-prescribed form entitled Request for Child and Dependent Adult Abuse Information. Upon verification of the identity of the person making the request, the county office shall transmit the request to the central registry. The central registry shall verify the identity of persons making requests for information directly to the central registry by telephone, mail, fax, or in person, on the department-prescribed form entitled Request for Child and Dependent Adult Abuse Information.

176.10(3) *Approval of requests.* The department shall grant access to dependent adult abuse information as authorized by Iowa Code section 235B.6. Upon approval of any request for dependent adult abuse information authorized by this rule, the department may withhold the name of the person who made the report of dependent adult abuse when the department finds that the disclosure of the person's identity would be detrimental to the person's interest.

176.10(4) *Requests concerning applicants for employment and employees of health care programs.* A health care program making a request for dependent adult abuse information for the purpose of determining employability, as authorized by Iowa Code section 235B.6, subsection 2, paragraph *"e,"* subparagraphs (6) and (7), and section 135C.33, subsection 6, shall request the information directly from the central registry or obtain the information from the Internet electronic information system maintained by the health facilities division of the department of inspections and appeals.

Requests made directly to the central registry shall be made on the department-prescribed form entitled Request for Child and Dependent Adult Abuse Information.

Health care programs requesting dependent adult abuse background checks on employee applicants and employees by use of the Internet electronic information system shall complete the department-prescribed form entitled Access to Confidential Abuse Information and Non-Redissemination Agreement. The form shall be signed by the administrator of the health care program and be sent to the central registry before receipt of the information from the department. The administrator shall agree not to redisseminate dependent adult abuse information obtained through the Internet electronic information system, except as authorized in Iowa Code sections 235B.6 and 235B.8.

176.10(5) *Dissemination of undetermined reports.* Rescinded IAB 8/6/03, effective 7/10/03.

176.10(6) *Access to unfounded dependent adult abuse information.* Access to unfounded dependent adult abuse information is authorized only to:

a. Persons identified as subjects of a report, including the dependent adult named in a report as a victim, a guardian of a dependent adult named in a report as a victim, a person named in a report as having abused a dependent adult, or an attorney representing any of the above;

b. An employee or agency of the department of human services responsible for the evaluation or assessment of a dependent adult abuse report;

c. Registry or department personnel, when necessary to the performance of their official duties, or a person or agency under contract with the department to carry out official duties and functions of the registry;

d. The mandatory reporter who reported dependent adult abuse in an individual case;

e. The long-term care resident advocate, if the victim resides in a long-term care facility or the alleged perpetrator is an employee of a long-term care facility; and

f. A multidisciplinary team, if the department approves the composition of the team and determines that access to the team is necessary to assist in the evaluation, diagnosis, assessment, and disposition of a dependent adult abuse case.

176.10(7) *Requests concerning employees of department facilities.* When a request is made by the hiring authority of a department operated facility which provides direct client care and the request is made for the purpose of determining continued employability of a person employed, with or without compensation, by the facility, the information shall be requested directly from the central registry. The information requested shall be disseminated to the personnel office of the department. The personnel office shall redisseminate the information to the hiring authority for the person involved only upon a finding that the information has a direct bearing on employability of the person involved.

When the personnel office determines that the information has no direct bearing on employability, the hiring authority shall be notified that no job-related dependent adult abuse information is available. If the central registry and local office files contain no information, the hiring authority shall be so informed.

176.10(8) *Dependent adult abuse information disseminated and redisseminated.* Notwithstanding subrule 176.10(1), written requests and oral requests are not required for dependent adult abuse information that is disseminated to an employee of the department of human services, a district court, or the attorney representing the department as authorized by Iowa Code section 235B.6.

176.10(9) *Required notification.* The department shall notify orally the subject of a report of the results of the evaluation or assessment. The department shall subsequently transmit a written notice to the subject which will include information regarding the results, the confidentiality provisions of Iowa Code sections 235B.6 and 235B.12, and the procedures for correction or expungement and appeal of dependent adult abuse information as provided in Iowa Code section 235B.10.

176.10(10) *Mandatory reporter notification.* The department shall attempt to notify orally the mandatory reporter who made the report in a dependent adult abuse case of the results of the evaluation or assessment and of the confidentiality provisions of Iowa Code sections 235B.6 and 235B.12. The department shall subsequently transmit a written adult protective notification on a form prescribed by the department to each mandatory reporter who made the report. The form shall include information regarding the results of the evaluation or assessment and confidentiality provisions. A copy of the written notice shall be transmitted to the registry and shall be maintained by the registry as provided in Iowa Code section 235B.8.

176.10(11) *Subjects informed of abuse history.* The department may inform a subject of a dependent adult abuse report of a person's abuse history if the department determines at any time that disclosure is necessary for the protection of the dependent adult. A subject may be informed that a person is listed on the child or dependent adult abuse registry as having a founded abuse report or is listed on the sex offender registry.

[**ARC 2427C**, IAB 3/2/16, effective 5/1/16; **ARC 4393C**, IAB 4/10/19, effective 6/1/19]

441—176.11(235B) Person conducting research. The person in charge of the central registry shall be responsible for determining whether a person requesting dependent adult abuse information is conducting bona fide research. To make this determination, the central registry may require these persons to submit credentials and the research design. If the registry determines that identified information is essential to the research design, the registry shall also determine the method by which written permission is to be secured from the dependent adult or guardians of the dependent adult who could be identified by the information to be researched. Any costs incurred in the dissemination of the information shall be assumed by the researcher. The department will keep a public record of persons conducting research.

441—176.12(235B) Examination of information. Examination of information contained in the central registry can be made at the site of the central registry between the hours of 8 a.m. and 12 p.m. or 1 p.m. and 4 p.m., Monday through Friday, except state authorized holidays.

The person, or that person's attorney, requesting to examine the information in the registry which refers to that person, shall be allowed to inspect the information after providing appropriate identification.

441—176.13(235B) Dependent adult abuse information registry. The department shall create a central abuse registry for dependent adult abuse information. The registry shall collect, maintain, and disseminate dependent adult abuse information as follows:

176.13(1) *Founded reports.* A report of dependent adult abuse determined to be founded shall be retained and sealed by the registry in accordance with Iowa Code section 235B.9.

176.13(2) *Unfounded reports.* A report of dependent adult abuse determined to be unfounded shall be expunged five years from the date it is determined to be unfounded, in accordance with Iowa Code section 235B.9, subsection 2, as amended by 2009 Iowa Acts, Senate File 484.

176.13(3) *Rejected intakes.* Reports that are found not to meet the criteria to be accepted for evaluation or assessment of abuse shall be kept in the local office for three years from the date the report of abuse was determined to be rejected.

176.13(4) *Assessments.* Reports classified as assessments shall not be included in the central registry but shall be maintained in the local office. The central registry shall be notified of the disposition of the assessment report.

a. *Self-denial of critical care.* Reports involving abuse as a result of the acts or omissions of the dependent adult will be assessments. These reports shall be retained in the dependent adult's case file in the local office for five years and then destroyed.

b. *Confirmed, not registered.* Reports of dependent adult abuse where physical abuse or denial of critical care committed by a caretaker is confirmed but is determined to be minor, isolated, and unlikely to reoccur shall be assessments. These reports shall be maintained in the local office for five years and then destroyed unless a subsequent report of dependent adult abuse on the same caretaker is founded. If a subsequent report on the same caretaker is founded within the five-year period, the confirmed, not registered report shall be maintained in the local office for ten years from the date of the subsequent report and then sealed.

[**ARC 8099B**, IAB 9/9/09, effective 8/13/09]

441—176.14(235B) Central registry. Rescinded IAB 10/30/91, effective 1/1/92.

441—176.15(235B) Multidisciplinary teams.

176.15(1) *Purpose of multidisciplinary teams.* The service area shall establish multidisciplinary teams for the purpose of assisting the department in assessment, diagnosis, and disposition of reported dependent adult abuse cases. The disposition of a case may include the provision for treatment recommendations and services.

176.15(2) *Execution of team agreement.* When the team is established, the service area manager or designee and all team members shall execute an agreement on a form prescribed by the department. The multidisciplinary team agreement shall specify:

a. That the team shall be consulted solely for the purpose of assisting the department in the assessment, diagnosis and treatment of dependent adult abuse cases.

b. That any team member may cause a dependent adult abuse case to be reviewed if approved by the department through use of the process of requesting adult abuse information specified in rule 441—176.10(235B).

c. That no team members shall redisseminate adult abuse information obtained solely through the multidisciplinary team. This shall not preclude redissemination of information as authorized by Iowa Code section 235B.6 when an individual team member has received information as a result of another authorized access provision of the Code.

d. That the department may consider the recommendation of the team in a specific dependent adult abuse case but shall not, in any way, be bound by the recommendations.

e. That any written report or document produced by the team pertaining to an individual case shall be made a part of the file for the case and shall be subject to all confidentiality provisions of Iowa Code sections 235B.6 and 235B.8 and of 441—Chapter 176.

f. That any written records maintained by the team which identify an individual dependent adult abuse case shall be destroyed when the agreement lapses.

g. That consultation team members shall serve without compensation.

h. That any party to the contract may withdraw with or without cause upon the giving of 30 days' notice.

i. The date on which the agreement will expire.

176.15(3) *Filing of agreement.* Whenever a team is created, a copy of the executed contract shall be filed with the central registry in addition to any other requirement placed upon execution of agreements by the department.

[**ARC 4393C**, IAB 4/10/19, effective 6/1/19]

441—176.16(235B) Medical and mental health examinations. In any year in which the legislature appropriates funds, the department shall administer a payment program for mental health or medical health examinations for subjects of dependent adult abuse reports.

176.16(1) *Conditions for payment.* The following conditions must be met before payment can be made:

a. Local resources to pay these costs must be exhausted.

b. The examination must be scheduled during the evaluation or assessment process.

c. Department staff must be involved in the decision to request the examination.

176.16(2) *Payment limits.* Payment for mental health examinations shall not exceed $250. Payment for a complete medical examination shall not exceed $160.

176.16(3) *Billing procedures.* Claims for payment shall be submitted to the division of behavioral, developmental, and protective services on Form GAX, General Accounting Expenditure, accompanied by a letter from department staff certifying that the necessary conditions for payment have been met.

441—176.17(235B) Request for correction or expungement. The department of human services is responsible for correction or expungement of reports prepared by department staff. The department of inspections and appeals is responsible for correction or expungement of reports prepared by that department's staff and that determination shall be binding on the registry.

176.17(1) Within six months of the date of the notice of evaluation results, a person may file with the registry a written statement to the effect that the dependent adult abuse information referring to the person is partially or entirely erroneous. The person may also request a correction of that information or of the findings of the report. The registry will record all requests and immediately forward the requests to the division of health facilities, department of inspections and appeals, when the reports were prepared by the department of inspections and appeals. The registry will notify the person requesting a correction that the report has been sent to the department of inspections and appeals.

176.17(2) Unless the designated department corrects the information or findings as requested, the designated department shall provide the person with an opportunity for a hearing as provided by 441—Chapter 7 to correct the information or the findings. The department may defer the hearing until the conclusion of a pending district court case relating to the information or findings.

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NATURAL RESOURCES DEPARTMENT[561]

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Rules of divisions under this Department "umbrella" include Energy and Geological Resources[565], Environmental Protection Commission[567], Natural Resource Commission[571], and Preserves, State Advisory Board[575]

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CHAPTER 16
STATE PARK AND RECREATION AREA FEES

561—16.1(455A) Definitions.

"Commission" means the natural resource commission.

"Department" means the department of natural resources.

"Director" means the director of the department of natural resources.

[**ARC 4395C**, IAB 4/10/19, effective 5/15/19]

561—16.2(455A) Camping, rental facilities, vessel storage, and other special privileges—fees.

16.2(1) *Fee methodology.* The director or the director's designee shall fix and publish on the department's website base fees for camping, the use of rental facilities, vessel storage and other special privileges at state parks and recreation areas under the jurisdiction of the department and the commission. The director or the director's designee may increase, reduce, or waive the base fees on a case-by-case basis in order to take advantage of marketing opportunities so as to encourage maximum use of state facilities. The director or the director's designee may consider the following factors when establishing and when adjusting base fees:

a. The specific park's or recreation area's amenities.

b. The size and features of a particular campsite or rental facility.

c. Use of campsites, rental facilities, or other special privileges.

d. Day of the week, season of the year, holidays, or other noteworthy occasions or special events.

e. Cost of operations.

f. Other considerations that the director or the director's designee deems appropriate.

16.2(2) *Fees honored.* The fee to be charged shall be the fee currently in effect at the time the reservation is made and paid for. Any change to a reservation shall be subject to the fees applicable to the campsite or rental facility, along with any applicable reservation change fee, at the time the reservation is modified.

[**ARC 4395C**, IAB 4/10/19, effective 5/15/19]

561—16.3(455A) Areas under management—varying fees. Fees charged for like services in state-owned areas under management by political subdivisions may vary from those established pursuant to this chapter.

[**ARC 4395C**, IAB 4/10/19, effective 5/15/19]

These rules are intended to implement Iowa Code section 455A.14.

[Filed ARC 4395C (Notice ARC 4226C, IAB 1/16/19), IAB 4/10/19, effective 5/15/19]

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PARKS AND RECREATION AREAS

CHAPTER 61
STATE PARKS, RECREATION AREAS, AND STATE FOREST CAMPING

[Prior to 12/31/86, Conservation Commission[290] Ch 45]

571—61.1(461A) Applicability. This chapter is applicable to all state-owned parks and recreation areas managed by the department and by political subdivisions unless otherwise noted. This chapter also governs camping activity in the following state forests:

1. Shimek State Forest in Lee and Van Buren Counties.
2. Stephens State Forest in Appanoose, Clarke, Davis, Lucas and Monroe Counties.
3. Yellow River State Forest in Allamakee County.

[**ARC 0383C**, IAB 10/3/12, effective 11/7/12]

571—61.2(461A) Definitions.

"Bank" or *"shoreline"* means the zone of contact of a body of water with the land and an area within 25 feet of the water's edge.

"Basic unit" or *"basic camping unit"* means the portable shelter used by one to six persons.

"Beach" is as defined in rule 571—64.1(461A).

"Beach house open shelter" means a building located on the beach which is open on two or more sides and which may or may not have a fireplace.

"Cabin" means a small, one-story dwelling of simple construction which is available for rental on a daily or weekly basis.

"Call center" means a phone center where operators process all telephone reservations, reservation changes and reservation cancellations for camping and rental facilities.

"Camping" means the erecting of a tent or shelter of natural or synthetic material or placing a sleeping bag or other bedding material on the ground or parking a motor vehicle, motor home, or trailer for the apparent purpose of overnight occupancy.

"Centralized reservation system" means a system that processes reservations using more than one method to accept reservations. Each method simultaneously communicates to a centralized database at a reservation contractor location to ensure that no campsite or rental facility is booked more than once.

"Chaperoned, organized youth group" means a group of persons 17 years of age and under, which is sponsored by and accompanied by adult representatives of a formal organization including, but not limited to, the Boy Scouts of America or Girl Scouts of America, a church, or Young Men's or Young Women's Christian Association. "Chaperoned, organized youth group" does not include families of members of a formal organization.

"Commission" means the natural resource commission.

"Department" means the department of natural resources.

"Fishing" means taking or attempting to take fish by utilizing hook, line and bait as described in Iowa Code section 481A.72, or use of permitted devices for taking rough fish as determined by Iowa Code sections 461A.42 and 481A.76.

"Free climbing" means climbing with the use of hands and feet only and without the use of ropes, pins and other devices normally associated with rappelling and rock climbing.

"Group camp" means those camping areas at Dolliver Memorial State Park and Lake Keomah State Park where organized groups (i.e., family groups or youth groups) may camp. Dining hall facilities are available.

"Immediate family" means spouses, parents or legal guardians, domestic partners, dependent children and grandparents.

"Lodge" means a day-use building which is enclosed on all four sides and may have kitchen facilities such as a stove or refrigerator and which is available for rent on a daily basis. "Lodge" does not include buildings that are open on two or more sides and that contain fireplaces only.

"Modern area" means a camping area which has showers and flush toilets.

"Nonmodern area" means a camping area in which no showers are provided and which contains only pit-type latrines or flush-type toilets. Potable water may or may not be available to campers.

"Open shelter" means a building which is open on two or more sides and which may or may not include a fireplace.

"Open shelter with kitchenette" means a building which is open on two or more sides and contains a lockable, enclosed kitchen area.

"Organized youth group campsite" means a designated camping area within or next to the main campground where chaperoned, organized youth groups may camp.

"Persons with disabilities parking permit" means an identification device bearing the international symbol of accessibility that is issued by the Iowa department of transportation or similar devices that are issued by other states. The device can be a hanging device or on a motor vehicle as a plate or sticker as provided in Iowa Code section 321L.2 or 321L.9.

"Person with physical disability" means any of the following: an individual, commonly termed a paraplegic or quadriplegic, with paralysis or a physical condition of the lower half of the body with the involvement of both legs, usually due to disease or injury to the spinal cord; a person who is a single or double amputee of the legs; or a person with any other physical affliction which makes it impossible to ambulate successfully in park or recreation area natural surroundings without the use of a wheeled conveyance.

"Possession" means exercising dominion or control with or without ownership over property.

"Prohibited activity" means any activity other than fishing as defined in this chapter including, but not limited to, picnicking and camping.

"Property" means personal property such as goods, money, or domestic animals.

"Recreation areas" means the following areas that have been designated by action of the commission:

Area	County
Badger Creek Recreation Area	Madison
Brushy Creek Recreation Area	Webster
Claire Wilson Park	Dickinson
Emerson Bay and Lighthouse	Dickinson
Fairport Recreation Area	Muscatine
Lower Gar Access	Dickinson
Marble Beach	Dickinson
Mines of Spain Recreation Area	Dubuque
Pleasant Creek Recreation Area	Linn
Templar Park	Dickinson
Volga River Recreation Area	Fayette
Wilson Island Recreation Area	Pottawattamie

These areas are managed for multiple uses, including public hunting, and are governed by rules established in this chapter as well as in 571—Chapters 52 and 105.

"Refuse" means trash, garbage, rubbish, waste papers, bottles or cans, debris, litter, oil, solvents, liquid or solid waste or other discarded material.

"Rental facilities" means those facilities that may be rented on a daily or nightly basis and includes open shelters, open shelters with kitchenettes, beach house open shelters, warming lodges, lodges, cabins, yurts and group camps.

"Reservation window" means a rolling period of time in which a person may reserve a campsite or rental facility.

"Scuba diving" means swimming with the aid of self-contained underwater breathing apparatus.

"State park" means the following areas managed by the state and designated by action of the commission:

Area	County
A. A. Call	Kossuth
Backbone	Delaware
Banner Lakes at Summerset	Warren
Beed's Lake	Franklin
Bellevue	Jackson
Big Creek	Polk
Black Hawk	Sac
Cedar Rock	Buchanan
Clear Lake	Cerro Gordo
Dolliver Memorial	Webster
Elinor Bedell	Dickinson
Elk Rock	Marion
Fort Atkinson	Winneshiek
Fort Defiance	Emmet
Geode	Henry and Des Moines
George Wyth	Black Hawk
Green Valley	Union
Gull Point	Dickinson
Honey Creek	Appanoose
Lacey-Keosauqua	Van Buren
Lake Ahquabi	Warren
Lake Anita	Cass
Lake Darling	Washington
Lake Keomah	Mahaska
Lake Macbride	Johnson
Lake Manawa	Pottawattamie
Lake of Three Fires	Taylor
Lake Wapello	Davis
Ledges	Boone
Lewis and Clark	Monona
Maquoketa Caves	Jackson
McIntosh Woods	Cerro Gordo
Mini-Wakan	Dickinson
Nine Eagles	Decatur
Okamanpedan	Emmet
Palisades-Kepler	Linn
Pikes Peak	Clayton
Pikes Point	Dickinson
Pilot Knob	Winnebago
Pine Lake	Hardin
Prairie Rose	Shelby
Preparation Canyon	Monona
Red Haw	Lucas
Rice Lake	Winnebago

Area	County
Rock Creek	Jasper
Shimek Forest Campground	Lee
Springbrook	Guthrie
Stephens Forest Campground	Lucas
Stone	Plymouth and Woodbury
Trapper's Bay	Dickinson
Twin Lakes	Calhoun
Union Grove	Tama
Viking Lake	Montgomery
Walnut Woods	Polk
Wapsipinicon	Jones
Waubonsie	Fremont
Wildcat Den	Muscatine
Yellow River Forest Campground	Allamakee

Use and management of these areas are governed by Iowa Code chapter 461A and by other restrictions prescribed on area signs pursuant to Iowa Code section 461A.44.

"State park managed by a management company" means the following area established by Iowa Code chapter 463C:

Area	County
Honey Creek Resort State Park	Appanoose

Use and management of this area are governed by rules established in this chapter, as well as by the indenture of trust entered into by and among the department, the treasurer of state, the Honey Creek Premiere Destination Park bond authority as established by Iowa Code chapter 463C, and Banker's Trust Corporation, dated October 1, 2006.

"State park managed by another governmental entity" means the following areas designated by action of the commission:

Area	County
Bobwhite	Wayne
Browns Lake-Bigelow Park	Woodbury
Cold Springs	Cass
Crystal Lake	Hancock
Eagle Lake	Hancock
Echo Valley	Fayette
Frank A. Gotch	Humboldt
Galland School	Lee
Heery Woods	Butler
Kearny	Palo Alto
Lake Cornelia	Wright
Lake Odessa Campground	Louisa
Margo Frankel Woods	Polk
Oak Grove	Sioux

Area	County
Pammel	Madison
Pioneer	Mitchell
Sharon Bluffs	Appanoose
Silver Lake	Delaware
Spring Lake	Greene
Swan Lake	Carroll

Use and management of these areas are governed by Iowa Code chapter 461A, by this chapter, and by rules adopted by the managing entity.

"State preserve" means the following areas or portion of the areas dedicated by actions pursuant to Iowa Code section 465C.10:

Area	County
A. F. Miller	Bremer
Ames High Prairie	Story
Anderson Prairie	Emmet
Behrens Ponds and Woodland	Linn
Berry Woods	Warren
Bird Hill	Cerro Gordo
Bixby	Clayton
Bluffton Fir Stand	Winneshiek
Brush Creek Canyon	Fayette
Brushy Creek	Webster
Cameron Woods	Scott
Casey's Paha	Tama
Catfish Creek	Dubuque
Cayler Prairie	Dickinson
Cedar Bluffs Natural Area	Mahaska
Cedar Hills Sand Prairie	Black Hawk
Cheever Lake	Emmet
Clay Prairie	Butler
Claybanks Forest	Cerro Gordo
Coldwater Cave	Winneshiek
Crossman Prairie	Howard
Decorah Ice Cave	Winneshiek
Derald Dinesen Prairie	Shelby
Doolittle Prairie	Story
Eureka Woods	Greene
Fallen Rock	Hardin
Fish Farm Mounds	Allamakee
Five Ridge Prairie	Plymouth
Fleming Woods	Poweshiek
Fort Atkinson	Winneshiek
Fossil and Prairie Park	Floyd
Freda Haffner Kettlehole	Dickinson
Gitchie Manitou	Lyon

Area	County
Glenwood	Mills
Hanging Bog	Linn
Hardin City Woodland	Hardin
Hartley Fort	Allamakee
Hartman Bluff	Black Hawk
Hayden Prairie	Howard
Hoffman Prairie	Cerro Gordo
Indian Bluffs Primitive Area	Jones
Indian Fish Trap	Iowa
Kalsow Prairie	Pocahontas
Kish-Ke-Kosh Prairie	Jasper
Lamson Woods	Jefferson
Liska-Stanek Prairie	Webster
Little Maquoketa River Mounds	Dubuque
Malanaphy Springs	Winneshiek
Malchow Mounds	Des Moines
Manikowski Prairie	Clinton
Mann Wilderness Area	Hardin
Marietta Sand Prairie	Marshall
Mericle Woods	Tama
Merrill A. Stainbrook	Johnson
Merritt Forest	Clayton
Montauk	Fayette
Mossy Glen	Clayton
Mount Pisgah Cemetery	Union
Mount Talbot	Woodbury and Plymouth
Nestor Stiles Prairie	Cherokee
Ocheyedan Mound	Osceola
Old State Quarry	Johnson
Palisades-Dows	Linn
Pecan Grove	Muscatine
Pellett Memorial Woods	Cass
Perkins Prairie	Greene
Pilot Grove	Iowa
Pilot Knob	Hancock
Retz Memorial Woods	Clayton
Roberts Creek	Clayton
Rock Creek Island	Cedar
Rock Island Botanical	Linn
Roggman Boreal Slopes	Clayton
Rolling Thunder Prairie	Warren
Savage Woods	Henry
Searryl's Cave	Jones
Sheeder Prairie	Guthrie

Area	County
Silver Lake Fen	Dickinson
Silvers-Smith Woods	Dallas
Slinde Mounds	Allamakee
St. James Lutheran Church	Winneshiek
Starr's Cave	Des Moines
Steele Prairie	Cherokee
Stinson Prairie	Kossuth
Strasser Woods	Polk
Sylvan Runkel	Monona
Toolesboro Mounds	Louisa
Turin Loess Hills	Monona
Turkey River Mounds	Clayton
Vincent Bluff	Pottawattamie
White Pine Hollow	Dubuque
Williams Prairie	Johnson
Wittrock Indian Village	O'Brien
Woodland Mounds	Warren
Woodman Hollow	Webster
Woodthrush Woods	Jefferson

Use and management of these areas are governed by rules established in this chapter as well as by management plans adopted by the preserves advisory board.

"Swim" or *"swimming"* means to propel oneself in water by natural means, such as movement of limbs, and includes but is not limited to wading and the use of inner tubes or beach toy-type swimming aids.

"Walk-in camper" means a person arriving at a campground without a reservation and wishing to occupy a first-come, first-served campsite or unrented, reservable campsite.

"Yurt" means a one-room circular fabric structure built on a platform which is available for rental on a daily or weekly basis.

[**ARC 8821B**, IAB 6/2/10, effective 7/7/10; **ARC 9541B**, IAB 6/1/11, effective 7/6/11; **ARC 0383C**, IAB 10/3/12, effective 11/7/12; **ARC 4396C**, IAB 4/10/19, effective 5/15/19]

DIVISION I
STATE PARKS AND RECREATION AREAS

571—61.3(461A) Centralized reservation system—operating procedures and policies. The centralized reservation system of the department accepts and processes reservations for camping and rental facilities in state parks, recreation areas and state forest campgrounds.

61.3(1) *Recreation facilities available on centralized reservation system.*

a. Rental facilities. All rental facilities are available on the centralized reservation system with the exception of the conservation education center rental at Springbrook State Park.

b. Campgrounds.

(1) All campgrounds are available on the centralized reservation system except for the campgrounds at A. A. Call State Park, Fort Defiance State Park and Preparation Canyon State Park and the backpack campsites located in state forests.

(2) No less than 50 percent and up to no more than 75 percent of the total number of campsites in each individual campground shall be designated as reservable sites on the reservation system. The determination of which campsites shall be included in the reservable designation shall be the responsibility of the park staff in each park. Park staff shall include a combination of electric,

nonelectric and sewer/water sites while taking into consideration campsite characteristics such as location, shade and size. The department will review the percentage of reservable sites and usage on a biennial basis and determine whether the percentage of reservable campsites should be changed. A reservable campsite will be identified with a reservable-site marker on the campsite post.

(3) All designated organized youth group campsites and campsites marked with the international symbol of accessibility are included in the reservation system.

(4) Reservations will not be accepted for camping stays that occur November 1 through March 31.

61.3(2) *Methods available to make reservations.* Persons may make reservations by telephone through the call center or through the Internet by using the reservation system website.

61.3(3) *Reservation transaction fees.* Fees to process a reservation, change a reservation or cancel a reservation shall be set contractually with the reservation system vendor and published on the department's website with the camping, rental facility and other special privilege fees set by the department pursuant to 561—Chapter 16.

61.3(4) *Reservation window.*

a. Camping. Camping reservations may be made up to 3 months before arrival but no later than 21 days before arrival if payment is made by paper check or money order and no later than 2 days before arrival if payment is made by credit card or debit card.

b. Rental facilities.

(1) Rentals for May 1 to September 30. Rental facility reservations may be made up to 12 months before arrival but not later than 21 days before arrival if payment is made by paper check or money order and no later than 4 days before arrival if payment is made by credit card or debit card.

(2) Rentals for October 1 to April 30. Rental facility reservations may be made up to 12 months before arrival but not later than 21 days before arrival if payment is made by paper check or money order and no later than 7 days before arrival if payment is made by credit card or debit card.

61.3(5) *Site-specific reservations.* All reservations shall be for a specific campsite, cabin, lodge or open shelter.

61.3(6) *Changing a reservation.* Changes to reservations shall not be made until the initial reservation has been paid in full.

a. Camping.

(1) The last day a person may make a change to a camping reservation is 4 days prior to the scheduled arrival date if payment is made by credit card or debit card or 21 days prior to the scheduled arrival date if payment is made by paper check or money order.

(2) Equestrian campers may make changes to a camping reservation less than 4 days prior to the arrival date if the equestrian trails are closed on the same day as the equestrian campers' scheduled arrival date or on the day before their scheduled arrival date.

b. Rental facilities. The last day a person may make a change to a rental facility reservation is 15 days prior to the scheduled arrival date if payment is made by credit card or debit card or 21 days prior to the scheduled arrival date if payment is made by paper check or money order.

61.3(7) *Canceling a reservation.* Persons who cancel their reservations prior to or on the scheduled arrival date shall receive a refund as follows:

a. Camping.

(1) Persons who cancel their reservations two or more days prior to the scheduled arrival date will receive a refund of all camping fees paid less the cancellation fee.

(2) Persons who cancel their reservations one day prior to the scheduled arrival date will receive a refund of all camping fees paid less the cancellation fee and forfeiture of one night's camping fee.

(3) Persons who cancel their reservations on the scheduled day of arrival will receive a refund of all camping fees paid less the cancellation fee and forfeiture of two nights' camping fees.

b. Cabins.

(1) Persons who cancel their reservations 30 or more days prior to the scheduled arrival date will receive a refund of all rental fees and tax paid less the cancellation fee.

(2) Persons who cancel their reservations 15 to 29 days prior to the scheduled arrival date will receive a refund of all rental fees and tax paid less the cancellation fee and forfeiture of one night's rental fee and tax.

(3) Persons who cancel their reservations less than 15 days prior to the scheduled arrival date or on the scheduled arrival date will receive a refund of all rental fees and tax paid less the cancellation fee and forfeiture of two nights' rental fees and tax.

c. *Lodges, open shelters, open shelters with kitchenettes, and beach house open shelters.*

(1) Persons who cancel their reservations 30 or more days prior to the scheduled arrival date will receive a refund of all rental fees and tax paid less the cancellation fee.

(2) Persons who cancel their reservations 15 to 29 days prior to the scheduled arrival date will receive a refund of all rental fees and tax paid less the cancellation fee and forfeiture of one day's rental fee and tax.

(3) Persons who cancel their reservations less than 15 days prior to the scheduled arrival date or on the scheduled arrival date will receive a refund of all rental fees and tax paid less the cancellation fee and forfeiture of two days' rental fees and tax, if applicable.

d. *Cancellation after scheduled arrival date.* Persons who cancel any reservation after the scheduled arrival date will receive no refund unless extenuating circumstances have been documented, reviewed, and approved in writing by the department.

e. *Cancellation fees exceeding camping or rental fees.* When the cancellation fee and forfeiture of camping fees or rental fees and tax exceed the total amount of camping fees or rental fees and tax paid, no refund will be issued.

[**ARC 9324B**, IAB 1/12/11, effective 2/16/11; **ARC 0383C**, IAB 10/3/12, effective 11/7/12; **ARC 4396C**, IAB 4/10/19, effective 5/15/19]

571—61.4(461A) Camping.

61.4(1) *Fees.* Camping fees shall be set by the department pursuant to 561—Chapter 16.

61.4(2) *Varying fees.* Rescinded IAB 4/10/19, effective 5/15/19.

61.4(3) *Procedures for camping registration.*

a. *Registration.*

(1) Registration of walk-in campers occupying nonreservable campsites or unrented, reservable campsites will be on a first-come, first-served basis and will be handled by a self-registration process. Registration forms will be provided by the department. Campers shall, within one-half hour of arrival at the campground, complete the registration form, place the appropriate fee or number of camping tickets in the envelope and place the envelope in the depository provided by the department. One copy of the registration form must then be placed in the campsite holder provided at the campsite. The camping length of stay identified on the camping registration form must begin with the actual date the camper registers, pays and posts the registration at the campsite.

(2) Park staff shall complete the registration of campers with reservations and place the registration in the campsite holder no later than one hour prior to check-in time on the day of the camper's arrival.

b. Campsites are considered occupied and registration for a campsite shall be considered complete when the requirements of 61.4(3)*"a"* have been met.

c. Campsite registration must be in the name of a person 18 years of age or older who will occupy the camping unit on that site for the full term of the registration.

d. Each camping ticket shall cover the cost of one night of camping in a modern area on a site where electricity is furnished. In addition to using the camping ticket, persons camping on equestrian sites or on sites which also have sewer and water hookups or cable television hookups available must pay the additional charges for these services. Use of a camping ticket in an area or on a site which would require a lesser fee than an electrical site in a modern area will not entitle the user to a refund or credit of any kind.

61.4(4) *Organized youth group campsite registration.*

a. Registration procedures for organized youth group campsites shall be governed by paragraphs *"a," "b"* and *"c"* of 61.4(3).

b. Chaperoned, organized youth groups may choose to occupy campsites not designated as organized youth group campsites. However, the group is subject to rules in 61.4(1), 61.4(3) and 61.4(5) pertaining to the campsite the group wishes to occupy, as well as all fees as set by the department pursuant to 561—Chapter 16.

61.4(5) *Restrictions on campsite/campground use.* This subrule sets forth conditions of public use which apply to all state parks and recreation areas. Specific areas as listed in 61.4(6), 571—61.7(461A) and 571—61.10(461A) are subject to additional restrictions or exceptions. The conditions in this subrule are in addition to specific conditions and restrictions set forth in Iowa Code chapter 461A.

a. Camping is restricted to designated camping areas within state parks and recreation areas and state forest campgrounds.

b. No more than six persons shall occupy a campsite except for the following:

(1) Families that exceed six persons may be allowed on one campsite if all members are immediate family and cannot logically be split to occupy two campsites.

(2) Campsites which are designated as chaperoned, organized youth group campsites.

c. Camping is restricted to one basic unit per site except that a small tent may be placed on a site with the basic unit. The area occupied by the small tent shall be no more than 8 feet by 10 feet and the tent shall hold no more than four people.

d. Each camping group shall utilize only the electrical outlet fixture designated for its particular campsite. No extension cords or other means of hookup shall be used to furnish electricity from one designated campsite to another.

e. Each camping group will be permitted to park one motor vehicle not being used for camping purposes at the campsite. Unless otherwise posted, one additional vehicle may be parked at the campsite.

f. All motor vehicles, excluding motorcycles, not covered by the provision in 61.4(5)*"e"* shall be parked in designated extra-vehicle parking areas.

g. Walk-in campers occupying nonreservable campsites or unrented, reservable campsites shall register as provided in subrule 61.4(3) within one-half hour of entering the campground.

h. Campers occupying nonreservable campsites shall vacate the campground or register for the night prior to 4 p.m. daily. Registration can be for more than 1 night at a time but not for more than 14 consecutive nights for nonreservable campsites. All members of the camping party must vacate the state park or recreation area campground after the fourteenth night and may not return to the state park or recreation area until a minimum of 3 nights has passed. All equipment must be removed from the site at the end of each stay. The 14-night limitation shall not apply to volunteers working under a department program.

i. Walk-in campers shall not occupy unrented, reservable campsites until 10 a.m. on the first camping day of their stay. Campers shall vacate the campground by 3 p.m. of the last day of their stay. Initial registration shall not exceed 2 nights. Campers may continue to register after the first 2 nights on a night-to-night basis up to a maximum of 14 consecutive nights, subject to campsite availability. All members of the camping party must vacate the state park or recreation area campground after the fourteenth night and may not return to the state park or recreation area until a minimum of 3 nights has passed. All equipment must be removed from the site at the end of each stay. The 14-night limitation shall not apply to volunteers working under a department program.

j. Campers with reservations shall not occupy a campsite before 4 p.m. of the first day of their stay. Campers shall vacate the site by 3 p.m. of the last day of their stay. Campers may register for more than 1 night at a time but not for more than 14 consecutive nights. All members of the camping party must vacate the state park or recreation area campground after the fourteenth night and may not return to the state park or recreation area until a minimum of 3 nights has passed. All equipment must be removed from the site at the end of each stay. The 14-night limitation shall not apply to volunteers working under a department program.

k. Minimum stay requirements for camping reservations. From May 1 to September 30, a two-night minimum stay is required for weekends. The two nights shall be designated as Friday and Saturday nights. However, if September 30 is a Friday, the Friday and Saturday night stay shall not

apply. If September 30 is a Saturday, the Friday and Saturday night stay shall apply. The following additional exceptions apply:

(1) A Friday, Saturday, and Sunday night stay is required for the national Memorial Day holiday and national Labor Day holiday weekends.

(2) A Thursday, Friday, and Saturday night stay is required for the Fourth of July holiday if the Fourth of July occurs on a Thursday, Friday or Saturday.

(3) A Friday, Saturday, and Sunday night stay is required for the Fourth of July holiday if the Fourth of July occurs on a Monday.

l. Buddy campsite reservations. Buddy campsites are between two to four individual sites that are grouped together and can only be reserved and used collectively. Campers reserving buddy campsites through the centralized reservation system must reserve both or all four of the individual sites that make up the group buddy campsite or buddy campsite.

m. Campsites marked with the international symbol of accessibility shall be used only by vehicles displaying a persons with disabilities parking permit. The vehicle must be in use by a person with a disability, either as an operator or a passenger.

n. In designated campgrounds, equine animals and llamas must be stabled at a hitching rail, individual stall or corral if provided. Equine animals and llamas may be hitched to trailers for short periods of time to allow for grooming and saddling. These animals may be stabled inside trailers if no hitching facilities are provided. Portable stalls/pens and electric fences are not permitted.

61.4(6) *Area-specific restrictions on campground use.* In addition to the general conditions of public use set forth in this chapter, special conditions shall apply to specific areas listed as follows:

a. Brushy Creek Recreation Area, Webster County.

(1) In the designated equestrian campgrounds, the maximum number of equine animals to be tied to the hitching rails is six. Persons with a number of equine animals in excess of the number permitted on the hitching rail at their campsite shall be allowed to stable their additional animals in a trailer or register and pay for an additional campsite if available.

(2) In the designated equestrian campgrounds, equine animals may be tied to trailers for short periods of time to allow grooming or saddling; however, the tying of equine animals to the exterior of trailers for extended periods of time or for stabling is not permitted.

b. Recreation area campgrounds. Access into and out of designated campgrounds shall be permitted from 4 a.m. to 10:30 p.m. From 10:30 p.m. to 4 a.m., only registered campers are permitted in and out of the campgrounds.

c. Lake Manawa State Park, Pottawattamie County. Except for the following limitations on campground length of stay, campsite use restrictions as stated in 61.4(5) shall apply to Lake Manawa. Campers may register for more than 1 night at a time but not for more than 14 consecutive nights. No person may camp at the Lake Manawa campground for more than 14 nights in any 30-day period.

d. Walnut Woods State Park, Polk County. Except for the following limitations on campground length of stay, campsite use restrictions as stated in 61.4(5) shall apply to Walnut Woods. Campers may register for more than 1 night at a time but not for more than 14 consecutive nights. No person may camp at the Walnut Woods campground for more than 14 nights in any 30-day period.

61.4(7) *Campground fishing.* Rule 571—61.11(461A) is not intended to prohibit fishing by registered campers who fish from the shoreline within the camping area.

[**ARC 7684B**, IAB 4/8/09, effective 5/13/09; **ARC 8821B**, IAB 6/2/10, effective 7/7/10; **ARC 0383C**, IAB 10/3/12, effective 11/7/12; **ARC 4396C**, IAB 4/10/19, effective 5/15/19]

571—61.5(461A) Rental facilities.

61.5(1) *Rental facility fees.* Rental facility fees shall be set by the department pursuant to 561—Chapter 16.

61.5(2) *Varying fees.* Rescinded IAB 4/10/19, effective 5/15/19.

61.5(3) *Procedures for rental facility registration and rentals.*

a. Registrations for all rental facilities must be in the name of a person 18 years of age or older who will be present at the facility for the full term of the reservation.

b. Rental stay requirements for cabins and yurts.

(1) Except as provided in subparagraphs 61.5(3)*"b"*(2) and 61.5(3)*"b"*(3), cabin reservations must be for a minimum of one week (Friday p.m. to Friday a.m.) beginning the Friday of the national Memorial Day holiday weekend through Thursday after the national Labor Day holiday. From the Friday after the national Labor Day holiday through the Thursday before the national Memorial Day holiday weekend, cabins may be reserved for a minimum of two nights.

(2) The cabins at Dolliver Memorial State Park; the camping cabins at Pleasant Creek and Wilson Island State Recreation Areas and Green Valley, Honey Creek, Lake Darling and Stone State Parks; the yurts at McIntosh Woods State Park; and the group camps at Dolliver Memorial and Lake Keomah State Parks may be reserved for a minimum of two nights throughout the entire rental season.

(3) The multifamily cabin at Springbrook State Park may be reserved for a minimum of two nights throughout the entire rental season with the following exceptions:

1. A Friday, Saturday, and Sunday night stay is required for the national Memorial Day holiday and national Labor Day holiday weekends.

2. A Thursday, Friday, and Saturday night stay is required for the Fourth of July holiday if the Fourth of July occurs on a Thursday, Friday, or Saturday.

3. A Friday, Saturday, and Sunday night stay is required for the Fourth of July holiday if the Fourth of July occurs on a Monday.

(4) All unreserved cabins, yurts and group camps may be rented for a minimum of two nights on a walk-in, first-come, first-served basis. No walk-in rentals will be permitted after 6 p.m.

(5) Reservations or walk-in rentals for more than a two-week stay will not be accepted for any facility.

c. Persons renting cabins, yurts or group camp facilities must check in at or after 4 p.m. on Saturday. Check-out time is 11 a.m. or earlier on Saturday.

d. Persons renting facilities listed in subparagraph 61.5(3)*"b"*(2) must check in at or after 4 p.m. on the first day of the two-night rental period. Check-out time is 11 a.m. or earlier on the last day of the two-night rental period.

e. Except by arrangement for late arrival with the park staff, no cabin, yurt or group camp reservation will be held past 6 p.m. on the first night of the reservation period if the person reserving the facility does not arrive. When arrangements for late arrival have been made, the person must appear prior to the park's closing time established by Iowa Code section 461A.46 or access will not be permitted to the facility until 8 a.m. the following day. Arrangements must be made with the park staff if next-day arrival is to be later than 9 a.m.

f. The number of persons occupying rental cabins is limited to six in cabins which contain one bedroom or less and eight in cabins with two bedrooms. Occupancy of the studio cabins at Pine Lake and all camping cabins is limited to four persons. Occupancy of the yurts is limited to four persons.

g. Except at parks or recreation areas with camping cabins or yurts, no tents or other camping units are permitted for overnight occupancy in the designated cabin area. One small tent shall be allowed at each cabin or yurt in the designated areas and is subject to the occupancy requirements of 61.4(5)*"b."*

h. Open shelters and beach house open shelters which are not reserved are available on a first-come, first-served basis. If the open shelters with kitchenettes are not reserved, the open shelter portions of these facilities are available on a first-come, first-served basis.

i. Except by arrangement with the park staff in charge of the area, persons renting a lodge, shelter, or beach house open shelter facility and all guests shall vacate the facility by 10 p.m.

61.5(4) *Damage deposits for cabins, lodges, open shelters with kitchenettes, and yurts.*

a. Upon arrival for the rental facility period, renters shall pay in full a damage deposit in an amount equal to the weekend daily rental fee for the facility or $50, whichever is greater. If a gathering with keg beer takes place in a lodge or open shelter with kitchenette, the damage deposit shall be waived in lieu of a keg damage deposit as specified in 571—subrule 63.5(3) if the keg damage deposit is greater than the lodge or open shelter with kitchenette damage deposit.

b. Damage deposits will be refunded only after authorized personnel inspect the rental facility to ensure that the facility and furnishings are in satisfactory condition.

c. If it is necessary for department personnel to clean up the facility or repair any damage beyond ordinary wear and tear, a log of the time spent in such cleanup or repair shall be kept. The damage deposit refund shall be reduced by an amount equivalent to the applicable hourly wage of the employees for the time necessary to clean the area or repair the damage and by the cost of any repairs of furnishings.

d. The deposit is not to be construed as a limit of liability for damage to state property. The department may take legal action necessary to recover additional damages.

[**ARC 7684B**, IAB 4/8/09, effective 5/13/09; **ARC 9186B**, IAB 11/3/10, effective 12/8/10; **ARC 0383C**, IAB 10/3/12, effective 11/7/12; **ARC 2052C**, IAB 7/8/15, effective 9/15/15; **ARC 4396C**, IAB 4/10/19, effective 5/15/19]

571—61.6(461A) Vessel storage fees. Vessel storage fees shall be set by the department pursuant to 561—Chapter 16.

This rule is intended to implement Iowa Code section 455A.14.

[**ARC 4396C**, IAB 4/10/19, effective 5/15/19]

571—61.7(461A) Restrictions—area and use. This rule sets forth conditions of public use which apply to all state parks and recreation areas. Specific areas as listed in 61.4(6), 571—61.8(461A) and 571—61.11(461A) are subject to additional restrictions or exceptions. The conditions in this rule are in addition to specific conditions and restrictions set forth in Iowa Code chapter 461A.

61.7(1) *Animals.*

a. The use of equine animals and llamas is limited to roadways or to trails designated for such use.

b. Animals are prohibited within designated beach areas.

c. Livestock are not permitted to graze or roam within state parks and recreation areas. The owner of the livestock shall remove the livestock immediately upon notification by department personnel in charge of the area.

d. Animals are prohibited in all park buildings, with the following exceptions:

(1) Service dogs and assistive animals.

(2) Dogs in designated cabins and yurts. A maximum of two dogs of any size shall be allowed in any designated cabin or yurt.

(3) Animals being used in education and interpretation programs.

e. Except for dogs being used in designated hunting or in dog training areas, pets such as dogs or cats shall not be allowed to run at large within state parks, recreation areas, or preserves. Such animals shall be on a leash or chain not to exceed six feet in length and shall be either led by or carried by the owner; attached to an anchor/tie-out or vehicle; or confined in a vehicle. Pets shall not be left unattended in campgrounds. Dogs shall be kenneled when left unattended in a cabin or yurt and shall not be left unattended if tied up outside of the cabin or yurt.

61.7(2) *Beach use/swimming.*

a. Except as provided in paragraphs *"b"* and *"c"* of this subrule, all swimming and scuba diving shall take place in the beach area within the boundaries marked by ropes, buoys, or signs within state parks and recreation areas. Inner tubes, air mattresses and other beach-type items shall be used only in designated beach areas.

b. Persons may scuba dive in areas other than the designated beach area provided they display the diver's flag as specified in rule 571—41.10(462A).

c. Swimming outside beach area.

(1) Persons may swim outside the beach area under the following conditions:

1. Swimming must take place between sunrise and sunset;

2. The swimmer must be accompanied by a person operating a vessel and must stay within 20 feet of the vessel at all times during the swim;

3. The vessel accompanying the swimmer must display a flag, which is at least 12-inches square, is bright orange, and is visible all around the horizon; and

4. The person swimming pursuant to this subparagraph must register with the park staff in charge of the area and sign a registration immediately prior to the swim.

(2) Unless swimming is otherwise posted as prohibited or limited to the designated beach area, a person may also swim outside the beach area provided that the person swims within ten feet of a vessel

which is anchored not less than 100 yards from the shoreline or the marked boundary of a designated beach. Any vessel, except one being uprighted, must be attended at all times by at least one person remaining on board.

(3) A passenger on a sailboat or other vessel may enter the water to upright or repair the vessel and must remain within ten feet of that vessel.

d. The provisions of paragraph *"a"* of this subrule shall not be construed as prohibiting wading in areas other than the beach by persons actively engaged in shoreline fishing.

e. Alcoholic liquor, beer, and wine, as each is defined in Iowa Code section 123.3, are prohibited on the beaches located within Lake Macbride State Park and Pleasant Creek State Recreation Area. This ban does not apply to rental facilities located within the 200-foot buffer of land surrounding the sand or fenced-in area that have been officially reserved through the department.

61.7(3) *Bottles.* Possession or use of breakable containers, the fragmented parts of which can injure a person, is prohibited in beach areas of state parks and recreation areas.

61.7(4) *Chainsaws.* Except by written permission of the director of the department, chainsaw use is prohibited in state parks and recreation areas. This provision is not applicable to employees of the department in the performance of their official duties.

61.7(5) *Firearms.* The use of firearms in state parks and recreation areas as defined in rule 571—61.2(461A) is limited to the following:

a. Lawful hunting as traditionally allowed at Badger Creek Recreation Area, Brushy Creek Recreation Area, Pleasant Creek Recreation Area, Mines of Spain Recreation Area (pursuant to rule 571—61.9(461A)), Volga River Recreation Area and Wilson Island Recreation Area.

b. Target and practice shooting in areas designated by the department.

c. Special events, festivals, and education programs sponsored or permitted by the department.

d. Special hunts authorized by the commission to control deer populations.

61.7(6) *Fishing off boat docks within state areas.* Persons may fish off all state-owned docks within state parks and recreation areas. Persons fishing off these docks must yield to boats and not interfere with boaters.

61.7(7) *Garbage.* Using government refuse receptacles for dumping household, commercial, or industrial refuse brought as such from private property is prohibited.

61.7(8) *Motor vehicle restrictions.*

a. Except as provided in these rules, motor vehicles are prohibited on state parks, recreation areas and preserves except on constructed and designated roads, parking lots and campgrounds.

b. Use of motorized vehicles by persons with physical disabilities. Persons with physical disabilities may use certain motorized vehicles to access specific areas in state parks, recreation areas and preserves, according to restrictions set out in this paragraph, in order to enjoy the same recreational opportunities available to others. Allowable vehicles include any self-propelled electric or gas vehicle which has at least three wheels, but no more than six wheels, and is limited in engine displacement to less than 800 cubic centimeters and in total dry weight to less than 1,450 pounds.

(1) Permits.

1. Each person with a physical disability must have a permit issued by the director in order to use a motorized vehicle in specific areas within state parks, recreation areas, and preserves. Such permits will be issued without charge. One nonhandicapped companion may accompany the permit holder on the same vehicle if that vehicle is designed for more than one rider; otherwise the companion must walk.

2. Existing permits. Those persons possessing a valid permit for use of a motorized vehicle on game management areas as provided in 571—51.7(461A) may use a motorized vehicle to gain access to specific areas for recreational opportunities and facilities within state parks, recreation areas and preserves.

(2) Approved areas. On each visit, the permit holder must contact the park staff in charge of the specific area in which the permit holder wishes to use a motorized vehicle. The park staff must designate on a park map the area(s) where the permit holder will be allowed to use a motorized vehicle. This restriction is intended to protect the permit holder from hazards or to protect certain natural resources. The map is to be signed and dated on each visit by the park staff in charge of the area. Approval for use

of a motorized vehicle on state preserves also requires consultation with a member of the preserves staff in Des Moines.

(3) Exclusive use. The issuance of a permit does not imply that the permittee has exclusive or indiscriminate use of an area. Permittees shall take reasonable care not to unduly interfere with the use of the area by others.

(4) Prohibited acts and restrictions.

1. Except as provided in 61.7(8)*"b,"* the use of a motorized vehicle on any park, recreation area or preserve by a person without a valid permit or at any site not approved on a signed map is prohibited. Permits and maps shall be carried by the permittee at any time the permittee is using a motorized vehicle in a park, recreation area or preserve and shall be exhibited to any department employee or law enforcement official upon request.

2. The speed limit for an approved motor vehicle off-road will be no more than 5 mph. The permit of a person who is found exceeding the speed limit will be revoked.

3. The permit of any person who is found causing damage to cultural and natural features or abusing the privilege of riding off-road within the park will be revoked.

(5) Employees exempt. Restrictions in subrule 61.7(8) shall not apply to department personnel, law enforcement officials, or other authorized persons engaged in research, management or enforcement when in performance of their duties.

61.7(9) *Noise.* Creating or sustaining any unreasonable noise in any portion of any state park or recreation area is prohibited at all times. The nature and purpose of a person's conduct, the impact on other area users, the time of day, location, and other factors which would govern the conduct of a reasonable, prudent person under the circumstances shall be used to determine whether the noise is unreasonable. Unreasonable noise includes, but is not necessarily limited to, the operation or utilization of motorized equipment or machinery such as an electric generator, motor vehicle, or motorized toy; or audio device such as a radio, television set, public address system, or musical instrument. Between the hours of 10:30 p.m. and 6 a.m., noise which can be heard at a distance of 120 feet or three campsites shall be considered unreasonable.

61.7(10) *Opening and closing times.* Except by arrangement or permission granted by the director or the director's authorized representative or as otherwise stated in this chapter, the following restrictions shall apply: All persons shall vacate all state parks and preserves before 10:30 p.m. each day, except authorized campers in accordance with Iowa Code section 461A.46, and no person or persons shall enter into such parks and preserves until 4 a.m. the following day.

61.7(11) *Paintball guns.* The use of any item generally referred to as a paintball gun is prohibited in state parks, recreation areas and preserves.

61.7(12) *Restrictions on picnic site use.*

a. Open picnic sites marked with the international symbol of accessibility shall be used only by a person or group with a person qualifying for and displaying a persons with disabilities parking permit on the person's vehicle.

b. Paragraph 61.7(12)*"a"* does not apply to picnic shelters marked with the international accessibility symbol. The use of the symbol on shelters shall serve only as an indication that the shelter is wheelchair accessible.

61.7(13) *Rock climbing or rappelling.* The rock climbing practice known as free climbing and climbing or rappelling activities which utilize bolts, pitons, or similar permanent anchoring equipment or ropes, harnesses, or slings are prohibited in state parks and recreation areas, except by persons or groups registered with the park staff in charge of the area. Individual members of a group must each sign a registration. Climbing or rappelling will not be permitted at Elk Rock State Park, Marion County; Ledges State Park, Boone County; Dolliver Memorial State Park, Webster County; Stone State Park, Woodbury and Plymouth Counties; Maquoketa Caves State Park, Jackson County; Wildcat Den State Park, Muscatine County; or Mines of Spain Recreation Area, Dubuque County. Other sites may be closed to climbing or rappelling if environmental damage or safety problems occur or if an endangered or threatened species is present.

61.7(14) *Speech or conduct interfering with lawful use of an area by others.*

a. Speech commonly perceived as offensive or abusive is prohibited when such speech interferes with lawful use and enjoyment of the area by another member of the public.

b. Quarreling or fighting is prohibited when it interferes with the lawful use and enjoyment of the area by another member of the public.

61.7(15) *Deer population control hunts.* Deer hunting as allowed under Iowa Code section 461A.42(1)*"c"* is permitted only during special hunts in state parks as provided under 571—Chapter 105 and as approved by the commission. During the dates of special hunts, only persons engaged in deer hunting shall use the area or portions thereof as designated by the department and signed as such.

61.7(16) *Special event permits.* Rescinded IAB 6/1/11, effective 7/6/11.

[**ARC 7683B**, IAB 4/8/09, effective 5/13/09; **ARC 9541B**, IAB 6/1/11, effective 7/6/11; **ARC 0383C**, IAB 10/3/12, effective 11/7/12; **ARC 2694C**, IAB 8/31/16, effective 10/5/16; see Delay note at end of chapter]

571—61.8(461A) Certain conditions of public use applicable to specific parks and recreation areas. In addition to the general conditions of public use set forth in this chapter, special conditions shall apply to the specific areas listed as follows:

61.8(1) *Brushy Creek State Recreation Area, Webster County.* Swimming is limited by the provisions of 61.7(2); also, swimming is prohibited at the beach from 10:30 p.m. to 6 a.m. daily.

61.8(2) *Hattie Elston Access and Claire Wilson Park, Dickinson County.*

a. Parking of vehicles overnight on these areas is prohibited unless the vehicle operator and occupants are actively involved in boating or are fishing as allowed under 571—61.11(461A).

b. Overnight camping is prohibited.

61.8(3) *Mines of Spain Recreation Area, Dubuque County.* All persons shall vacate all portions of the Mines of Spain Recreation Area prior to 10:30 p.m. each day, and no person or persons shall enter into the area until 4 a.m. the following day.

61.8(4) *Pleasant Creek Recreation Area, Linn County.* Swimming is limited by the provisions of 61.7(2); also, swimming is prohibited at the beach from 10:30 p.m. to 6 a.m. daily. Access into and out of the north portion of the area between the east end of the dam to the campground shall be closed from 10:30 p.m. to 4 a.m., except that walk-in overnight fishing will be allowed along the dam. The areas known as the dog trial area and the equestrian area shall be closed from 10:30 p.m. to 4 a.m., except for equestrian camping and for those persons participating in a department-authorized field trial. From 10:30 p.m. to 4 a.m., only registered campers are permitted in the campground.

61.8(5) *Wapsipinicon State Park, Jones County.* The land adjacent to the park on the southeast corner and generally referred to as the "Ohler property" is closed to the public from 10:30 p.m. to 4 a.m.

[**ARC 0383C**, IAB 10/3/12, effective 11/7/12]

571—61.9(461A) Mines of Spain hunting, trapping and firearms use.

61.9(1) The following described portions of the Mines of Spain Recreation Area are established and will be posted as wildlife refuges:

a. That portion within the city limits of the city of Dubuque located west of U.S. Highway 61 and north of Mar Jo Hills Road.

b. The tract leased by the department from the city of Dubuque upon which the E. B. Lyons Interpretive Center is located.

c. That portion located south of the north line of Section 8, Township 88 North, Range 3 East of the 5th P.M. between the west property boundary and the east line of said Section 8.

d. That portion located north of Catfish Creek, east of the Mines of Spain Road and south of the railroad tracks. This portion contains the Julien Dubuque Monument.

61.9(2) Trapping and archery hunting for all legal species are permitted in compliance with all open-season, license and possession limits on the Mines of Spain Recreation Area except in those areas designated as refuges by 61.9(1).

61.9(3) Firearms use is prohibited in the following described areas:

a. The areas described in 61.9(1).

b. The area north and west of Catfish Creek and west of Granger Creek.

61.9(4) Deer hunting and hunting for all other species are permitted using shotguns only and are permitted only during the regular gun season as established by 571—Chapter 106. Areas not described in 61.9(3) are open for hunting. Hunting shall be in compliance with all other regulations.

61.9(5) Turkey hunting with shotguns is allowed only in compliance with the following regulations:

a. Only during the first shotgun hunting season established in 571—Chapter 98, which is typically four days in mid-April.

b. Only in that area of the Mines of Spain Recreation Area located east of the established roadway and south of the Horseshoe Bluff Quarry.

61.9(6) The use or possession of a handgun or any type of rifle is prohibited on the entire Mines of Spain Recreation Area except as provided in 61.9(4). Target and practice shooting with any type of firearm is prohibited.

61.9(7) All forms of hunting, trapping and firearms use not specifically permitted by 571—61.9(461A) are prohibited in the Mines of Spain Recreation Area.

[**ARC 0383C**, IAB 10/3/12, effective 11/7/12]

571—61.10(461A) After-hours fishing—exception to closing time. Persons shall be allowed access to the areas designated in rule 571—61.11(461A) between the hours of 10:30 p.m. and 4 a.m. under the following conditions:

1. The person shall be actively engaged in fishing.
2. The person shall behave in a quiet, courteous manner so as not to disturb other users of the park.
3. Access to the fishing site from the parking area shall be by the shortest and most direct trail or access facility.
4. Vehicle parking shall be in the lots designated by signs posted in the area.
5. Activities other than fishing are allowed with permission of the director or an employee designated by the director.

[**ARC 0383C**, IAB 10/3/12, effective 11/7/12]

571—61.11(461A) Designated areas for after-hours fishing. These areas are open from 10:30 p.m. to 4 a.m. for fishing only. The areas are described as follows:

61.11(1) *Black Hawk Lake, Sac County.* The area of the state park between the road and the lake running from the marina at Drillings Point on the northeast end of the lake approximately three-fourths of a mile in a southwesterly direction to a point where the park boundary decreases to include only the roadway.

61.11(2) *Claire Wilson Park, Dickinson County.* The entire area including the parking lot, shoreline and fishing trestle facility.

61.11(3) *Clear Lake State Park, Ritz Unit, Cerro Gordo County.* The boat ramp, courtesy dock, fishing dock and parking lots.

61.11(4) *Elinor Bedell State Park, Dickinson County.* The entire length of the shoreline within state park boundaries.

61.11(5) *Elk Rock State Park, Marion County.* The Teeter Creek boat ramp area just east of State Highway 14, access to which is the first road to the left after the entrance to the park.

61.11(6) *Green Valley State Park, Union County.* The shoreline adjacent to Green Valley Road commencing at the intersection of Green Valley Road and 130th Street and continuing south along the shoreline to the parking lot on the east side of the dam, and then west along the dam embankment to the shoreline adjacent to the parking lot on the west side of the spillway.

61.11(7) *Hattie Elston Access, Dickinson County.* The entire area including the parking lot shoreline and boat ramp facilities.

61.11(8) *Honey Creek State Park, Appanoose County.* The boat ramp area located north of the park office, access to which is the first road to the left after the entrance to the park.

61.11(9) *Geode State Park, Des Moines County portion.* The area of the dam embankment that is parallel to County Road J20 and lies between the two parking lots located on each end of the embankment.

61.11(10) *Lake Keomah State Park, Mahaska County.*

a. The embankment of the dam between the crest of the dam and the lake.

b. The shoreline between the road and the lake from the south boat launch area west and north to the junction with the road leading to the group camp shelter.

61.11(11) *Lake Macbride State Park, Johnson County.* The shoreline of the south arm of the lake adjacent to the county road commencing at the "T" intersection of the roads at the north end of the north-south causeway proceeding across the causeway thence southeasterly along a foot trail to the east-west causeway, across the causeway to the parking area on the east end of that causeway.

61.11(12) *Lake Manawa State Park, Pottawattamie County.* The west shoreline including both sides of the main park road, commencing at the north park entrance and continuing south 1.5 miles to the parking lot immediately north of the picnic area located on the west side of the southwest arm of the lake.

61.11(13) *Lower Pine Lake, Hardin County.* West shoreline along Hardin County Road S56 from the beach southerly to the boat ramp access.

61.11(14) *Mini-Wakan State Park, Dickinson County.* The entire area.

61.11(15) *North Twin Lake State Park, Calhoun County.* The shoreline of the large day-use area containing the swimming beach on the east shore of the lake.

61.11(16) *Pikes Point State Park, Dickinson County.* The shoreline areas of Pikes Point State Park on the east side of West Okoboji Lake.

61.11(17) *Prairie Rose State Park, Shelby County.* The west side of the embankment of the causeway across the southeast arm of the lake including the shoreline west of the parking area located off County Road M47 and just north of the entrance leading to the park office.

61.11(18) *Rock Creek Lake, Jasper County.* Both sides of the County Road F27 causeway across the main north portion of the lake.

61.11(19) *Union Grove State Park, Tama County.*

a. The dam embankment from the spillway to the west end of the parking lot adjacent to the dam.

b. The area of state park that parallels BB Avenue, from the causeway on the north end of the lake southerly to a point approximately one-tenth of a mile southwest of the boat ramp.

61.11(20) *Upper Pine Lake, Hardin County.* Southwest shoreline extending from the boat launch ramp to the dam.

61.11(21) *Viking Lake State Park, Montgomery County.* The embankment of the dam from the parking area located southeast of the dam area northwesterly across the dam structure to its intersection with the natural shoreline of the lake.

[**ARC 9186B**, IAB 11/3/10, effective 12/8/10]

571—61.12(461A) Vessels prohibited. Rule 571—61.11(461A) does not permit the use of vessels on the artificial lakes within state parks after the 10:30 p.m. park closing time. All fishing is to be done from the bank or shoreline of the permitted area.

571—61.13(461A) Severability. Should any rule, subrule, paragraph, phrase, sentence or clause of this chapter be declared invalid or unconstitutional for any reason, the remainder of this chapter shall not be affected thereby.

571—61.14(461A) Restore the outdoors program. Funding provided through the appropriation set forth in Iowa Code section 461A.3A, and subsequent Acts, shall be used to renovate, replace or construct new vertical infrastructure and associated appurtenances in state parks and other public facilities managed by the department.

The intended projects will be included in the department's annual five-year capital plan in priority order by year and approved by the commission for inclusion in its capital budget request.

The funds appropriated by Iowa Code section 461A.3A, and subsequent Acts, will be used to renovate, replace or construct new vertical infrastructure through construction contracts, agreements with local government entities responsible for managing state parks and other public facilities, and agreements with the department of corrections to use offender labor where possible. Funds shall also be used to support site survey, design and construction contract management through consulting

engineering and architectural firms and for direct survey, design and construction management costs incurred by department engineering and architectural staff for restore the outdoors projects. Funds shall not be used to support general department oversight of the restore the outdoors program, such as accounting, general administration or long-range planning.
[**ARC 0383C**, IAB 10/3/12, effective 11/7/12]

571—61.15(461A,463C) Honey Creek Resort State Park. This chapter shall not apply to Honey Creek Resort State Park, with the exception that subrules 61.7(3) through 61.7(9) and 61.7(11) through 61.7(15) shall apply to the operation and management of Honey Creek Resort State Park. Where permission is required to be obtained from the department, an authorized representative of the department's management company may provide such permission in accordance with policies established by the department.
[**ARC 0383C**, IAB 10/3/12, effective 11/7/12; **ARC 2052C**, IAB 7/8/15, effective 9/15/15]

571—61.16 to **61.19** Reserved.

DIVISION II
STATE FOREST CAMPING

571—61.20(461A) Camping areas established and marked.

61.20(1) Areas to be utilized for camping shall be established within each of the state forests listed in rule 571—61.1(461A).

61.20(2) Signs designating the established camping areas shall be posted along the access roads into these areas and around the perimeter of the area designated for camping use.

61.20(3) Areas approved for backpack camping (no vehicular access) shall be marked with appropriate signs and shall contain fire rings.
[**ARC 0383C**, IAB 10/3/12, effective 11/7/12]

571—61.21(461A) Campground reservations. Procedures and policies regarding camping reservations in established state forest campgrounds shall be the same as those cited in rule 571—61.3(461A). Reservations will not be accepted for backpack campsites.
[**ARC 0383C**, IAB 10/3/12, effective 11/7/12]

571—61.22(461A) Camping fees and registration.

61.22(1) *Fees.*

a. Backpack campsites. No fee will be charged for the use of the designated backpack campsites.

b. The fees for camping in established state forest campgrounds shall be set by the department pursuant to 561—Chapter 16.

61.22(2) *Procedures for camping registration.*

a. Backpack campsites. Persons using backpack campsites shall register at the forest area check station or other designated site.

b. The procedures for camping registration in established state forest campgrounds shall be the same as those cited in paragraphs 61.4(3)*"a," "b,"* and *"c."*

c. Organized youth group campsites. The procedures for camping registration for organized youth group campsites shall be the same as those cited in subrule 61.4(4).
[**ARC 0383C**, IAB 10/3/12, effective 11/7/12; **ARC 4396C**, IAB 4/10/19, effective 5/15/19]

571—61.23(461A) Restrictions—area and use.

61.23(1) Restrictions of campsite or campground use in established state forest campgrounds shall be the same as those cited in paragraphs 61.4(5)*"a"* through *"c," "e"* through *"k," "m,"* and *"n."*

61.23(2) Hours. Access into and out of the established camping areas shall be permitted from 4 a.m. to 10:30 p.m. From 10:31 p.m. to 3:59 a.m., only registered campers are permitted in the campgrounds.

61.23(3) Firearms use prohibited. Except for peace officers acting in the scope of their employment, the use of firearms, fireworks, explosives, and weapons of all kinds by the public is prohibited within the established camping area as delineated by signs marking the area.

61.23(4) Pets. Pets such as dogs or cats shall not be allowed to run at large within established state forest camping areas. Such animals shall be on a leash or chain not to exceed six feet in length and shall be either led by or carried by the owner; attached to an anchor, tie-out or vehicle; or confined in a vehicle.

61.23(5) Noise. Subrule 61.7(9) shall apply to established state forest camping areas.

[**ARC 0383C**, IAB 10/3/12, effective 11/7/12]

These rules are intended to implement Iowa Code sections 422.43, 455A.4, 461A.3, 461A.3A, 461A.35, 461A.38, 461A.39, 461A.42, 461A.43, 461A.45 to 461A.51, 461A.57, and 723.4 and Iowa Code chapters 463C and 724.

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◊ Two or more ARCs

1 Effective date of subrule 61.6(2) and rule 61.7(7/31/91) delayed 70 days by the Administrative Rules Review Committee at its meeting held 7/12/91.

2 Amendments to 61.4(2)*"f"* and 61.3(5)*"a"* effective January 1, 1993.

3 Amendments to 61.4(2)*"a"* to *"d"* effective October 31, 1993.

4 October 5, 2016, effective date of ARC 2694C [61.7(2)*"e"*] delayed until the adjournment of the 2017 General Assembly by the Administrative Rules Review Committee at its meeting held September 13, 2016.

CHAPTER 95
VITAL RECORDS: GENERAL ADMINISTRATION

[Prior to 12/12/12, see [641] Ch 96, 98.1, Chs 103, 104]

641—95.1(144) Definitions. For the purpose of 641—Chapters 95 to 100, the following definitions shall apply:

"Administrative costs" means costs for the registration, collection, preservation, modification and certification of records, including but not limited to costs related to copying, regular mailing, searching, staffing, and maintenance of systems.

"Advanced registered nurse practitioner" or *"ARNP"* means an individual licensed pursuant to Iowa Code chapter 152.

"Age of majority" means the chronological moment when a child legally assumes majority control over the child's own person and actions and decisions, thereby terminating the legal control and legal responsibilities of the child's parents over and for the child. The period of minority extends to the age of 18 years, but every minor attains majority by marriage.

"Amendment" means a change made by the state registrar upon request from an entitled person as described in 641—95.8(144) to an obvious error, omission, or transposition of letters in a word of common knowledge one year or more after the event.

"Birth center" means a facility or institution, which is not an ambulatory surgical center or a hospital or in a hospital, in which births are planned to occur following a normal, uncomplicated, low-risk pregnancy.

"Birthing institution" means a private or public hospital licensed pursuant to Iowa Code chapter 135B that has a licensed obstetric unit or is licensed to provide obstetric services.

"Burial-transit permit" means a permit which is required to assume custody of a dead body or fetus pursuant to Iowa Code section 144.32.

"Certificate" means the written or electronic legal document containing the facts of an event; also used interchangeably with the term "record."

"Certificate of birth resulting in stillbirth," pursuant to Iowa Code section 144.31A, means a noncertified copy issued based upon a properly filed fetal death certificate to record the birth of a stillborn fetus.

"Certified copy" means an official copy of a registered vital record that is authenticated by the state registrar or county registrar. A certified copy contains a statement certifying the facts are true and accurate as recorded, is printed on security paper, and has authentication seals and signatures. A certified copy excludes all entries indicated as confidential or for statistical information.

"Commemorative certificate," pursuant to Iowa Code section 144.45A, means a commemorative abstract of an Iowa birth or marriage record that has been properly filed.

"Competent and disinterested person" means an individual of legal age who is acquainted with both applicants who plan to marry.

"Confidential information" means data or information that is on a vital record, is not considered public information, and is restricted as to its release pursuant to Iowa Code chapter 144 or other provision of federal or state law.

"Correction" means a change made by the state registrar upon observation, upon query, or upon request from an entitled person as described in 641—95.8(144) to an obvious error, omission, or transposition of letters in a word of common knowledge within one year and prior to the first anniversary of the event.

"County registrar" means the county recorder with the authority to record vital records and issue certified copies. The county registrar operates under the state vital records laws and rules and the guidance of the state registrar pursuant to Iowa Code sections 144.5 and 144.9. Pursuant to Iowa Code section 331.601(4), if the office of the county recorder has been abolished, "county registrar" means the office to which the duties are assigned by the county board of supervisors.

"County resident copy" means a properly filed, clearly marked working copy of a decedent's death certificate which is sent to and recorded by the county registrar of the county of the decedent's residence in the event the death occurred outside the county of the decedent's residence.

"Court of competent jurisdiction" means the appropriate court for the type of action. When used to refer to inspection of an original certificate of birth based upon an adoption, "court of competent jurisdiction" means the court in which the adoption was ordered.

"Custody" means guardianship or control of vital records, including both physical possession, referred to as physical custody, and legal responsibility, referred to as legal custody, unless one or the other is specified. The state registrar shall not transfer legal custody of vital records to another agency for purposes of granting public access until all the records have been purged of all confidential information.

"Day" means calendar day.

"Dead human body" means a lifeless human body or parts or bones of a body, if, from the state of the body, parts, or bones, it may reasonably be concluded that death recently occurred.

"Death" means the condition as defined in Iowa Code section 702.8.

"Declaration of paternity registry" means a registry for a putative father to declare paternity pursuant to Iowa Code section 144.12A. The declaration does not constitute an affidavit of paternity filed pursuant to Iowa Code section 252A.3A.

"Delayed birth record" means the registration of a live birth event occurring in Iowa one or more years after the date of birth which is clearly marked as delayed and shall show on its face the date of the delayed registration.

"Delayed death record" means the registration of a death event occurring in Iowa one or more years after the date of death which is clearly marked as delayed and shall show on its face the date of the delayed registration.

"Delayed marriage record" means the registration of a marriage event occurring in Iowa one or more years after the event which is clearly marked as delayed and shall show on its face the date of the delayed registration.

"Department" means the Iowa department of public health.

"Disinterment permit" means a permit which allows the removal of a dead human body or fetus from its original place of burial, entombment or interment for the purpose of autopsy or reburial.

"Electronic access" means authority given by the state registrar to a county registrar to access electronic vital records through the electronic statewide vital records system for purposes of retrieving information. The state registrar shall provide guidelines for electronic access and the retrieval of information from the electronic statewide vital records system.

"Electronic statewide vital records system" means the combined vital records system for registration of birth records, registration of death records, issuance of certified copies of vital records by the state registrar and county registrar, and fee accounting.

"Emancipated minor" means a person younger than 18 years of age who has obtained the age of majority by court order.

"Fetal death" means a death prior to the complete expulsion or extraction from its mother of a product of human conception, irrespective of the duration of pregnancy which is not an induced termination of pregnancy. The death is indicated by the fact that, after such expulsion or extraction, the fetus does not breathe or show any other evidence of life such as beating of the heart, pulsation of the umbilical cord or definite movement of voluntary muscles. In determining a fetal death, heartbeats shall be distinguished from transient cardiac contractions, and respirations shall be distinguished from fleeting respiratory efforts or gasps.

"Filing" means the presentation of a certificate, report, or other record of a live birth, death, fetal death, adoption, marriage, dissolution, or annulment for registration pursuant to Iowa Code chapter 144.

"Final disposition" means the burial, interment, cremation, removal from the state, or other disposition of a dead body or fetus.

"Foundling" means a living infant of unknown parentage whose place of birth is where the infant is found and whose date of birth shall be determined by approximation.

"Funeral director" means a person licensed in Iowa to practice mortuary science pursuant to Iowa Code chapter 156.

"Gestational surrogate arrangement" or *"surrogate mother arrangement,"* as defined in Iowa Code section 710.11, means an arrangement whereby a female agrees to be artificially inseminated with the sperm of a donor, to bear a child, and to relinquish all rights regarding that child to the donor or donor couple.

"Health care provider" means an individual licensed under Iowa Code chapter 148, 148C, 148D, or 152 or any individual who provides medical services under the authorization of the licensee.

"Induced termination of pregnancy" means the use of any means to terminate the pregnancy of a woman known to be pregnant with the intent other than to produce a live birth or to remove a dead fetus as defined in Iowa Code section 144.29A(8).

"Institution" means a facility as defined in Iowa Code section 144.1(10), including "hospital" as defined in Iowa Code section 135B.1(3) but not including "birth center" as defined in Iowa Code section 135.61(2).

"Institutional health facility" means a hospital as defined in Iowa Code section 135B.1, including a facility providing medical or health services that is open 24 hours per day, seven days per week and that is a hospital emergency room or a health care facility as defined in Iowa Code section 135C.1.

"Jurisdiction" means the state or county to which legal authority for the system of vital statistics has been granted by statute.

"Last name" means surname.

"Lineal consanguinity" means the existence of a line of descent in which one person is descended in a direct lineal relationship to another: as between the registrant and the registrant's parent, grandparent, great-grandparent, and so upward, in the direct ascending line; or between the registrant and the registrant's child, grandchild, great-grandchild and so downward in the direct descending line; or any siblings of the registrant.

"Live birth" means the complete expulsion or extraction from its mother of a product of human conception, irrespective of the duration of pregnancy, which after such expulsion or extraction, breathes or shows any other evidence of life, such as beating of the heart, pulsation of the umbilical cord, or definite movement of voluntary muscles, whether or not the umbilical cord has been cut or the placenta is attached. In determining a live birth, heartbeats shall be distinguished from transient cardiac contractions, and respirations shall be distinguished from fleeting respiratory efforts or gasps.

"Marriage license valid date" means the day on which the marriage license becomes valid and on or after which the parties are authorized to marry. When the marriage license valid date is computed, the date of application shall be excluded. The marriage license shall become valid after the expiration of three calendar days after the date of application, unless earlier validated by a court of competent jurisdiction.

"Medical certification" means a statement which attests that the medical information reported on the certificate of death or fetal death is accurate to the best of the medical certifier's knowledge.

"Medical certifier" means an Iowa-licensed physician, physician assistant, advanced registered nurse practitioner, or medical examiner who attests that the death event has taken place and who determines the cause and manner of death.

"Medical examiner" means the medical legal officer who makes the determination of the cause of death in nonroutine deaths such as non-natural, sudden, or unattended deaths or other deaths which affect the public interest.

"Modification" means any change made to a record that has been accepted and registered, such as a correction, an amendment, a change after adoption or paternity determination, or any other change.

"Mutual consent voluntary adoption registry" means a registry which authorizes adult adopted children, adult siblings, and the biological parents of adult adoptees to register to obtain identifying birth information.

"Natural cause of death" means a death due to a disease or the aging process and not due to external causes.

"Newborn safe haven registration" means the registration of the birth of a living infant of unknown parentage who has been abandoned or left at some unknown time after birth in a location other than the place of delivery.

"Non-birthing institution" means a private or public hospital licensed pursuant to Iowa Code chapter 135B that does not have a licensed obstetric unit or is not licensed to provide obstetric services but may provide obstetric services on an emergency basis.

"Non-institution birth" means a live birth that occurs outside of an institution and not en route to an institution.

"Non-natural cause of death," pursuant to Iowa Code section 144.28(1)*"a,"* means the death is a direct or indirect result of physical, chemical, thermal, or electrical trauma, or drug or alcohol intoxication or other poisoning.

"Notification of record search" means the document issued to the applicant when the record requested cannot be located through a search of registered records. The document contains a certification statement, is printed on security paper, and has authentication seals and signatures.

"Officiant" means (1) a judge of the Iowa supreme court, court of appeals, or district court, including a district associate judge, an associate juvenile judge, or a judicial magistrate, and including a senior judge as defined in Iowa Code section 602.9202(3), or (2) a person ordained or designated as a leader of the person's religious faith.

"Physician" means an individual licensed pursuant to Iowa Code chapter 148.

"Physician assistant" means an individual licensed pursuant to Iowa Code chapter 148C.

"Presumptive death" means a death event presumed to have occurred in Iowa where no human body is found and a court of competent jurisdiction has determined the death has occurred.

"Putative father" means a man who is alleged to be or who claims to be the biological father of a child born to a woman to whom the man is not married at the time of the conception or birth of the child or at any time during the period between the conception and birth of the child.

"Record of death" means the compilation of those entries of a death, whether electronic or paper, which are contained in indexed systems which record the death event occurring in Iowa. "Record of death" shall include the certificate of death.

"Record of fetal death" means the compilation of those entries of a fetal death, whether electronic or paper, which are contained in indexed systems which record a fetal death event occurring in Iowa. "Record of fetal death" shall include the certificate of fetal death.

"Record of foreign born adoption" means the compilation of those entries of a live birth event for a child born in a foreign country and adopted by an Iowa resident. "Record of foreign born adoption" shall include the certificate of foreign birth and shall not constitute U.S. citizenship.

"Record of live birth" means the compilation of those entries of a live birth event, whether electronic or paper, which are contained in indexed systems which record a live birth event occurring in Iowa. "Record of live birth" shall include the certificate of live birth.

"Record of marriage" means the compilation of those entries of a marriage event, whether electronic or paper, which are contained in indexed systems which record a marriage event occurring in Iowa. "Record of marriage" shall include the certificate of marriage.

"Registrant" means the person named on the certificate as the person who was born, died, or was married.

"Registration" means the process by which vital statistics records are completed, filed, and incorporated by the state registrar in the official records.

"Report of dissolution or annulment" means the statistical report of dissolution or annulment, whether electronic or paper, excluding all entries indicated as confidential or for statistical information only.

"Report of termination of pregnancy" means the aggregated compilation of the information received by the department on terminations of pregnancies for each information item listed, with the exception of the report tracking number, the health care provider code, and any set of information for which the number is so small that the confidentiality of any person to whom the information relates may be compromised.

"Research" means the systematic investigation designed primarily to develop or contribute to scientific, medical, public health or psychosocial disciplines and generalized knowledge and not for private gain.

"Sealed" means the removal from inspection of any copy of an original certificate in the custody of the county registrar and the state registrar.

"Security paper" means standardized paper for issuing certified copies of vital record events that meets, at a minimum, national requirements for security features embedded within the paper to deter tampering, counterfeiting, photocopying, or imaging in order to help prevent fraudulent use of the certified copy and prevent identity theft.

"Single parent birth" means any record of live birth for which there is a reference or statement on the certificate or entry which directly indicates "no" regarding "born in wedlock" or "married"; or any record of live birth for which there is reference or statement on the certificate or entry that either parent is "unknown" or "anonymous"; or any certificate or entry which reflects the omission or absence of the name of the father of the child.

"Spontaneous termination of pregnancy" means the occurrence of an unintended termination of pregnancy at any time during the period from conception to 20 weeks' gestation and is not a spontaneous termination of pregnancy at any time during the period from 20 weeks or greater which is reported to the department as a fetal death under Iowa Code section 144.29.

"Standard birth registration" means a vital record of a live birth event that occurred in Iowa which was submitted and accepted for registration within one year of the event.

"State registrar" means the director of the department or the director's designee.

"Stillbirth" means an unintended fetal death occurring after a gestation period of 20 completed weeks or more or an unintended fetal death of a fetus with a weight of 350 or more grams.

"System of vital statistics" or *"system"* means the registration, collection, preservation, amendment, and certification of vital statistics records, and activities and records related thereto including the data processing, analysis, and publication of statistical data derived from such records.

"Uncertified copy" means an unofficial copy of a registered vital record which is not printed on security paper and which does not contain any authentication by the issuing jurisdiction. Uncertified copies shall contain an overstamp such as: "Not for Legal Purposes," "Administrative Use Only," "Deceased," "For Genealogical Purposes Only," "Working Copy," or any other overstamp as authorized by the state registrar.

"Vital records" means certificates or reports of birth, death, fetal death, marriage, dissolution, annulment, and related data.

"Vital statistics" means data derived from reports, certificates, and records of live birth, death, fetal death, induced termination of pregnancy, marriage, dissolution of marriage or annulment, and data related thereto.

[**ARC 0483C**, IAB 12/12/12, effective 1/16/13; see Delay note at end of chapter; **ARC 2275C**, IAB 12/9/15, effective 1/13/16]

641—95.2(144) Vital records and statistics. There is established a division in the department which shall install, maintain, and operate the system of vital statistics throughout the state. No official system for the registration of births, deaths, fetal deaths, adoptions, marriages, dissolutions, and annulments shall be maintained in the state or any of its political subdivisions other than the one provided for in Iowa Code chapter 144, including, but not limited to, a system maintained by any agency or private entity.

95.2(1) No person shall prepare or issue any certificate which purports to be an original certified copy or a copy of a certificate of birth, death, fetal death, adoption, marriage, dissolution, or annulment except as provided for in Iowa Code chapter 144 and authorized by the state registrar.

95.2(2) The state registrar and the county registrar shall not maintain or issue copies of any vital record of an event occurring outside the state registrar's or county registrar's jurisdiction except as provided for in Iowa Code chapter 144 and authorized by the state registrar.

[**ARC 0483C**, IAB 12/12/12, effective 1/16/13; see Delay note at end of chapter; **ARC 2933C**, IAB 2/1/17, effective 3/8/17; see Delay note at end of chapter]

641—95.3(144) Forms—property of department. All forms, certificates and reports pertaining to the registration of vital events are the property of the department and shall be surrendered to the state registrar upon demand. Official designated forms used for the express purpose of creating a vital record event shall not be accessible to the general public unless authorized by rule.

95.3(1) The forms supplied or approved for reporting vital events shall be used for official purposes as provided for by law, rules and instructions of the state registrar.

95.3(2) No forms, except those furnished or approved by the state registrar, shall be used in the reporting of vital events or the making of copies of vital records.

95.3(3) Security paper used to report vital events shall be maintained in a secure location accessible only to the state and county registrars and their employees for administrative purposes.

95.3(4) Security paper shall be used to issue certified copies of Iowa vital records and shall be maintained in a secure location accessible only to the state and county registrars and their employees for administrative purposes.

[**ARC 0483C**, IAB 12/12/12, effective 1/16/13; see Delay note at end of chapter; **ARC 4398C**, IAB 4/10/19, effective 5/15/19]

641—95.4(144) Information by others.

95.4(1) Any person having knowledge of the facts shall furnish information that the person possesses regarding any birth, death, fetal death, adoption, marriage, dissolution, or annulment, upon demand of the state registrar.

95.4(2) Every person in charge of an institution, or the person's designee, shall maintain a record of personal particulars and data concerning each person admitted or confined to the institution pursuant to Iowa Code section 144.47. This record shall include information required by the standard certificate of birth, death, and fetal death forms issued under the direction of the state registrar. The record shall be made at the time of admission based on the information provided by such person, but when information cannot be obtained from the person, it shall be obtained from the most knowledgeable relative or person acquainted with the facts. The name and address of the person providing the information shall be a part of the record.

95.4(3) Records maintained under this rule shall be retained for a period of not less than ten years and shall be made available for inspection by the state registrar upon demand.

[**ARC 0483C**, IAB 12/12/12, effective 1/16/13; see Delay note at end of chapter]

641—95.5(144) Handling of vital records.

95.5(1) State equipment and state vital records shall not be handled or accessed except by the state registrar, the state registrar's employees, or other authorized personnel for administrative purposes.

95.5(2) The county registrar shall provide assistance to the public in accessing vital records designated as public records in the custody of the county registrar.

[**ARC 0483C**, IAB 12/12/12, effective 1/16/13; see Delay note at end of chapter]

641—95.6(144) Fees.

95.6(1) *Fees for services provided by state registrar or county registrar.* The following fees shall be charged and remitted for the various services provided by the state registrar or the county registrar.

a. The state registrar or county registrar, as applicable, shall charge a fee of $20 for a certified copy of a vital record. If, following a search, no record is found and no certified copy is printed, the $20 fee may be retained. On and after July 1, 2019, this fee will revert to $15.

b. The state registrar shall charge a fee of $20 to prepare an adoption certificate, to amend a certificate, to amend a certificate of live birth to reflect a legal change of name, to prepare a delayed certificate, to process other administrative or legal actions, or for preparation of copies of supporting documents on file in the state registrar's office. On and after July 1, 2019, this fee will revert to $15. No fee shall be charged for establishment of paternity.

c. The state registrar shall charge a fee of $25 to file a completed application for the mutual consent voluntary adoption registry.

d. The state registrar shall charge a fee of $5 to update applicant information maintained in the mutual consent voluntary adoption registry and the declaration of paternity registry.

e. The state registrar shall charge a fee of $20 to amend an abstract or other legal documentation in support of the preparation of a new certificate. On and after July 1, 2019, this fee will revert to $15.

f. The state registrar shall charge a fee of $35 to issue a commemorative copy of a certificate of birth or a certificate of marriage pursuant to Iowa Code section 144.45A. Fees collected shall be deposited in the emergency medical services fund established in Iowa Code section 135.25.

g. The state registrar shall charge a fee of $20 for the purpose of issuing an uncertified copy of a certificate of birth resulting in stillbirth pursuant to Iowa Code section 144.31A. On and after July 1, 2019, this fee will revert to $15.

95.6(2) *Overpayments.* Any overpayment of $5 or less received by the state registrar for the copying of vital records or for the preparation or amending of a certificate shall not be refunded and shall be retained by the department.

95.6(3) *Certified copy of modified vital record.* When an individual is in possession of a previously issued certified copy of a vital record and the original record is subsequently modified, the individual may request and receive a certified copy of the modified record without charge if the certified copy prior to modification is relinquished to the registrar's office that issued the certified copy, unless otherwise directed by the state registrar.

95.6(4) *Search of county registrar's records—fee for uncertified copy.* A person who is requesting an uncertified copy of a record in the custody of the county registrar shall conduct the search of the county files to locate the record. If a copy is requested, the county registrar may charge a fee of no more than $5 for an uncertified copy of the county record. The fee shall be retained by the county.

95.6(5) *Distribution of fees.*

a. All fees collected by the county registrar and the state registrar shall be distributed as follows:

(1) For fees collected by a county registrar, with the exception of the fee in subrule 95.6(4), the county registrar shall retain $4 of each $20 fee collected by that office. On and after July 1, 2019, this $20 fee will revert to $15. Fees collected shall be divided as follows:

1. For a birth certificate or a marriage certificate, the state registrar shall receive $13, and $3 shall be deposited in the general fund of the state, except for the fee collected pursuant to paragraph 95.6(1)*"f."* On and after July 1, 2019, the amount received by the state registrar will revert to $8.

2. For a death certificate, the state registrar shall receive $11, the office of the state medical examiner shall receive $3, and $2 shall be deposited in the general fund of the state. On and after July 1, 2019, the amount received by the state registrar will revert to $6.

(2) For fees collected by the state registrar, the state registrar shall retain all fees, with the exception of the fees in paragraph 95.6(1)*"a,"* of which the state registrar shall retain $14 of each $20 fee collected for the issuance of certified copies. On and after July 1, 2019, the fee collected will revert to $15 and the amount retained by the state registrar will revert to $9. The $6 balance of certified copy fees collected by the state registrar shall be divided as follows:

1. For a birth certificate or a marriage certificate, $6 shall be deposited in the general fund of the state.

2. For a death certificate, the office of the state medical examiner shall receive $3, and $3 shall be deposited in the general fund of the state.

b. All fees retained by the state registrar shall be added to the vital records fund established by the department pursuant to Iowa Code section 144.46A.

c. All fees received by the office of the state medical examiner shall be added to the operating budget established for the operation of that office.

95.6(6) *Fee for search to verify vital statistics record.* A fee shall be charged by the state registrar for each search conducted for the purpose of providing verification of vital statistics data to an agency authorized to receive such data under subrule 95.12(2).

a. The amount of the fee shall be determined in an agreement with the department and shall be dependent on the nature and scope of the project and the resources required to obtain the data requested.

b. The state registrar shall retain the full amount of all fees collected under this subrule in the vital records fund established pursuant to Iowa Code section 144.46A.

95.6(7) *Fee for researcher access to vital statistics data.* A fee shall be charged to each researcher who is provided access to vital statistics data in accordance with Iowa Code section 144.44 and the required agreement executed with the department. The amount of the fee shall be based on the nature and scope of the research project and resources required to obtain the data requested.

a. The state registrar shall allocate the fees for copies of birth, marriage, and death certificates provided to researchers pursuant to the distribution of fees set forth in subrule 95.6(5).

b. The state registrar shall retain in the vital records fund established pursuant to Iowa Code section 144.46A the full amount of fees collected from researchers for searching files or records to create a data file.

95.6(8) *Service member who died while on active duty—waiver of fee.* The certified copy fee for a birth certificate or a death certificate of a service member, as defined in Iowa Code section 29A.90, who died while on active duty shall be waived for a period of one year from the date of death. Application for the certified copy shall be made by an entitled family member as described in 641—95.8(144) of the deceased service member or the entitled family member's legal representative. Documentation shall be submitted at the time of application to substantiate the date of death and active duty status.

95.6(9) *Retention of applications and reports.* An application for a certified copy of a vital record in Iowa shall be retained by the county registrar for a minimum of six months from date of issuance of the certified copy. All financial reports for vital records fees shall be retained by the county registrar for a minimum of three calendar years.

[**ARC 0483C**, IAB 12/12/12, effective 1/16/13; see Delay note at end of chapter; **ARC 1074C**, IAB 10/2/13, effective 1/1/14; see Delay note at end of chapter; **ARC 1402C**, IAB 4/2/14, effective 5/7/14; **ARC 2275C**, IAB 12/9/15, effective 1/13/16; **ARC 4398C**, IAB 4/10/19, effective 5/15/19]

641—95.7(144) General public access of vital records in the custody of the county registrar. A vital record may be in the custody of the county registrar if the event occurred in that county and the record is not excluded by statute or definition for purposes of confidentiality.

95.7(1) There shall be public access and the right to inspect all vital records in the custody of the county registrar after the vital records are purged of confidential information pursuant to rule 641—95.11(144). The county registrar shall allow the general public access to the electronic statewide vital records system to search as a public user as a right under Iowa Code chapter 22 for events which occurred in that county.

95.7(2) Information inspected and copied shall not be used to establish an official system for the registration of vital statistics except as authorized by Iowa Code chapter 144.

95.7(3) County registrars may issue uncertified copies of vital records held in the registrars' physical custody or accessible through the electronic statewide vital records system, except those records excluded by statute. Uncertified copies issued by the county registrar shall be issued on plain white paper and clearly stamped "not for legal purposes." Security paper provided by the state registrar shall not be used to produce uncertified copies.

95.7(4) For records available in the electronic statewide vital records system, the state registrar shall send to the county registrars a list of all records that have been modified. County registrars shall, as directed by the state registrar, remove all forms of any vital record in their physical custody from the county vital records system if the vital record appears on the list of modified records.

95.7(5) For records not available in the electronic statewide vital records system, the state registrar shall send a copy of any modified vital record to the county of event and, if the record is a death record, to the county of residence.

[**ARC 0483C**, IAB 12/12/12, effective 1/16/13; see Delay note at end of chapter; **ARC 2275C**, IAB 12/9/15, effective 1/13/16; **ARC 2933C**, IAB 2/1/17, effective 3/8/17; see Delay note at end of chapter]

641—95.8(144) Direct tangible interest in and entitlement to a vital record. Certified copies of vital records may be issued by the state registrar or county registrar upon written application, payment of the required fee pursuant to paragraph 95.6(1)*"a,"* and demonstration of a verifiable, direct tangible interest and entitlement.

95.8(1) The following persons shall be considered to have a direct tangible interest and entitlement and are authorized to obtain a certified copy of a vital record:

a. The registrant, if the registrant is of legal age, has reached the age of majority, or is an emancipated minor.

b. A member of the registrant's immediate legal family, including:

(1) Current spouse or surviving spouse;

(2) Children;

(3) Mother or father if listed on the registrant's birth certificate;

(4) Sibling, if sibling has reached the age of majority;

(5) Maternal grandparents, or paternal grandparents if the father is listed on the birth certificate; or

(6) Step-parent or step-child if:

1. Legal parent and step-parent are currently married at the time of application; or

2. Step-parent is the surviving spouse of the legal parent and not remarried.

c. The documented legal representative of the registrant or the registrant's immediate legal family, including:

(1) An attorney;

(2) A court-appointed guardian;

(3) A foster parent;

(4) A funeral director, for up to one year following the decedent's date of death; or

(5) A legal executor.

d. Other persons who demonstrate a direct tangible interest and entitlement when it is shown that the certified copy is needed to determine or protect a personal or property interest and the interest is for the benefit of the registrant.

95.8(2) The following persons shall not be deemed to have direct tangible interest and entitlement or be authorized to secure vital records:

a. Biological parents of adopted persons in the absence of a court order from the court of competent jurisdiction;

b. Biological family members of adopted persons;

c. Adopted persons requesting biological family records; or

d. Commercial firms or agencies requesting lists of vital record events, or lists of names, or lists of addresses, or that are not legal representatives requesting records on behalf of entitled individuals.

[**ARC 0483C**, IAB 12/12/12, effective 1/16/13; see Delay note at end of chapter; **ARC 4398C**, IAB 4/10/19, effective 5/15/19]

641—95.9(144) Search and issuance of a certified copy of a vital record. The search and issuance of a certified copy of a vital record shall be requested from the state registrar or county registrar.

95.9(1) Only entitled applicants as described in rule 641—95.8(144) may submit requests for certified copies of vital records.

95.9(2) A person requesting a search and issuance of a certified copy of a vital record shall provide in writing the following:

a. The name of the person or persons whose vital record is to be searched;

b. The purpose of such request;

c. The relationship to the registrant of the person making the request; and

d. The notarized signature and the address of the person making the request.

95.9(3) In addition to a completed written application, the applicant shall provide:

a. A current, legible government-issued photo identification of the applicant making the request or other identification documents acceptable to the state registrar; and

b. Payment of the required fee before the search is conducted.

95.9(4) The state registrar and county registrar shall have the authority to require additional supporting documents to prove direct tangible interest and entitlement pursuant to rule 641—95.8(144).

95.9(5) If, after the search is conducted, no record is on file and the state registrar or county registrar issues a "notification of record search" on certified paper, the fee for the search may be retained pursuant to paragraph 95.6(1)*"a."*

95.9(6) If a certified copy of a vital record is issued and sent to the applicant using a mail service and the applicant does not receive the certified copy, the state registrar or the county registrar may replace the certified copy without an additional fee using an Affidavit of Non-Receipt. The applicant must contact the issuing registrar within 90 days of the date of request. A minimum of 30 days must have elapsed from the time the certified copy was mailed. The applicant shall read the instructions, complete the Affidavit of Non-Receipt and have the applicant's signature notarized. The original Affidavit of Non-Receipt and a photocopy of the applicant's driver's license must be reviewed by the issuing registrar before the certified copy can be replaced for no additional fee. The state registrar or county registrar may refuse any Affidavit of Non-Receipt when the state registrar or county registrar determines proof of receipt, fraud or misrepresentation. The state registrar shall give to the registrant a notice in writing of the state registrar's reason and intention to refuse the Affidavit of Non-Receipt.

95.9(7) If printed from the electronic statewide vital records system by a county registrar, the certified copy of a vital record shall be stamped by the issuing county registrar to reflect the county in which the certified copy was issued.

[**ARC 0483C**, IAB 12/12/12, effective 1/16/13; see Delay note at end of chapter; **ARC 2275C**, IAB 12/9/15, effective 1/13/16]

641—95.10(144) Search and issuance for genealogy or family history. The search and issuance of a vital record for genealogy may be requested from the state registrar or county registrar upon written application and payment of the required fee pursuant to paragraph 95.6(1)*"a."*

95.10(1) The state registrar or county registrar may issue certified copies of a vital record for genealogy or family history to an applicant who can satisfactorily demonstrate a line of direct lineal consanguinity and to aunts, uncles, and cousins not past twice removed.

95.10(2) All certified copies issued for genealogy or family history shall be clearly marked "for genealogical purposes only."

95.10(3) No certified copy shall be issued for genealogy or family history if the registrant is known to be living.

95.10(4) If, after the search is conducted, no record is on file, the state registrar or county registrar shall issue a "notification of record search" on certified paper, and the fee for the search shall be retained pursuant to paragraph 95.6(1)*"a."*

[**ARC 0483C**, IAB 12/12/12, effective 1/16/13; see Delay note at end of chapter; **ARC 2933C**, IAB 2/1/17, effective 3/8/17; see Delay note at end of chapter]

641—95.11(144) Registrars' responsibility for maintenance of confidentiality.

95.11(1) The state registrar and county registrar shall maintain the confidentiality of the following material, records, and information:

a. Entries indicated as confidential or statistical in nature on the face of the record or otherwise confidential by law;

b. Any record which is ordered sealed by the state registrar or pursuant to a court order.

95.11(2) The county registrar shall take all necessary steps to ensure that confidential information reflected on vital records has been redacted from general public access. If confidential information is included with accessible information, only accessible information shall be made available to the general public for examination.

95.11(3) The county registrar shall employ at a minimum all of the following methods to ensure confidentiality:

a. Permanently cover or remove, by appropriate means, confidential information;

b. Promptly process the notice to seal a record as directed by the state registrar; and

c. Seal and not reproduce confidential information when copies of vital records are made.

95.11(4) The county registrar may charge reasonable administrative costs to reflect the expenses for efforts required to allow general public access, examination and the assurance of confidentiality of this material and information pursuant to the authority of Iowa Code chapter 22.

a. The administrative cost is to be paid by persons who request the services provided by the county registrar, including supervising, copying or providing a suitable place for such work.

b. The county registrar shall retain all administrative costs collected to allow general public access, examination, and the assurance of confidentiality of the vital record and information pursuant to the authority of Iowa Code chapter 22.

[**ARC 0483C**, IAB 12/12/12, effective 1/16/13; see Delay note at end of chapter; **ARC 2275C**, IAB 12/9/15, effective 1/13/16]

641—95.12(144) Disclosure of data.

95.12(1) The state registrar may disclose data from the system of vital statistics to federal, state, county or municipal agencies of government that request such data in the conduct of their official duties, subject to conditions the state registrar may impose to ensure that the use of the data is limited to official purposes.

a. The aforementioned agencies shall not provide the certified copy or a copy of the vital record, or release information contained therein, to the person named on the certificate, a member of the person's legal family, or the person's legal representative.

b. Certified copies issued to the aforementioned agencies shall be appropriately stamped, for example, "administrative purposes only" or "for veteran affairs purposes only."

95.12(2) Confidential verifications of the facts contained in vital records may be furnished by the state registrar to any federal, state, county or municipal government agency or other entity in the conduct of the agency's or entity's official duties, subject to conditions the state registrar may impose to ensure that the verification is limited to official purposes. Confidential verification of the facts contained in vital records may be furnished by a county registrar to another county office, within the county jurisdiction, in the conduct of the county's official duties, subject to conditions the state and county registrar may impose to ensure that the verification is limited to official purposes.

a. Such confidential verifications shall be on forms prescribed and furnished by the state registrar or on forms furnished by the requesting agency or entity and acceptable to the state registrar, or the state registrar may authorize the verification in other ways.

b. The aforementioned agencies and entities shall not provide the original or a copy of the verified certificate, or release information contained therein, to the person named on the certificate, a member of the person's legal family, or the person's legal representative.

95.12(3) The state registrar may permit the use of data from vital statistics for research purposes subject to conditions the state registrar may impose to ensure the use of the data is limited to such research purposes. No data shall be furnished from vital statistics for research purposes until the state registrar has prepared in writing the conditions under which the data may be used and has received an agreement signed by a responsible agent of the research organization agreeing to meet and conform to such conditions.

95.12(4) The state registrar may transmit to the county registrar data needed to produce certified copies of vital records pursuant to rule 641—95.8(144).

95.12(5) The state registrar may transmit to the statewide immunization registry information from birth certificates for the sole purpose of identifying those children in need of immunizations. The state registrar may impose conditions to ensure that the use of the information is limited to official purposes.

95.12(6) The state medical examiner or the county medical examiner may request an uncertified copy of a death certificate before the death certificate is accepted and filed at the county registrar's office.

a. The copy shall be clearly stamped "administrative purposes only."

b. The death certificate shall be for the sole use of the state medical examiner or county medical examiner and shall not be used as a legal document, be distributed, be copied or be maintained other than to be made a part of the investigatory file.

c. If the state medical examiner or any county medical examiner determines the death does not warrant further investigation, the state medical examiner or county medical examiner shall destroy the uncertified copy of the death certificate.

[**ARC 0483C**, IAB 12/12/12, effective 1/16/13; see Delay note at end of chapter; **ARC 2275C**, IAB 12/9/15, effective 1/13/16]

641—95.13(144) Preparation of certified copies. Certified copies of vital records may be prepared and issued by the state registrar or the county registrar pursuant to rules 641—95.3(144) and 641—95.9(144).

95.13(1) Certified copies of vital records may be made by mechanical, electronic, or other reproductive processes, except for confidential information. Certified copies shall be issued using security paper that is prescribed by the state registrar.

95.13(2) When a certified copy is issued, each certification shall contain a statement certifying that the facts are the true facts recorded in the issuing office, the date issued, the name of the issuing office, the registrar's signature or an authorized copy thereof, and the seal of the issuing office.

95.13(3) No person shall prepare or issue any certificate which purports to be an original, certified copy, or copy of a certificate of birth, death, fetal death, or marriage.

[**ARC 0483C**, IAB 12/12/12, effective 1/16/13; see Delay note at end of chapter]

641—95.14(144) Cancellation of fraudulent records.

95.14(1) When the state registrar determines that a certificate was registered through fraud or misrepresentation, the state registrar shall give to the registrant a notice in writing of the state registrar's intention to cancel said certificate.

95.14(2) The notice of cancellation shall give the registrant an opportunity to appear and show cause why the certificate shall not be canceled.

a. The notice may be served on the registrant, or, in the case of a minor or incompetent person, on the parent or guardian, by the forwarding of the notice by certified mail to the last-known address on file in the office of the state registrar.

b. The certificate shall not be available for certification unless the registrant, parent or guardian within 30 days after the date of mailing the notice shows cause satisfactory to the state registrar why the certificate shall not be canceled.

95.14(3) Upon presentation to the state registrar of a court order stating a marriage certificate was registered through fraud or misrepresentation, the state registrar shall remove said record from the vital statistics system. The state registrar shall order the county registrar to remove any record related to the marriage.

[**ARC 0483C**, IAB 12/12/12, effective 1/16/13; see Delay note at end of chapter]

641—95.15(144) Unlawful acts.

95.15(1) *Serious misdemeanors.* Any person who reports information required under Iowa Code chapter 144 and who commits any of the following acts is guilty of a serious misdemeanor:

a. Willfully and knowingly makes any false statement in a report, record, or certificate required to be filed or in an application for an amendment or willfully and knowingly supplies false information intending that such information be used in the preparation or amendment of any such report, record, or certificate.

b. Without lawful authority and with the intent to deceive, makes, alters, amends, or mutilates any report, record, or certificate required to be filed or a certified copy of such report, record, or certificate.

c. Willfully and knowingly uses or attempts to use or furnish to another for use for any purpose of deception any certificate, record, or report or certified copy thereof.

d. Willfully and knowingly alters, amends, or mutilates any copy, certified copy, record or report.

e. Willfully, with the intent to deceive, uses or attempts to use any certificate of birth or certified copy of a record of birth knowing that such certificate or certified copy was issued based upon a record which is false in whole or in part or which relates to the birth of another person.

f. Willfully and knowingly furnishes a certificate of birth or certified copy of a record of birth with the intention that it be used by a person other than the person to whose birth the record relates.

g. Disinterring a body in violation of Iowa Code section 144.34.

h. Knowingly violates a provision of Iowa Code section 144.29A.

95.15(2) *Simple misdemeanors.* Any person committing any of the following acts is guilty of a simple misdemeanor:

a. Knowingly transports or accepts for transportation, interment, or other disposition a dead body without an accompanying permit as provided in Iowa Code sections 144.32, 144.33, and 144.34.

b. Refuses to provide information required by Iowa Code chapter 144.

c. Willfully violates any of the provisions of Iowa Code chapter 144 or refuses to perform any of the duties imposed upon the person.
[**ARC 0483C**, IAB 12/12/12, effective 1/16/13; see Delay note at end of chapter]

641—95.16(144) Enforcement assistance.

95.16(1) The department shall report cases of alleged violations to the proper county attorney, with a statement of the facts and circumstances, for such action as is appropriate.

95.16(2) Upon request of the department, the attorney general shall assist in the enforcement of the provisions of Iowa Code chapter 144.
[**ARC 0483C**, IAB 12/12/12, effective 1/16/13; see Delay note at end of chapter]

These rules are intended to implement Iowa Code chapter 144 as amended by 2015 Iowa Acts, House File 662.

[Filed ARC 0483C (Notice ARC 0376C, IAB 10/3/12), IAB 12/12/12, effective 1/16/13][1]
[Filed ARC 1074C (Notice ARC 0926C, IAB 8/7/13), IAB 10/2/13, effective 1/1/14][2]
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[1] January 16, 2013, effective date of the rescission of Chapter 95 and the adoption of new Chapter 95 [ARC 0483C] delayed until adjournment of the 2013 General Assembly by the Administrative Rules Review Committee at its meeting held January 8, 2013; delay lifted at the meeting held March 8, 2013.

[2] January 1, 2014, effective date of 95.6(2) [ARC 1074C, Item 2] delayed 70 days by the Administrative Rules Review Committee at its meeting held October 8, 2013.

[3] March 8, 2017, effective date of 95.2, 95.7 and 95.10 [ARC 2933C] delayed 70 days by the Administrative Rules Review Committee at its meeting held February 10, 2017.

CHAPTER 96
BIRTH REGISTRATION

[Prior to 12/12/12, see [641] 95.1 to 95.4, Ch 99, 100.3]

641—96.1(144) Definitions. For the purpose of this chapter, the definitions in 641—Chapter 95 shall apply.
[**ARC 0483C**, IAB 12/12/12, effective 1/16/13; see Delay note at end of chapter]

641—96.2(144) Forms—property of department. All forms, certificates and reports pertaining to the registration of vital events are the property of the department and shall be surrendered to the state registrar upon demand.

96.2(1) The forms supplied or approved for reporting birth events shall be used for official purposes as provided for by law, rules and instructions of the state registrar.

96.2(2) No forms, except those furnished or approved by the state registrar, shall be used in the reporting of birth events or the making of copies of vital records.
[**ARC 0483C**, IAB 12/12/12, effective 1/16/13; see Delay note at end of chapter]

641—96.3(144) Standard birth registration—up to seven days.

96.3(1) A certificate of live birth for each live birth which occurs in this state shall be filed as directed by the state registrar within seven days after the birth.

96.3(2) The person responsible for registering the certificate of live birth pursuant to rules 641—96.5(144), 641—96.6(144) and 641—96.7(144) shall:

a. Utilize the official birth worksheet to report all information and any additional documentation as needed to complete the standard form for a certificate of live birth; and

b. Submit all required fees and reports with the birth registration.
[**ARC 0483C**, IAB 12/12/12, effective 1/16/13; see Delay note at end of chapter]

641—96.4(144) Standard birth registration—seven days to one year.

96.4(1) After seven days but within one year, a certificate of live birth for each live birth which occurs in this state shall be filed as directed by the state registrar.

96.4(2) The person responsible for registering the certificate of live birth pursuant to rules 641—96.5(144), 641—96.6(144) and 641—96.7(144) shall:

a. Utilize the official birth worksheet to report all information and any additional documentation as needed to complete the standard form for a certificate of live birth; and

b. Submit all required fees and reports with the birth registration.
[**ARC 0483C**, IAB 12/12/12, effective 1/16/13; see Delay note at end of chapter]

641—96.5(144) Birthing institutions.

96.5(1) When a live birth occurs in an institution or en route to an institution, the person in charge of the institution or the person's designated representative, utilizing the official birth worksheet, shall within seven days:

a. Obtain the personal data;

b. Obtain the signature of the mother or her legal spouse or other signature as directed by the state registrar;

c. Provide the medical information required;

d. Certify that the child was born alive at the place, date, and time stated; and

e. File the certificate using the electronic birth registration system or as directed by the state registrar.

96.5(2) The birthing institution shall submit the fee report and remit the fees to the state registrar pursuant to rule 641—96.16(144).

96.5(3) The birthing institution shall maintain the birth worksheet for a minimum of ten years.

96.5(4) Upon demand of the state registrar, the birth worksheet and other information about the birth event shall be made available for inspection by the state registrar.
[**ARC 0483C**, IAB 12/12/12, effective 1/16/13; see Delay note at end of chapter; **ARC 1075C**, IAB 10/2/13, effective 11/6/13]

641—96.6(144) Non-birthing institutions.

96.6(1) Institutions that do not register birth records through the electronic birth registration system shall request instructions from the state registrar.

96.6(2) The person in charge of the non-birthing institution or the person's designee shall submit to the state registrar for registration of the live birth at a minimum the following:

a. A cover letter that is on business letterhead of the institution and that identifies the live birth submitted for registration, supports the facts of the live birth, and contains the original signature of the person responsible for registering the live birth;

b. A copy of the hospital delivery report, emergency department admittance, or physician notes;

c. The original Iowa official birth worksheet completed and signed by the mother, or her legal spouse, or as directed by the state registrar; and

d. Payment of the fees, which shall be included with the birth worksheet.

[**ARC 0483C**, IAB 12/12/12, effective 1/16/13; see Delay note at end of chapter; **ARC 1075C**, IAB 10/2/13, effective 11/6/13]

641—96.7(144) Non-institution birth.

96.7(1) In case of a non-institution Iowa live birth, the official non-institution birth worksheet shall be completed and filed with the state registrar by one of the following in the indicated order of priority:

a. The physician in attendance at or immediately after the live birth.

b. Any other person, including a certified nurse midwife or any person providing assistance with the birth, in attendance at or immediately after the live birth.

c. The mother or her legal spouse.

d. The person in charge of the premises where the live birth occurred.

96.7(2) Evidence in support of the facts of live birth shall be included in a cover letter, which shall contain the notarized signature of the person responsible for registering the birth. A certificate of live birth shall be completed and filed upon presentation of the following clear and convincing evidence by the individual responsible for filing the certificate:

a. Evidence of pregnancy including:

(1) Prenatal record;

(2) A statement from a physician, certified nurse midwife, or other health care provider qualified to determine pregnancy;

(3) A statement from a public health nurse or other health care provider documenting a prenatal home visit; or

(4) Other evidence acceptable to the state registrar.

b. Evidence the infant was born alive including:

(1) A statement from the physician, certified nurse midwife or other health care provider who saw or examined the infant;

(2) A statement from a public health nurse or other health care provider documenting a postnatal home visit; or

(3) Other evidence acceptable to the state registrar.

c. Clear and convincing evidence acceptable to the state registrar of the mother's presence in this state at the reported place and date of the live birth.

96.7(3) An Iowa-licensed certified nurse midwife may preregister with the state registrar by submitting a completed Iowa-Licensed CNM Pre-Registration Application For Home Births and a clear photocopy of that person's current government-issued photo identification.

a. To register a live birth, certified nurse midwives who are preregistered shall submit to the state registrar the following:

(1) A cover letter that is on the business letterhead, that identifies the live birth submitted for registration, that supports the facts of the live birth, and that contains the original signature of the person responsible for registering the live birth;

(2) The original official non-institution birth worksheet completed and signed pursuant to subrule 96.7(5) or as directed by the state registrar;

(3) Payment of fees, which shall be included with the birth worksheet; and

(4) Other evidence acceptable to the state registrar as requested.

b. It is the responsibility of the individual preregistering to update any information provided in the individual's original registration.

96.7(4) A certified nurse midwife, or any person providing assistance with the birth, who is not preregistered prior to submitting a certificate of live birth for registration shall follow subrules 96.7(1), 96.7(2) and 96.7(5) for all live births the person attends outside a birthing institution.

96.7(5) The official non-institution birth worksheet shall include a notarized signature of the mother or her legal spouse and shall be accompanied by a clear photocopy of that person's current government-issued photo identification. If photo identification is unavailable, other identifying documentation may be acceptable to the state registrar.

[**ARC 0483C**, IAB 12/12/12, effective 1/16/13; see Delay note at end of chapter; **ARC 1075C**, IAB 10/2/13, effective 11/6/13; **ARC 4398C**, IAB 4/10/19, effective 5/15/19]

641—96.8(144) Gestational surrogate arrangement birth registration. Establishment of a certificate of live birth for a child born of a gestational surrogate arrangement shall conform to the process established pursuant to rule 641—99.15(144).

[**ARC 0483C**, IAB 12/12/12, effective 1/16/13; see Delay note at end of chapter]

641—96.9(144) Foundling birth registration.

96.9(1) The person assuming physical custody of a foundling shall, within one business day of finding the infant, contact the state registrar for specific directions and guidance for filing the certificate of live birth.

96.9(2) Foundling registration shall be completed in the standard manner by the state registrar pursuant to Iowa Code section 144.14. Within five days after assuming physical custody of the foundling, the custodian of the foundling shall provide on the official birth worksheet the following minimum birth data and other data required by the state registrar:

a. The date when and the place where the child was found;

b. The sex, color or race, and approximate age of the child;

c. The name and address of the person or institution that has assumed physical custody of the child;

d. The name given to the child by the custodian;

e. The name, title, and license number, if any, of the person acting as the certifier to the facts of the foundling registration;

f. Parentage information, if the parent is known;

g. A cover letter with supporting documentation; and

h. Any additional information known.

96.9(3) The place where the child was found shall be entered as the place of birth and the date of birth shall be determined by approximation. The information provided on the official birth worksheet shall constitute the certificate of live birth.

96.9(4) The record shall be on file only at the state registrar's office, and all supporting documentation shall be placed in a sealed file, which shall be opened only by order of a court of competent jurisdiction or for vital records administrative purposes.

96.9(5) Pursuant to Iowa Code section 144.14, if the child is properly identified after the registration, the certificate of live birth shall be reestablished as needed and all records pertaining to the foundling registration shall be sealed along with the original supporting documentation, which shall be opened only by order of a court of competent jurisdiction or for vital records administrative purposes.

[**ARC 0483C**, IAB 12/12/12, effective 1/16/13; see Delay note at end of chapter]

641—96.10(144) Newborn safe haven registration.

96.10(1) Newborn safe haven registration procedures shall apply to living infants who have been abandoned or left at an institutional health facility.

96.10(2) The person assuming physical custody of the living infant pursuant to Iowa Code section 233.2(2)*"a"* shall, within one business day of assuming custody, contact the state registrar for specific directions and guidance for registering the birth.

96.10(3) If the name of the parent is unknown, newborn safe haven registration shall be completed in the standard manner by the state registrar pursuant to Iowa Code section 144.14. Within five days after assuming physical custody of the infant, the custodian shall provide on the official birth worksheet the following minimum birth data and other data required by the state registrar:

a. The date when and the place where the child was found;

b. The sex, color or race, and approximate age of the child;

c. The name and address of the person or institution that has assumed physical custody of the child;

d. The name given to the child by the custodian;

e. The name, title, and license number, if any, of the person acting as the certifier to the facts of the newborn safe haven registration;

f. A cover letter with supporting documentation; and

g. Any additional information known.

96.10(4) If the name of the parent is disclosed to the institutional health facility, the facility shall file the certificate of live birth as required pursuant to Iowa Code sections 144.13 and 233.2(2)*"c."*

96.10(5) Pursuant to Iowa Code section 144.14, if the child is properly identified after the newborn safe haven registration, the birth record shall be reestablished as needed and all records pertaining to the newborn safe haven registration shall be sealed along with the original supporting documentation, which shall be opened only by order of a court of competent jurisdiction or for vital records administrative purposes.

96.10(6) The record shall be on file only at the state registrar's office, and all supporting documentation shall be placed in a sealed file which shall be opened only by order of a court of competent jurisdiction or for vital records administrative purposes. The confidentiality of the live birth certificate shall be maintained pursuant to Iowa Code sections 233.2(2)*"c"* and 144.43.

[**ARC 0483C**, IAB 12/12/12, effective 1/16/13; see Delay note at end of chapter]

641—96.11(144) Birth registration following a foreign-born adoption.

96.11(1) A certificate of foreign birth shall be established by the state registrar for a child born in a foreign nation upon the state registrar's receipt of a completed Certificate of Adoption Report form from an Iowa court of competent jurisdiction or upon request of the resident adoptive parent or parents and the state registrar's receipt of all of the following documents:

a. The authenticated adoption decree in both the foreign language and the English translation, which shall contain the official signature of the translator, or a certified copy of an adoption decree from an Iowa court of competent jurisdiction;

b. If the decree does not contain information to establish the certificate of foreign birth, the adoptee's authenticated birth certificate in both the foreign language and the English translation, which shall contain the official signature of the translator;

c. Evidence of the adoptee's permanent residence such as a passport or citizenship papers;

d. A certified copy of the certificate of live birth of each adoptive parent; and

e. A notarized statement that is on letterhead from the licensed adoption agency or certified adoption investigator and that establishes the parent or parents were residents of Iowa at the time the adoption was final in the foreign nation. The statement will not be required if the parent's or parents' Iowa address is shown in the adoption documents.

96.11(2) The certificate of foreign birth shall not constitute U.S. citizenship.

96.11(3) The state registrar shall charge the adoptive parent or parents the appropriate fee for the registration of a certificate of foreign birth for a foreign-born child adopted by a parent who resided in Iowa at the time of adoption pursuant to Iowa Code section 144.13A.

96.11(4) Administrative and certified copy fees shall be charged and remitted as provided in rule 641—95.6(144).

96.11(5) The evidence presented shall be on file only at the state registrar's office, and all supporting documentation shall be placed in a sealed file which shall be opened only by order of a court of competent jurisdiction or for vital records administrative purposes.
[**ARC 0483C**, IAB 12/12/12, effective 1/16/13; see Delay note at end of chapter]

641—96.12(144) Birth registration fees. A fee is required for each birth registered pursuant to Iowa Code sections 144.13, 144.13A, 144.15, 144.18, 144.23, 144.25A, and 600.15.

96.12(1) The parents shall be charged and the person responsible for filing the certificate of live birth shall remit to the state registrar the $20 fee for the standard registration of a certificate of live birth and the $15 fee for a certified copy of the birth certificate pursuant to Iowa Code section 144.13A.

96.12(2) The individual filing a delayed certificate of live birth shall be charged and shall remit to the state registrar the $20 fee for the registration of a delayed certificate of live birth for a registrant 17 years of age or younger pursuant to Iowa Code sections 144.13A, 144.15, and 144.18.

96.12(3) The adoptive parents shall be charged and shall remit to the state registrar the $20 fee for the registration of a certificate of foreign birth pursuant to Iowa Code sections 144.13A and 144.25A.
[**ARC 0483C**, IAB 12/12/12, effective 1/16/13; see Delay note at end of chapter]

641—96.13(144) Fee collection. If a person responsible for the registration of a certificate of live birth under Iowa Code section 144.13 is not the parent, the person shall collect the fees from the parent and remit the fees to the state registrar.

96.13(1) The person collecting the fee on behalf of the state registrar shall not charge an administrative fee for collection of the registration and certified copy fees pursuant to Iowa Code section 144.13A(3).

96.13(2) A person is discharged from the duty to collect and remit the fees when the person has made a good-faith effort to collect the fees from the parent or has established that the fees are to be waived pursuant to Iowa Code section 144.13A(3).
[**ARC 0483C**, IAB 12/12/12, effective 1/16/13; see Delay note at end of chapter]

641—96.14(144) Waivers. The registration fee and certified copy fee are waived if the expenses of the birth are reimbursed under the medical assistance program established by Iowa Code chapter 249A or if the parent is indigent and unable to pay the expenses of the birth and no other means of payment is available to the parent.
[**ARC 0483C**, IAB 12/12/12, effective 1/16/13; see Delay note at end of chapter]

641—96.15(144) Fee deposit. Birth registration and certified copy fees collected on behalf of the state registrar and forwarded to the state registrar shall be remitted to the treasurer of state for deposit in the appropriate state fund.
[**ARC 0483C**, IAB 12/12/12, effective 1/16/13; see Delay note at end of chapter]

641—96.16(144) Responsibilities of institutions. Institutions responsible for filing certificates of live birth shall collect both the registration fee and the certified copy fee from the parent.

96.16(1) The institution shall complete the Summary of Fee Report for Birth Registration and Certified Copy form. The institution shall submit the completed form and the total fee amount by check or money order, to the state registrar, within seven days of the live birth or as directed by the state registrar. All live births shall be reported and indicate for each birth that:

a. The fee was collected for the registration and certified copy;

b. The fee was waived, as applicable, and the reason for waiver; or

c. No fee was collected after a good-faith effort was made.

96.16(2) If a late birth registration fee is received, it shall be noted on the original Summary of Fee Report for Birth Registration and Certified Copy form.

96.16(3) The institution shall maintain copies of the submitted Summary of Fee Report for Birth Registration and Certified Copy form for three state fiscal years.
[**ARC 0483C**, IAB 12/12/12, effective 1/16/13; see Delay note at end of chapter]

641—96.17(144) Responsibility for births occurring in non-institutions and non-birthing institutions.

96.17(1) The state registrar shall collect the registration and certified copy fees and complete a Summary of Fee Report for Birth Registration and Certified Copy form.

96.17(2) If a late birth registration fee is received, it shall be noted on the original Summary of Fee Report for Birth Registration and Certified Copy form.

[**ARC 0483C**, IAB 12/12/12, effective 1/16/13; see Delay note at end of chapter]

641—96.18(144) Delayed birth registration—one year or more after event. All Iowa births registered one year or more after the date of the birth shall be prepared on a Delayed Certificate of Live Birth form. The state registrar shall require documentary evidence to prove the facts of the birth pursuant to subrule 96.18(2). The delayed birth record shall be registered and maintained solely at the state registrar's office.

96.18(1) *Application—certificate form.* A completed Delayed Certificate of Live Birth form shall be signed before a notary and filed with the state registrar by the following applicants in the indicated order of priority:

a. The registrant, if 18 years of age or older, whose birth occurred in Iowa but was not recorded within one year of the birth;

b. The registrant's parent or current legal court-appointed guardian; or

c. If no parent or legal guardian exists, a member of the registrant's family who has direct tangible interest and entitlement and who is competent to affirm to the accuracy of the information.

96.18(2) *Facts to be established.*

a. The applicant shall submit a notification of record search certified by the state registrar, which shall indicate that no prior certificate of live birth is on file for the person whose delayed birth record is to be filed. The notification of record search shall be returned to the applicant and shall not be exchanged for a certified copy of delayed certificate of live birth.

b. The applicant shall substantiate the following with documentary evidence:

(1) The full name of the registrant at the time of the birth, except that the delayed certificate may reflect the name established by adoption or legitimation when such evidence is submitted;

(2) The date and place of the birth;

(3) The full name of the mother prior to any marriage as it is listed on her birth certificate;

(4) The full name of the mother at the time of the birth; and

(5) The full name of the mother's legal spouse. However, if the mother was not married at the time of conception or birth or at any time during the period between conception and birth, the name of a second parent shall not be entered on the delayed certificate unless the child has been adopted or legitimated or parentage has been determined by a court of competent jurisdiction.

96.18(3) *Documentary evidence.*

a. To be acceptable for purposes of registration, the name of the registrant and the date and place of birth entered on a Delayed Certificate of Live Birth form shall be supported at a minimum by the following documentary evidence:

(1) Two pieces of dated documentary evidence if the Delayed Certificate of Live Birth form is filed within seven years after the registrant's date of birth; or

(2) Three pieces of dated documentary evidence if the Delayed Certificate of Live Birth form is filed seven years or more after the registrant's date of birth.

b. Each piece of documentary evidence must be from an independent source. Facts of parentage shall be supported by at least one of the documents.

c. Documentary evidence shall be in the form of the original record, a certified copy thereof, or a notarized statement from the custodian of the record or document on the custodian's letterhead.

d. All documentary evidence submitted shall consistently support the facts of birth to be established.

e. All documentary evidence shall have been executed at least five years prior to the date of filing or shall have been established prior to the registrant's seventh birthday.

f. Documents not acceptable to establish a delayed certificate of live birth include, but are not limited to:

(1) Baptismal record,

(2) Confirmation record,

(3) Family bible entries,

(4) Hospital commemorative birth certificate,

(5) Crib card,

(6) Cradle roll,

(7) Baby book memento, and

(8) Personal affidavit.

96.18(4) *Abstraction and certification by the state registrar.* The state registrar shall abstract on the Delayed Certificate of Live Birth form a description of each document submitted to support the facts of birth. This description shall include:

a. The title or description of the document;

b. The name and address of the custodian who has attested to the fact on the original documents in the custodian's custody;

c. The date of the original filing of the document being abstracted; and

d. The information regarding the registrant's birth and parentage.

96.18(5) *Acceptance of documentary evidence for registration.*

a. The state registrar shall by signature certify that:

(1) No prior certificate of live birth is on file for the person whose birth is to be recorded;

(2) The evidence has been reviewed and substantiates the alleged facts of the birth; and

(3) The abstract of the evidence appearing on the Delayed Certificate of Live Birth form accurately reflects the nature and content of the documents.

b. All documents submitted in support of the delayed registration of live birth shall be returned to the applicant after review, abstraction, and registration.

96.18(6) *Denial of registration.*

a. When the applicant does not submit substantiating evidence or the state registrar finds reason to question the validity or adequacy of the evidence submitted to establish a delayed certificate of live birth, the state registrar shall not register the delayed certificate of live birth. The written notice of refusal from the state registrar shall include:

(1) The rejected form;

(2) The Delayed Birth Evidence Refusal form; and

(3) Information related to the applicant's right of appeal to the district court pursuant to Iowa Code sections 144.17 and 144.18.

b. The application to establish a delayed certificate of live birth shall be dismissed if not actively pursued within six months of the date the notice of refusal was sent to the applicant.

96.18(7) *Duties of the county registrar.* The county registrar may assist the registrant, registrant's parent, or current court-appointed guardian in the completion and notarization of the delayed form, excluding the portion restricted for state use only. The county registrar may forward the form, documents and fees to the state registrar for final review and possible acceptance.

96.18(8) *Fees.* Administrative and certified copy fees shall be charged as provided in rule 641—95.6(144).

[**ARC 0483C**, IAB 12/12/12, effective 1/16/13; see Delay note at end of chapter; **ARC 1075C**, IAB 10/2/13, effective 11/6/13]

These rules are intended to implement Iowa Code sections 144.12, 144.13, 144.13A, 144.14, 144.15, 144.17, 144.18, 233.2(2)*"c"* and 600.15.

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[1] January 16, 2013, effective date of the rescission of Chapter 96 and the adoption of new Chapter 96 [ARC 0483C] delayed until adjournment of the 2013 General Assembly by the Administrative Rules Review Committee at its meeting held January 8, 2013; delay lifted at the meeting held March 8, 2013.

CHAPTER 98
MARRIAGE REGISTRATION
[Prior to 12/12/12, see [641] Ch 96, 99.13]

641—98.1(144,595) Definitions. For the purpose of this chapter, the definitions in 641—Chapter 95 shall apply.
[**ARC 0483C**, IAB 12/12/12, effective 1/16/13; see Delay note at end of chapter]

641—98.2(144,595) Forms—property of department. All forms, certificates and reports pertaining to the registration of a marriage are the property of the department and shall be surrendered to the state registrar upon demand.

98.2(1) The forms supplied or approved for reporting a marriage shall be used for official purposes as provided for by statute, rules and instructions of the state registrar.

98.2(2) No forms, except those furnished or approved by the state registrar, shall be used in the reporting of a marriage or the making of copies of vital records.
[**ARC 0483C**, IAB 12/12/12, effective 1/16/13; see Delay note at end of chapter]

641—98.3(144,595) Standard registration of marriage—up to one year. A marriage event that takes place in Iowa shall be prepared on the standard Certificate of Marriage form and submitted for registration within one year from the date of marriage.

98.3(1) Prior to marriage, the applicants shall:

a. Obtain an Application for a License to Marry in Iowa form from the county registrar;

b. Submit to the county registrar the completed application and fee pursuant to Iowa Code section 331.605(6); and

c. Receive a license to marry in Iowa and a Certificate of Marriage form from the county registrar.

98.3(2) Once the marriage is solemnized, the completed certificate of marriage shall be filed with the county registrar where the license to marry was issued. The county registrar shall then forward the certificate of marriage to the state registrar for filing.
[**ARC 0483C**, IAB 12/12/12, effective 1/16/13; see Delay note at end of chapter]

641—98.4(144,595) Application for a license to marry in Iowa.

98.4(1) The Application for a License to Marry in Iowa form is available from any county registrar. The applicants are the parties to be married.

98.4(2) The application shall not be processed until all items on the double-sided application form, including the affidavit of a competent and disinterested person, have been completed. The affidavit shall be completed and signed in front of a notary public by an individual of legal age who is acquainted with both applicants who plan to marry. A family member may serve as the competent and disinterested person.

98.4(3) Each applicant shall verify the personal information by notarized signature.

98.4(4) If an applicant is 16 or 17 years of age, the Certificate of Consent of Underage Party to Marry form shall be completed in accordance with Iowa Code section 595.2(4) and shall be approved by a judge in the county's judicial district before the application for a marriage license may be accepted by the county registrar. Persons 15 years of age or younger may not marry in Iowa.

98.4(5) The Application for a License to Marry in Iowa form shall be signed in front of a notary public by both parties to be married and their competent and disinterested person. By signature, the applicants and their competent and disinterested person are attesting that the applicants are:

a. Eighteen years of age or older or, if either or both are 16 or 17 years of age, that they have provided a signed Certificate of Consent of Underage Party to Marry form;

b. Competent to enter into a civil contract pursuant to Iowa Code section 595.1A;

c. Not legally married to each other and that neither is legally married to someone else who is living; and

d. Acknowledging that they have provided accurate information on the application form.

98.4(6) An applicant is not required to be a U.S. citizen.

98.4(7) The application for a license to marry in Iowa shall be submitted to the registrar in the county where the application and marriage certificate are to be filed. The marriage license is valid in any county in Iowa.

98.4(8) A fee is due upon the submittal of a completed application for the license to marry pursuant to Iowa Code section 331.605(1)*"g."*

98.4(9) At the time of completion of the Application for a License to Marry in Iowa form, the applicants shall indicate the adoption of the legal name to be used after marriage pursuant to Iowa Code section 595.5(1). When the application is filed, the county registrar shall enter the legal name on the License to Marry in Iowa form and the original Certificate of Marriage form. Once the application is filed, any changes to the legal name to be adopted shall only be made prior to the marriage by reapplication and repayment of the application fee unless it can be proven that an obvious typographical error was made when the license or the certificate was prepared. An individual shall have only one legal name at any one time pursuant to Iowa Code section 595.5(2).

98.4(10) The original certificate of marriage shall not later be modified to reflect a court-ordered legal change of name.

[**ARC 0483C**, IAB 12/12/12, effective 1/16/13; see Delay note at end of chapter]

641—98.5(144,595) License to marry.

98.5(1) Upon receipt and acceptance of a completed application for a license to marry in Iowa, the county registrar may issue the license to marry. When the marriage license valid date is computed, the day of application shall be excluded. The license shall become valid after the expiration of three calendar days after the date of application to marry.

98.5(2) The three-day waiting period may be waived by a district judge in the county's judicial district pursuant to Iowa Code section 595.4. An Application for Waiver of 3-Day Waiting Period form is available from the county registrar. If the waiver is granted, the county registrar shall collect the $5 fee for the waiver pursuant to Iowa Code section 595.4.

98.5(3) When a license is issued, the county registrar shall deliver to the applicant the Certificate of Marriage form and provide instructions to ensure the return of a complete and accurate certificate of marriage for filing.

98.5(4) If the license to marry in Iowa is not retrieved from the county registrar within six months from the date of application, the application is void.

98.5(5) The license to marry is proof that proper application to marry in Iowa has been made. The parties to be married shall present the license to the person who will solemnize the marriage pursuant to Iowa Code section 595.10.

[**ARC 0483C**, IAB 12/12/12, effective 1/16/13; see Delay note at end of chapter]

641—98.6(144, 595) Certificate of marriage.

98.6(1) At the time the license to marry in Iowa is issued, the county registrar shall also prepare the original copy of the Certificate of Marriage form. The person solemnizing the marriage shall complete the blank items pertaining to the marriage ceremony and obtain the required signatures.

98.6(2) All participants in the marriage ceremony shall be present at the same time and location within the geographic boundaries of the state of Iowa, including the parties to be married, two witnesses and the officiant. Marriage ceremonies shall not occur by proxy, telephone, or other electronic means.

98.6(3) After the marriage ceremony:

a. The parties married shall sign, at a minimum, their first and last legal name on the Certificate of Marriage form as indicated on the Application for a License to Marry in Iowa form; and

b. Two witnesses present at the ceremony and the officiant shall sign and print their names on the Certificate of Marriage form in the spaces provided. If there is more than one officiant, the signature and name of only one of the officiants shall be on the Certificate of Marriage form.

98.6(4) Photocopies of the certificate of marriage are prohibited prior to registration of the certificate with the county registrar. The officiant shall not affix any kind of seal to the certificate of marriage.

98.6(5) Within 15 days after the marriage ceremony, the officiant who solemnized the marriage shall file for registration the certificate of marriage with the county registrar that issued the marriage license, except as directed pursuant to Iowa Code section 595.16.

98.6(6) Upon registration of the certificate of marriage, the application for a license to marry becomes part of the record of marriage, including the three-day waiver and consent to marriage of a minor, if applicable.

98.6(7) Original certificates of marriage registered by the county registrar shall be forwarded to the state registrar weekly or as directed by the state registrar.

[**ARC 0483C**, IAB 12/12/12, effective 1/16/13; see Delay note at end of chapter]

641—98.7(144,595) Delayed registration of marriage—one year or more after date of event. All Iowa marriages registered one year or more after the date of the marriage shall be prepared on the Delayed Certificate of Marriage form. The state registrar shall require documentary evidence to establish the facts of the marriage pursuant to Iowa Code section 144.16 and subrule 98.7(2). The delayed marriage record shall be registered and maintained solely at the state registrar's office.

98.7(1) *Application.* A completed Delayed Certificate of Marriage form shall be signed before a notary by both parties to the marriage and filed with the state registrar.

98.7(2) *Facts to be established.*

a. The applicant shall submit a notification of record search certified by the state registrar, which shall indicate that no prior certificate of marriage is on file for the persons whose delayed marriage record is to be filed. The notification of record search shall be returned to the applicant and shall not be exchanged for a certified copy of delayed certificate of marriage.

b. The applicant shall substantiate the following with documentary evidence:

(1) The county in Iowa where the license to marry was issued;

(2) The full name of the registrants before and after the marriage;

(3) The date and place of the marriage in Iowa;

(4) The full names of the registrants' parents;

(5) The full names of the two witnesses present at the marriage ceremony; and

(6) The full name and address of the officiant who performed the marriage ceremony.

98.7(3) *Documentary evidence.*

a. To be acceptable for purposes of registration by the state registrar, the delayed certificate of marriage must be supported by:

(1) All of the following:

1. A copy of the issued license to marry in Iowa or the completed application for the license to marry in Iowa secured from the county registrar in the county where the license to marry was issued;

2. A notarized affidavit from two witnesses to the wedding ceremony attesting to the facts of the marriage; and

3. A certified copy transcribed from the official records where the marriage was performed including the date and place of such marriage as attested to by the custodian of such records; or

(2) An affidavit of the person who performed the ceremony documenting that there was a marriage and the date and place of such marriage.

b. The state registrar may require additional documentary evidence to prove the facts of the marriage event.

98.7(4) *Abstraction and certification by the state registrar.* The state registrar shall abstract on the Delayed Certificate of Marriage form a description of each document submitted to support the facts of the marriage event. This abstract shall include:

a. The title, description and signatory from each document presented;

b. The date of the original filing of the document being abstracted; and

c. The facts of the marriage event as established pursuant to paragraph 98.7(2)*"b."*

98.7(5) *Acceptance of documentary evidence for registration.* All documents submitted in support of the delayed registration shall be returned to the applicant after review, abstraction, and registration. The state registrar shall by signature certify that:

a. No prior certificate of marriage is on file for the registrants;

b. The evidence has been reviewed and substantiates the facts of the marriage event; and

c. The abstract of the evidence appearing on the delayed certificate of marriage accurately reflects the nature and content of the document.

98.7(6) *Denial of registration.* In the absence of adequate substantiating evidence or if the state registrar finds reason to question the validity or adequacy of the evidence required to establish a delayed certificate of marriage, the state registrar shall not register the delayed record.

a. The written notice of rejection from the state registrar shall include:

(1) The Delayed Certificate of Marriage form stamped "rejected"; and

(2) The Delayed Evidence Refusal form.

b. Applications for delayed certificates which have not been completed within one year from the date of application may be dismissed at the discretion of the state registrar. Upon dismissal, the state registrar shall advise the applicant, and all documents submitted in support of such registration shall be returned to the applicant. The state registrar shall provide information related to the applicant's right of appeal to the district court.

c. If a request to establish a delayed certificate of marriage is rejected under the provisions of Iowa Code section 144.16, a petition may be filed with the district court for an order to establish a delayed certificate of marriage. The petition shall:

(1) Be made on a form prescribed and furnished by the state registrar.

(2) Allege that diligent efforts by the petitioner have failed to obtain the evidence required in accordance with Iowa Code section 144.16.

(3) Allege that the state registrar has refused to establish the delayed certificate of marriage.

(4) Include such other allegations as may be required.

(5) Be accompanied by a statement of the registration official made in accordance with Iowa Code section 144.16 and all documentary evidence which was submitted to the registration official in support of such registration.

(6) Be verified by the petitioner.

98.7(7) *Duties of county registrar.* The county registrar may assist the applicant in the completion and notarization of the delayed form, excluding the portion restricted for state use only. The county registrar may forward the partially completed delayed form, documents and fees to the state registrar for final review and possible acceptance.

98.7(8) *Fees.* Administrative and certified copy fees shall be charged as provided in rule 641—95.6(144).

[**ARC 0483C**, IAB 12/12/12, effective 1/16/13; see Delay note at end of chapter; **ARC 4398C**, IAB 4/10/19, effective 5/15/19]

641—98.8(144,595) Dissolution of marriage or annulment.

98.8(1) The completed Report of Dissolution of Marriage or Annulment form shall be filed with the clerk of district court within one month from the date of the dissolution of marriage or annulment and be prepared on the official paper issued by the state registrar by one of the following means:

a. Use of a typewriter using a dark blue or black ribbon on the standard form of the report;

b. Use of a computer program that is preapproved by the state registrar;

c. Use of an electronic form prescribed by the state registrar; or

d. As directed by the state registrar.

98.8(2) If an attorney or clerk of district court uses a computer software program to generate the report of dissolution of marriage or annulment, the form shall be reviewed by the state registrar for approval. The state registrar shall deny approval if the form does not conform to the standard Report of Dissolution of Marriage or Annulment form as prescribed.

98.8(3) Clerks of district court shall submit reports of dissolution of marriage or annulment to the state registrar weekly or as directed by the state registrar.

[**ARC 0483C**, IAB 12/12/12, effective 1/16/13; see Delay note at end of chapter]

These rules are intended to implement Iowa Code sections 144.12, 144.16, 331.605(1)*"f"* and *"g,"*595.2(4), 595.4, 595.5, 595.10, and 595.16.

[Filed ARC 0483C (Notice ARC 0376C, IAB 10/3/12), IAB 12/12/12, effective 1/16/13][1]
[Filed ARC 4398C (Notice ARC 4127C, IAB 11/21/18), IAB 4/10/19, effective 5/15/19]

[1] January 16, 2013, effective date of the rescission of Chapter 98 and the adoption of new Chapter 98 [ARC 0483C] delayed until adjournment of the 2013 General Assembly by the Administrative Rules Review Committee at its meeting held January 8, 2013; delay lifted at the meeting held March 8, 2013.

CHAPTER 99
VITAL RECORDS MODIFICATIONS

[Prior to 12/12/12, see [641] Chs 100, 102]

641—99.1(144) Definitions. For the purpose of this chapter, the definitions in 641—Chapter 95 shall apply.
[**ARC 0483C**, IAB 12/12/12, effective 1/16/13; see Delay note at end of chapter]

641—99.2(144) Forms—property of department. All forms, certificates and reports pertaining to the registration of vital events are the property of the department and shall be surrendered to the state registrar upon demand.

99.2(1) The forms supplied or approved for reporting vital events shall be used for official purposes as provided for by law, rules and instructions of the state registrar.

99.2(2) No forms, except those furnished or approved by the state registrar, shall be used in the reporting or modification of vital events or the making of copies of vital records.
[**ARC 0483C**, IAB 12/12/12, effective 1/16/13; see Delay note at end of chapter]

641—99.3(144) Forms used in the establishment of new records. The standard certificate form for reporting of live birth, death, fetal death, or marriage in use at the time of the event shall be used to prepare a new certificate.
[**ARC 0483C**, IAB 12/12/12, effective 1/16/13; see Delay note at end of chapter]

641—99.4(144) Corrections of minor error in vital record—within one year of event.

99.4(1) Corrections of minor errors may be made by the state registrar within one year and prior to the first anniversary of the date of the event upon observation, upon request of the data provider, upon query, or upon request from an entitled person. Minor errors include obvious errors, omissions, or transpositions of letters in words of common knowledge.

99.4(2) For a certificate of live birth, entitled persons include in the following descending order of priority:

a. Either parent as shown on the child's certificate of live birth; or

b. The legal guardian or agency having legal custody of the child.

99.4(3) For a certificate of death or fetal death other than the medical certification, entitled persons include in the following descending order of priority:

a. The surviving spouse as shown on the certificate of death;

b. A parent as shown on the certificate of death or fetal death;

c. The informant as shown on the certificate; or

d. The data provider in the case of a data entry error.

99.4(4) For a certificate of marriage, entitled persons include:

a. The county registrar that issued the license to marry; or

b. Either of the parties married.

99.4(5) Entitled persons requesting a correction shall submit to the state registrar:

a. A notarized statement and a legible copy of current government-issued photo identification or other identification documents acceptable to the state registrar; and

b. Supporting evidence if requested by the state registrar.

(1) The state registrar shall determine a priority of best evidence and may, at the state registrar's discretion, require additional documentary evidence to support the requested correction.

(2) The state registrar shall evaluate the evidence submitted in support of any correction, and when there is reason to question the validity or adequacy of the evidence, the state registrar may reject the request for correction and shall advise the applicant of the reasons for this action.

99.4(6) Only the state registrar shall make corrections on a vital record. The source of information and the date of correction shall be documented on the record but shall not appear on the certified copy.

99.4(7) There are no administrative fees required to correct a certificate pursuant to this rule.

99.4(8) Certificates corrected pursuant to this rule shall not be marked "amended."

99.4(9) Any certified copies of the incorrect certificate shall be surrendered to the state registrar for replacement at no cost pursuant to 641—subrule 95.6(3). Additional certified copies of the corrected certificate may be obtained upon receipt of a notarized application, legible copy of a current government-issued photo identification or other identification documents acceptable to the state registrar and payment of the fee pursuant to 641—paragraph 95.6(1)*"a."*

99.4(10) The corrected certificate shall be on file at the county registrar's office pursuant to rule 641—95.7(144).

[**ARC 0483C**, IAB 12/12/12, effective 1/16/13; see Delay note at end of chapter; **ARC 1075C**, IAB 10/2/13, effective 11/6/13]

641—99.5(144) Amendment of certificate of live birth to add first or middle given name—within one year of event.

99.5(1) The first or middle given name for a child whose birth was reported without a first or middle given name may be amended to add the first or middle given name within one year and prior to the first anniversary of the date of the live birth based upon a completed and notarized Affidavit to Add Child's Given Name form as provided by the department pursuant to Iowa Code section 144.38. The affidavit shall be submitted to the state registrar by entitled persons in the following descending order of priority:

a. The single parent or both parents as shown on the child's certificate of live birth;

b. The mother, in the case of the death or incapacity of the second parent;

c. The second parent if listed on the birth certificate, in the case of the death or incapacity of the mother; or

d. The legal guardian or agency having legal custody of the child.

99.5(2) A first or middle given name may be added to the certificate of live birth once in this manner. Thereafter, a first or middle given name shall be changed only upon submission of a court order for a legal change of name from a court of competent jurisdiction pursuant to Iowa Code chapter 674.

99.5(3) An administrative fee shall be charged and remitted pursuant to 641—paragraph 95.6(1)*"b."*

99.5(4) The original certificate shall be marked "amended" and shall be endorsed on the certified copy. The date of amendment and a summary description of the evidence submitted in support of the amendment shall be made a part of the record.

99.5(5) The certificate shall be on file at the county registrar's office pursuant to rule 641—95.7(144).

99.5(6) Any certified copies of the incorrect certificate shall be surrendered for replacement at no cost. Additional certified copies of the amended certificate may be obtained upon the state registrar's receipt of a notarized application, legible copy of a current government-issued photo identification or other identification documents acceptable to the state registrar, and payment of the fee pursuant to rule 641—95.6(144).

[**ARC 0483C**, IAB 12/12/12, effective 1/16/13; see Delay note at end of chapter; **ARC 1075C**, IAB 10/2/13, effective 11/6/13]

641—99.6(144) Amendment of vital record—one year or more after the event.

99.6(1) Amendments of vital records may be made by the state registrar one year or more after the date of the event upon request from an entitled person or by an order to amend the record by a court of competent jurisdiction. Amendments include the correction of obvious errors, omissions, or transposition of letters in words of common knowledge.

99.6(2) For a certificate of live birth, entitled persons include in the following descending order of priority:

a. The registrant, if the registrant is of legal age, has reached the age of majority or is an emancipated minor;

b. Either parent as shown on the child's certificate of live birth; or

c. The legal guardian or agency having legal custody of the child.

99.6(3) For a certificate of death or fetal death other than the medical certification, entitled persons include:

a. The surviving spouse as shown on the certificate of death;

b. A parent as shown on the certificate of death or fetal death; or

c. The informant as shown on the certificate of death or fetal death.

99.6(4) Amendment of a medical certification of cause of death or fetal death shall be requested solely by the medical certifier listed on the certificate of death or fetal death.

99.6(5) For a certificate of marriage, entitled persons include either of the parties married.

99.6(6) Entitled persons requesting an amendment shall submit the following to the state registrar:

a. A completed and notarized amendment request on the applicable form as follows:

(1) Amendment to Certificate of Live Birth form.

(2) Amendment to Certificate of Death or Fetal Death form.

(3) Amendment to Certificate of Marriage form;

b. A legible copy of a current government-issued photo identification or other identification documents acceptable to the state registrar;

c. Certified copies of one or more pieces of documentary evidence supporting the amendment; and

d. The required fees pursuant to rule 641—95.6(144).

99.6(7) The documentary evidence shall have been established at least five years prior to the date of the application or within seven years of the date of the event.

a. The state registrar shall determine a priority of best evidence and may, at the state registrar's discretion, require additional documentary evidence to support the requested amendment.

b. The state registrar shall evaluate the evidence submitted in support of any amendment, and when there is reason to question the validity or adequacy of the evidence, the state registrar may reject the amendment and shall advise the applicant of the reasons for this action and provide information related to the applicant's right of appeal to the district court pursuant to Iowa Code section 144.38.

c. If a request to amend a certificate of birth is rejected under the provisions of Iowa Code section 144.38, a petition may be filed with the district court for an order amending a vital record. The petition shall:

(1) Be made on a form prescribed and furnished by the state registrar.

(2) Allege that diligent efforts by the petitioner have failed to obtain the evidence required in accordance with Iowa Code section 144.38.

(3) Allege that the state registrar has refused to amend the certificate of vital record.

(4) Include such other allegations as may be required.

(5) Be accompanied by a statement of the registration official made in accordance with Iowa Code section 144.38 and all documentary evidence which was submitted to the registration official in support of such registration.

(6) Be verified by the petitioner.

99.6(8) An administrative fee shall be charged and remitted pursuant to rule 641—95.6(144).

99.6(9) The original certificate shall be clearly marked "amended" and the date of the amendment shall be endorsed on the certified copy. A summary description of the evidence submitted in support of the amendment shall be made a part of the record.

99.6(10) The amended certificate shall be on file at the county registrar's office pursuant to rule 641—95.7(144).

99.6(11) Any certified copies of the incorrect certificate shall be surrendered for replacement at no cost. Additional certified copies of the amended certificate may be obtained upon the state registrar's receipt of a notarized application, legible copy of a current government-issued photo identification or other identification documents acceptable to the state registrar and payment of the fee pursuant to rule 641—95.6(144).

[**ARC 0483C**, IAB 12/12/12, effective 1/16/13; see Delay note at end of chapter; **ARC 1075C**, IAB 10/2/13, effective 11/6/13; **ARC 4398C**, IAB 4/10/19, effective 5/15/19]

641—99.7(144) Method of amendment of vital records.

99.7(1) Records not on the electronic vital records system shall be amended by drawing a single line through the incorrect item and inserting the correct or missing data immediately above or to the side of the item or by completing a blank item. In all cases in which a line must be drawn through an original

entry, the line must not obliterate the original entry. The following shall be endorsed on or made a part of the record:

a. The word "amended" and the date of the amendment action; and

b. A summary of the evidence submitted in support of the amendment.

99.7(2) Records on the electronic vital records system shall be amended by correction of the incorrect item. The following shall be endorsed on or made a part of the record:

a. The word "amended" and the date of the amendment action;

b. A statement identifying the amendment; and

c. A summary of the evidence submitted in support of the amendment.

[**ARC 0483C**, IAB 12/12/12, effective 1/16/13; see Delay note at end of chapter]

641—99.8(144) Correction or amendment of same item more than once. After a correction or an amendment is made on a vital record, that entry shall not be corrected again unless:

99.8(1) It can be proven that an error was made in processing the first correction or amendment; or

99.8(2) A court order is received from a court of competent jurisdiction to correct or amend the item. If a court order for a correction or an amendment is received, an administrative fee shall be charged and remitted pursuant to rule 641—95.6(144).

[**ARC 0483C**, IAB 12/12/12, effective 1/16/13; see Delay note at end of chapter]

641—99.9(144) Other amendments to certificate of live birth.

99.9(1) The parent's name or both parents' names as reported by the parent or parents on the birth worksheet used to establish the certificate of live birth shall only be amended if the amendment is supported by a certified copy of a vital record or amended by an order from a court of competent jurisdiction.

99.9(2) Certificates of live birth of deceased persons shall only be amended if the amendment is supported by a certified copy of a vital record or amended by an order from a court of competent jurisdiction.

[**ARC 0483C**, IAB 12/12/12, effective 1/16/13; see Delay note at end of chapter; **ARC 4398C**, IAB 4/10/19, effective 5/15/19]

641—99.10(144) Correction or amendment to medical certification of cause of death.

99.10(1) Corrections or amendments to the medical certification of cause of death shall be requested solely by the medical certifier listed on the certificate of death or fetal death.

99.10(2) The medical certifier may correct the medical certification of cause of death within 90 days following the date of death or fetal death. The request shall be submitted on official letterhead signed and dated by the medical certifier listed on the certificate of death or fetal death.

99.10(3) Any amendment after 90 days following the date of death or fetal death shall be made by order of a court of competent jurisdiction. However, the medical certification of cause of death may be amended at any time upon submission of a report of autopsy or toxicological findings or additional findings by the county or state medical examiner.

99.10(4) No fee shall be charged for correction or amendment made pursuant to this rule.

[**ARC 0483C**, IAB 12/12/12, effective 1/16/13; see Delay note at end of chapter]

641—99.11(144) Correction or amendment to a certificate of marriage.

99.11(1) The request to correct a certificate of marriage during the first year may be made by the county registrar that issued the license to marry. The written request shall be submitted to the state registrar with supporting evidence.

99.11(2) The request to correct or amend a certificate of marriage may be made by either of the parties married. The written request shall be submitted to the state registrar with supporting evidence.

99.11(3) An order from a court of competent jurisdiction is required to correct or amend a legal name after marriage.

[**ARC 0483C**, IAB 12/12/12, effective 1/16/13; see Delay note at end of chapter; **ARC 4398C**, IAB 4/10/19, effective 5/15/19]

641—99.12(144) Correction to a report of dissolution of marriage or annulment.

99.12(1) A written notice to correct a report of dissolution of marriage or annulment may be submitted to the state registrar by the clerk of district court maintaining the record from which the original report was prepared. The notice shall state in what manner the report shall be corrected.

99.12(2) Those items appearing on the Report of Dissolution of Marriage or Annulment form that are not a part of the divorce decree may be corrected either by query or upon application of either party to the dissolution of marriage or annulment or the legal representative.

99.12(3) Corrections to the report of dissolution of marriage or annulment shall be accepted only within the first year from the date of dissolution of marriage or annulment.

[**ARC 0483C**, IAB 12/12/12, effective 1/16/13; see Delay note at end of chapter]

641—99.13(144) Minimum information required to establish a new certificate of live birth.

99.13(1) A request to establish a new certificate of live birth shall be submitted to the state registrar and include at a minimum the following information:

a. The full name of the child as stated on the original certificate of live birth;

b. The full name of the child to be listed on the new certificate of live birth;

c. The date and place of birth as stated on the original certificate of live birth;

d. The full name of the parent or parents as listed on the original certificate of live birth; and

e. The full name, place of birth, date of birth, and complete residential address of the parent or parents to be listed on the new certificate of live birth.

99.13(2) The new certificate of live birth shall contain the same state file number and registration file date as were assigned to the original certificate of live birth.

[**ARC 0483C**, IAB 12/12/12, effective 1/16/13; see Delay note at end of chapter]

641—99.14(144) Establishment of new certificate of live birth following adoption.

99.14(1) Upon receipt of a completed Certificate of Adoption Report form or a certified copy of the decree of adoption from a court of competent jurisdiction and the information required pursuant to rule 641—99.13(144), the state registrar shall establish a new certificate of live birth for a person who was born in Iowa and has been adopted.

99.14(2) The new certificate of live birth shall not be marked "amended."

99.14(3) When a new certificate of live birth is established, the actual date and place of birth shall be shown on the certificate.

99.14(4) The county registrar and state registrar shall seal the original certificate of live birth. The state registrar shall place the original certificate of live birth and all related adoption information in a sealed file, and the file shall not be opened and inspected except by the state registrar for administrative purposes or upon an order from a court of competent jurisdiction pursuant to Iowa Code section 144.24.

99.14(5) The new certificate of live birth after adoption shall not be on file at the county registrar's office.

99.14(6) The state registrar shall reveal the date of the adoption and the name and address of the court that issued the adoption decree upon the receipt of a completed, notarized Revelation of County of Adoption form from an adult adopted person, a biological parent, an adoptive parent, or the legal representative of the adult adopted person, the biological parent, or the adoptive parent pursuant to Iowa Code section 144.24.

99.14(7) Administrative and certified copy fees shall be charged and remitted pursuant to rule 641—95.6(144).

[**ARC 0483C**, IAB 12/12/12, effective 1/16/13; see Delay note at end of chapter]

641—99.15(144) Establishment of new certificate of live birth following a birth by gestational surrogate arrangement.

99.15(1) All live births shall be considered the product of the woman who delivered the live infant and shall be filed in the standard manner, with that woman named as the birth mother on the original record submitted for registration.

99.15(2) For the purpose of filing for registration the record of a live birth by a gestational surrogate, the institution's or non-institution's person responsible for filing the certificate of live birth shall:

a. Notify the state registrar of the birth of a child pursuant to a gestational surrogate arrangement;

b. Follow directives for completion of the official birth worksheet;

c. Submit the birth record for registration based on the birth mother's information; and

d. Notify the state registrar when the birth record has been submitted for registration.

99.15(3) In addition, the institution's or non-institution's person responsible for filing the record for registration shall:

a. Provide the prenatal and medical data on the medical portion of the birth worksheet pertinent to the pregnancy and the birth mother's prenatal care;

b. Waive all birth registration and copy fees as collected on behalf of the state registrar;

c. Indicate on the registration that the birth mother does not have custody of the infant;

d. Assist in advising the intended parents of the procedures required to file the original birth record for registration and to reestablish the record to reflect the intended parents' information; and

e. Advise the birth mother to complete the mother's portion of the birth worksheet and to mark "no" for the social security card for the child.

99.15(4) Two intended parents—both intended parents are biological parents to the child. If the intended mother is the egg donor and the intended father is the sperm donor to the child being carried by the gestational surrogate:

a. After the birth of the child, the intended parents shall petition a court of competent jurisdiction to establish legal paternity and maternity of the child.

b. The court shall enter an order requiring the state registrar to reestablish the certificate of live birth naming the intended mother and father as the legal mother and father and requiring the state registrar to seal the original birth certificate and all related documentation.

c. The court order shall:

(1) Identify the child's full name as stated on the original certificate of live birth;

(2) State the child's date of birth and place of birth;

(3) Identify the full names of the birth mother and her legal spouse, if married;

(4) Disestablish the birth mother and her legal spouse, if married, as the legal parents of the child; and

(5) Identify the intended parents' full names prior to any marriage, full current legal names, dates of birth, birthplaces, social security numbers, and full current residential address including county.

d. The intended parents or their legal representative shall:

(1) Submit a certified copy of the court order to the state registrar;

(2) Remit administrative and certified copy fees pursuant to rule 641—95.6(144); and

(3) Include a notarized written request with mailing instructions for the certified copy of the certificate of live birth.

99.15(5) Two intended parents—intended mother is biological mother to the child; her legal spouse is not a biological parent. If the intended mother is the egg donor but her legal spouse is not the sperm donor, the intended mother shall petition a court of competent jurisdiction after the birth of the child to establish legal maternity.

a. The court shall enter an order requiring the state registrar to reestablish the certificate of live birth naming the intended mother as the legal mother and shall require the state registrar to seal the original certificate of live birth and all related documents.

b. The court order establishing legal maternity shall:

(1) Identify the child's full name as stated on the original certificate of live birth;

(2) State the child's date of birth and place of birth;

(3) Identify the full names of the birth mother and her legal spouse, if married;

(4) Disestablish the birth mother and her legal spouse, if married, as the legal parents of the child; and

(5) Identify the intended mother's full name prior to any marriage, full current name, date of birth, birthplace, social security number, and full current residential address including county.

c. The intended mother or her legal representative shall:

(1) Submit a certified copy of the court order to the state registrar;

(2) Remit administrative and certified copy fees pursuant to rule 641—95.6(144); and

(3) Include a notarized written request with mailing instructions for the certified copy of the certificate of live birth.

99.15(6) Two intended parents—intended father is biological father to the child; his legal spouse is not a biological parent.

a. If the surrogate birth mother is unmarried and the intended father is the sperm donor, the unmarried surrogate birth mother and the intended father may complete a Voluntary Paternity Affidavit form after the child's birth to place the intended father's name and information on the certificate of live birth.

b. If the surrogate birth mother is married and the intended father is the sperm donor, the married surrogate birth mother and the intended father shall by court order disestablish the surrogate birth mother's legal spouse as the legal parent and may complete a Voluntary Paternity Affidavit form pursuant to Iowa Code section 144.13.

c. The court order that disestablishes the married surrogate birth mother's legal spouse and the completed Voluntary Paternity Affidavit form shall be submitted to the state registrar.

d. If a certified copy of the certificate of live birth is requested, a notarized written request shall also be submitted to the state registrar with the certified copy fee and mailing instructions.

e. There is no administrative fee to process the completed Voluntary Paternity Affidavit form.

f. Adoption laws shall be followed to reestablish the certificate of live birth by establishing the nonbiological parent on the certificate of live birth pursuant to Iowa Code chapter 600.

99.15(7) Two intended parents—neither biological parent to the child. If the intended parents are neither the egg donor nor sperm donor, adoption laws shall be followed to reestablish the certificate of live birth by disestablishing the birth mother and her legal spouse, if any, and establishing the nonbiological parents on the certificate of live birth pursuant to Iowa Code chapter 600.

99.15(8) One female intended parent—biological mother to the child. If the intended mother is the egg donor to the child being carried by the gestational surrogate:

a. After the birth of the child, the intended mother shall petition a court of competent jurisdiction to establish legal maternity of the child.

b. The court shall enter an order requiring the state registrar to reestablish the certificate of live birth naming the intended mother as the legal mother and requiring the state registrar to seal the original certificate of live birth and all related documentation.

c. The court order shall:

(1) Identify the child's full name as stated on the original certificate of live birth;

(2) State the child's date of birth and place of birth;

(3) Identify the full names of the birth mother and her legal spouse, if married;

(4) Disestablish the birth mother and her legal spouse, if married, as the legal parents of the child; and

(5) Identify the intended parent's full name prior to any marriage, full current legal name, date of birth, birthplace, social security number, and full current residential address including county.

d. The intended parent or her legal representative shall:

(1) Submit a certified copy of the court order to the state registrar;

(2) Remit administrative and certified copy fees pursuant to rule 641—95.6(144); and

(3) Include a notarized written request with mailing instructions for the certified copy of the certificate of live birth.

99.15(9) One male intended parent—biological father to the child.

a. If the surrogate birth mother is unmarried and the intended father is the sperm donor, the unmarried surrogate birth mother and the intended father may complete a Voluntary Paternity Affidavit form after the child's birth to place the intended father's name and information on the certificate of live birth.

b. If the surrogate birth mother is married and the intended father is the sperm donor, the married surrogate birth mother and the intended father shall by court order disestablish the surrogate birth

mother's legal spouse as the legal parent and may complete a Voluntary Paternity Affidavit form pursuant to Iowa Code section 144.13.

c. The court order that disestablishes the married surrogate birth mother's legal spouse and the completed Voluntary Paternity Affidavit form shall be submitted to the state registrar.

d. If a certified copy of the certificate of live birth is requested, a notarized written request shall also be submitted to the state registrar with the certified copy fee and mailing instructions.

e. There is no administrative fee to process the completed Voluntary Paternity Affidavit form.

f. If the intended father has been established as the legal father pursuant to paragraph 99.15(9)*"a"* or *"b"* and the surrogate birth mother and the intended father wish to remove the surrogate birth mother as the legal mother from the certificate of live birth, the parties shall seek a court order. The court order disestablishing legal maternity shall:

(1) Identify the child's full name as stated on the original certificate of live birth;

(2) State the child's date of birth and place of birth;

(3) Identify the full name of the birth mother; and

(4) Disestablish the birth mother as the legal parent of the child.

g. The intended parent or his legal representative shall:

(1) Submit a certified copy of the court order to the state registrar;

(2) Remit administrative and certified copy fees pursuant to rule 641—95.6(144); and

(3) Include a notarized written request with mailing instructions for the certified copy of the certificate of live birth.

99.15(10) One intended parent—not biological parent to the child. If the intended parent is neither the egg donor nor sperm donor, adoption laws shall be followed to reestablish the certificate of live birth by disestablishing the birth mother and her legal spouse, if any, and establishing the nonbiological parent on the certificate of live birth pursuant to Iowa Code chapter 600.

99.15(11) The state registrar shall seal the original certificate of live birth. The state registrar shall place the original certificate of live birth and all related documents in a sealed file, and the file shall not be opened and inspected except by the state registrar for administrative purposes or upon an order from a court of competent jurisdiction pursuant to Iowa Code section 144.24.

99.15(12) The new certificate of live birth shall not be marked "amended."

99.15(13) The new certificate of live birth shall not be on file at the county registrar's office pursuant to rule 641—95.7(144).

99.15(14) A certified copy fee and an administrative fee to replace a parent's information on a certificate of live birth shall be charged and remitted pursuant to rule 641—95.6(144).

[**ARC 0483C**, IAB 12/12/12, effective 1/16/13; see Delay note at end of chapter; **ARC 1075C**, IAB 10/2/13, effective 11/6/13]

641—99.16(144) Certificate of live birth following voluntary paternity affidavit.

99.16(1) If the birth mother was legally married at the time of conception or birth or at any time during the period between conception and birth, the name of her spouse shall be entered on the certificate of live birth as a parent pursuant to Iowa Code section 144.13.

99.16(2) If the birth mother was not legally married at the time of conception or birth or at any time during the period between conception and birth, the birth mother and the alleged biological father may:

a. Complete a Voluntary Paternity Affidavit form after the birth of the child; and

b. Submit the completed form to the state registrar.

99.16(3) If the birth mother was legally married at the time of conception or birth or at any time during the period between conception and birth, and her legal spouse is not the biological father, the birth mother and the alleged biological father may:

a. Complete a Voluntary Paternity Affidavit form after the birth of the child;

b. Obtain a court order that disestablishes her legal spouse as a parent; and

c. Submit the completed form and a certified copy of the court order to the state registrar.

99.16(4) If the birth mother and the biological father of an Iowa-born child subsequently marry each other after a voluntary affidavit of paternity has been processed, the parents may submit a second

completed Voluntary Paternity Affidavit form with a certified copy of the parents' certificate of marriage to establish a new certificate changing the child's last name to that of the father.

99.16(5) If another man is shown as the father on the original certificate of live birth, a new certificate of live birth may be established only when a determination of paternity is made by a court of competent jurisdiction.

99.16(6) There is no age limitation and no fee for filing a completed Voluntary Paternity Affidavit form.

99.16(7) The county registrar and the state registrar shall seal the original certificate of live birth. The state registrar shall place the original certificate of live birth and all related documents in a sealed file, and the file shall not be opened and inspected except by the state registrar for administrative purposes or upon an order from a court of competent jurisdiction pursuant to Iowa Code section 144.24.

99.16(8) A copy of the completed and processed Voluntary Paternity Affidavit form may be acquired by either parent or either parent's legal representative upon notarized application and payment of the fee pursuant to rule 641—95.6(144). The notarized application shall include at a minimum the following items:

a. The child's full name;

b. The child's date and place of birth;

c. The mother's full name prior to any marriage; and

d. The full name and mailing address of the applicant.

99.16(9) The new certificate of live birth shall not be marked "amended."

99.16(10) The new certificate of live birth shall be on file at the county registrar's office pursuant to rule 641—95.7(144).

99.16(11) The birth mother and the biological father shall surrender any incorrect certified copies of the child's certificate of live birth for replacement at no cost. Additional certified copies of the new certificate of live birth shall be acquired upon receipt of a notarized application, legible copy of a current government-issued photo identification or other identification documents acceptable to the state registrar and payment of the fee pursuant to rule 641—95.6(144).

[**ARC 0483C**, IAB 12/12/12, effective 1/16/13; see Delay note at end of chapter; **ARC 1075C**, IAB 10/2/13, effective 11/6/13]

641—99.17(144) Certificate of live birth following court determination of paternity.

99.17(1) If the birth mother was married at the time of conception or birth or at any time during the period between conception and birth, the name of her spouse shall be entered on the certificate of live birth as a parent unless paternity has been determined otherwise by a court of competent jurisdiction pursuant to Iowa Code section 144.13.

99.17(2) Upon receipt of a certified copy of the court determination of paternity order from a court of competent jurisdiction or the completed Abstract From Court Determination of Paternity form, the state registrar shall establish a new certificate of live birth to be filed in place of the original certificate of live birth.

99.17(3) The new certificate of live birth shall list the name of the child as stated in the court determination of paternity order.

99.17(4) The state child support recovery unit may not change the child's name.

99.17(5) After a court determination of paternity has been completed, the parents as listed on the court order may submit a completed Voluntary Paternity Affidavit form to change the child's last name to that of the established father.

99.17(6) The county registrar and the state registrar shall seal the original certificate of live birth. The state registrar shall place the original certificate of live birth and all related documents in a sealed file, and the file shall not be opened and inspected except by the state registrar for administrative purposes or upon an order from a court of competent jurisdiction pursuant to Iowa Code section 144.24.

99.17(7) The new certificate of live birth shall not be marked "amended."

99.17(8) The new certificate of live birth shall be on file at the county registrar's office pursuant to rule 641—95.7(144).

99.17(9) There are no administrative fees required to establish a new certificate of live birth following a court determination of paternity.

99.17(10) Any incorrect certified copy of the child's certificate of live birth shall be surrendered for replacement at no cost. Additional certified copies of the new certificate of live birth shall be acquired upon receipt of a notarized application, legible copy of a current government-issued photo identification or other identification documents acceptable to the state registrar and payment of the fee pursuant to rule 641—95.6(144).

[**ARC 0483C**, IAB 12/12/12, effective 1/16/13; see Delay note at end of chapter; **ARC 1075C**, IAB 10/2/13, effective 11/6/13]

641—99.18(144) Certificate of live birth following recision of paternity affidavit or disestablishment of paternity.

99.18(1) An application to rescind a voluntary paternity affidavit shall be made on the Recision of Paternity Affidavit form by either the birth mother or the putative father who originally completed and signed the Voluntary Paternity Affidavit form pursuant to Iowa Code section 252A.3A.

a. The completed Recision of Paternity Affidavit form shall be notarized and received by the state registrar within the earlier of either 60 days from the latest notarized parental signature on the original Voluntary Paternity Affidavit form or entry of a court order regarding the child by the Iowa child support recovery unit pursuant to Iowa Code section 252A.3A.

b. Acceptance of the completed Recision of Paternity Affidavit form shall remove the alleged biological father's information from the certificate of live birth and rescind the voluntary paternity affidavit.

c. The child's last name shall revert to the last name as it was listed on the certificate of live birth prior to the voluntary paternity affidavit.

d. The state registrar shall send a written notice of the recision to the last-known address of the signatory of the voluntary paternity affidavit who did not sign the Recision of Paternity Affidavit form.

e. After the completed Recision of Paternity Affidavit form has been accepted and processed, the state registrar shall not accept any subsequent Voluntary Paternity Affidavit forms signed by the same mother and putative father relating to the same child pursuant to Iowa Code section 252A.3A.

99.18(2) Upon receipt of a court-ordered disestablishment of paternity, the father's information shall be removed from the certificate of live birth. The child's last name shall revert to the last name as it was listed on the certificate of live birth prior to the establishment of paternity.

99.18(3) An administrative fee shall be charged and remitted pursuant to rule 641—95.6(144).

99.18(4) The county registrar and the state registrar shall seal the original certificate of live birth. The state registrar shall place the recision of paternity information in the same sealed file as the original certificate of live birth and all previous related documents. The file shall not be opened and inspected except by the state registrar for administrative purposes or upon an order from a court of competent jurisdiction pursuant to Iowa Code section 144.24.

99.18(5) The new certificate of live birth shall not be marked "amended."

99.18(6) The new certificate of live birth shall be on file at the county registrar's office pursuant to rule 641—95.7(144).

99.18(7) Any incorrect certified copies of the child's certificate of live birth shall be surrendered for replacement at no cost. Additional certified copies of the new certificate of live birth shall be acquired upon receipt of a notarized application, legible copy of a current government-issued photo identification or other identification documents acceptable to the state registrar and payment of the fee pursuant to rule 641—95.6(144).

[**ARC 0483C**, IAB 12/12/12, effective 1/16/13; see Delay note at end of chapter]

641—99.19(144) Certificate of live birth following court-ordered change of name.

99.19(1) For a court-ordered name change, a certified copy of an order from a court of competent jurisdiction pursuant to Iowa Code chapter 674 or an Abstract to Change Registrant's Legal Name form completed by the clerk of district court changing the name shall be submitted to the state registrar.

99.19(2) Only the person named on the record, parent or parents if the registrant is a minor child, legal guardian, or legal representative may request a court-ordered change of name.

99.19(3) The court order or abstract shall contain:

a. The registrant's full name as it appears on the original certificate of live birth;

b. The registrant's date and place of birth;

c. The mother's full maiden name and father's full name as it appears on the original certificate of live birth;

d. The registrant's full new name; and

e. The certification of the clerk of district court.

99.19(4) The certified copy of a certificate of live birth after a legal change of name shall be clearly marked "legal change of name" and note the following:

a. The registrant's full name as shown on the original certificate;

b. Any previous legal name changes;

c. The registrant's full new name according to the court order;

d. The date the legal change of name order was granted; and

e. The name of the court that ordered the name change pursuant to Iowa Code chapter 674.

99.19(5) A parent cannot be added to the certificate of live birth with a court-ordered change of name.

99.19(6) The county registrar and the state registrar shall seal the original certificate of live birth. The state registrar shall place the original certificate of live birth and all related documents in a sealed file, and the file shall not be opened and inspected except by the state registrar for administrative purposes or upon an order from a court of competent jurisdiction pursuant to Iowa Code section 144.24.

99.19(7) After the court-ordered change of name, the certificate of live birth shall not be on file at the county registrar's office pursuant to rule 641—95.7(144).

99.19(8) An administrative fee shall be charged and remitted pursuant to rule 641—95.6(144).

99.19(9) Any incorrect certified copies of the certificate shall be surrendered for replacement at no cost. Additional certified copies of the new certificate shall be acquired upon receipt of a notarized application, legible copy of a current government-issued photo identification or other identification documents acceptable to the state registrar and payment of the fee pursuant to rule 641—95.6(144).

[**ARC 0483C**, IAB 12/12/12, effective 1/16/13; see Delay note at end of chapter]

641—99.20(144) Certificate of live birth following sex designation change.

99.20(1) After surgery or other treatment to change a sex designation, the registrant shall submit to the state registrar a notarized affidavit from the physician and surgeon, or osteopathic physician and surgeon, completing the sex designation treatment stating the following:

a. The sex designation has been permanently changed by surgery or other treatment;

b. Description of the medical procedures; and

c. The physician and surgeon or osteopathic physician and surgeon's full name, address, state of medical license, and medical license number.

99.20(2) The medical affidavit shall be accompanied by a completed and notarized Amendment to Certificate of Live Birth form.

99.20(3) If the registrant's name is to be changed on the certificate of live birth, the registrant shall submit to the state registrar a certified copy of the court-ordered change of name.

99.20(4) Pursuant to Iowa Code section 144.23, the state registrar may make further investigation or require further information necessary to determine whether a sex change has occurred.

99.20(5) The county registrar and the state registrar shall seal the original certificate of live birth. The state registrar shall place the original certificate of live birth and all related documents in a sealed file, and the file shall not be opened and inspected except by the state registrar for administrative purposes or upon an order from a court of competent jurisdiction pursuant to Iowa Code section 144.24.

99.20(6) The certificate of live birth after the sex designation change shall not be on file at the county registrar's office pursuant to rule 641—95.7(144).

99.20(7) The new certificate of live birth shall not be marked "amended."

99.20(8) Administrative fees shall be charged and remitted pursuant to rule 641—95.6(144).

99.20(9) Any incorrect certified copies of the certificate shall be surrendered for replacement at no cost. Additional certified copies of the new certificate shall be acquired upon receipt of a notarized application, legible copy of a current government-issued photo identification or other identification documents acceptable to the state registrar and payment of the fee pursuant to rule 641—95.6(144).
[**ARC 0483C**, IAB 12/12/12, effective 1/16/13; see Delay note at end of chapter]

These rules are intended to implement Iowa Code sections 144.19 to 144.21, 144.23, 144.24, 144.25A, 144.38 to 144.41, 252A.3A, 600.15, 600.16A, 674.2, 674.7 and 674.9.

[Filed ARC 0483C (Notice ARC 0376C, IAB 10/3/12), IAB 12/12/12, effective 1/16/13][1]
[Filed ARC 1075C (Notice ARC 0925C, IAB 8/7/13), IAB 10/2/13, effective 11/6/13]
[Filed ARC 4398C (Notice ARC 4127C, IAB 11/21/18), IAB 4/10/19, effective 5/15/19]

[1] January 16, 2013, effective date of the rescission of Chapter 99 and the adoption of new Chapter 99 [ARC 0483C] delayed until adjournment of the 2013 General Assembly by the Administrative Rules Review Committee at its meeting held January 8, 2013; delay lifted at the meeting held March 8, 2013.

CHAPTER 154
MEDICAL CANNABIDIOL PROGRAM

641—154.1(124E) Definitions. For the purposes of these rules, the following definitions shall apply:

"Acceptance criteria" means the specified limits placed on characteristics of an item or method that are used to determine data quality.

"Accreditation" means the procedure by which an authoritative body gives formal recognition that an organization is competent to carry out specific tasks and verifies that the appropriate quality management system is in place.

"Accredited nonpublic school" means any nonpublic school accredited by the Iowa state board of education, excluding home schools.

"Action level" means the threshold value that provides the criterion for determining whether a sample passes or fails a test performed pursuant to these rules.

"Aliquot" means a portion of a sample that is used in an analysis.

"Analyte" means a chemical, compound, element, bacteria, yeast, fungus, or toxin to be identified or measured.

"Analytical batch" means a group of samples that are prepared together for the same analysis and analyzed sequentially using the same instrument calibration curve and common analytical quality control checks.

"Analytical method" means a technique used qualitatively or quantitatively to determine the composition of a sample or a microbial contamination of a sample.

"Audit" means a financial review by an independent certified public accountant that includes select scope engagement or other methods of review that analyze operational or compliance issues.

"Background investigation" means a thorough review of an entity, an owner, investors, and employees conducted by the department of public safety, including but not limited to state and national criminal history records, credit records, and internal revenue service records.

"Batch" means a set of cannabis plants that are grown, harvested, and processed together, such that they are exposed to substantially similar conditions throughout cultivation and processing.

"Batch number" means a unique numeric or alphanumeric identifier assigned to a batch of cannabis plants by a manufacturer when the batch is first planted. The batch number shall contain the manufacturer's number and a sequence to allow for inventory and traceability.

"Biosecurity" means a set of preventative measures designed to reduce the risk of transmission of:

1. Infectious diseases in crops;
2. Quarantined pests;
3. Invasive alien species;
4. Living modified organisms.

"Bordering state" means the same as defined in Iowa Code section 331.910.

"Cannabinoid" means a chemical compound that is unique to and derived from cannabis.

"Cannabis" means seeds, plants, cuttings, or plant waste material from *Cannabis sativa* L. or *Cannabis indica* used in the manufacture of medical cannabidiol.

"CAS number" means a unique numerical identifier assigned to every chemical substance described in the open literature by Chemical Abstracts Service.

"CBD" means cannabidiol, Chemical Abstracts Service number 13956-29-1.

"CBDA" means cannabidiolic acid, Chemical Abstracts Service number 1244-58-2.

"CBG" means cannabigerol, Chemical Abstracts Service number 25654-31-3.

"CBN" means cannabinol, Chemical Abstracts Service number 521-35-7.

"Certificate of analysis" means the report prepared for the requester about the analytical testing performed and the results obtained by a laboratory.

"Certification" means a procedure by which a third party gives written assurance (certificate of conformity) that a product, process or service conforms to specified requirements.

"Certified" means that a laboratory demonstrates to the satisfaction of the department its ability to consistently produce valid data within the acceptance limits as specified in the department's

requirements for certification and meets the minimum requirements of this chapter and all applicable regulatory requirements.

"Certified reference material" means a reference material prepared by a certifying body.

"Crop input" means any substance applied to or used in the cultivation and growth of a cannabis plant. "Crop input" includes, but is not limited to, pesticides, fungicides, fertilizers, and other soil or medium amendments.

"Data-quality assessment" means a scientific and statistical process that establishes whether the collected data are of the right type, quality, and quantity to support the intended use of the data.

"Date of expiration" means one year from the date of issuance of the medical cannabidiol registration card by the department of transportation.

"Date of issuance" means the date of issuance of the medical cannabidiol registration card by the department of transportation.

"Debilitating medical condition" means any of the following:

1. Cancer, if the underlying condition or treatment produces one or more of the following:
   - Severe or chronic pain.
   - Nausea or severe vomiting.
   - Cachexia or severe wasting.
2. Multiple sclerosis with severe and persistent muscle spasms.
3. Seizures, including those characteristic of epilepsy.
4. AIDS or HIV as defined in Iowa Code section 141A.1.
5. Crohn's disease.
6. Amyotrophic lateral sclerosis.
7. Any terminal illness, with a probable life expectancy of under one year, if the illness or its treatment produces one or more of the following:
   - Severe or chronic pain.
   - Nausea or severe vomiting.
   - Cachexia or severe wasting.
8. Parkinson's disease.
9. Untreatable pain.

"Department" means the Iowa department of public health.

"Department of transportation" means the Iowa department of transportation.

"Director" means the director of the Iowa department of public health.

"Dispensary" means an individual or entity licensed by the department to dispense medical cannabidiol to patients and primary caregivers pursuant to Iowa Code chapter 124E and these rules. "Dispensary" includes the employees and agents of the dispensary.

"Dispensary facility" means any secured building, space, grounds, and physical structure of a dispensary licensed by the department to dispense medical cannabidiol and where the dispensing of medical cannabidiol is authorized.

"Dispense" or *"dispensing"* means to supply medical cannabidiol to patients pursuant to Iowa Code chapter 124E and these rules.

"Disqualifying felony offense" means a violation under federal or state law of a felony under federal or state law, which has as an element the possession, use, or distribution of a controlled substance, as defined in 21 U.S.C. §802(6).

"Edible medical cannabidiol products" means food items containing medical cannabidiol. "Edible medical cannabidiol products" does not include pills, tinctures, oils, or other forms of medical cannabidiol that may be consumed orally or through the nasal cavity that do not contain food or food additives; provided that food or food additives used as carriers, excipients, or processing aids shall not be considered food or food additives.

"Field duplicate sample" means a sample that is taken in the identical manner and from the same batch, process lot, or lot being sampled as the primary sample. A field duplicate sample is analyzed separately from the primary sample and is used for quality control only.

"Form and quantity" means the types and amounts of medical cannabidiol allowed to be dispensed to a patient or primary caregiver as approved by the department subject to recommendation by the medical cannabidiol board and approval by the board of medicine.

"Frequency" means the number of items occurring in a given category. Frequency may be determined by analytical method or laboratory-specific requirements for the purpose of accuracy, precision of the analysis, or statistical calculation.

"Health care practitioner" means an individual licensed under Iowa Code chapter 148 to practice medicine and surgery or osteopathic medicine and surgery who is a patient's primary care provider. "Health care practitioner" shall not include a physician assistant licensed under Iowa Code chapter 148C or an advanced registered nurse practitioner licensed pursuant to Iowa Code chapter 152 or 152E.

"Increment" or *"sample increment"* means a smaller sample that, together with other increments, makes up the primary sample.

"Inspection" means an on-site evaluation by the department, the department of public safety, or a department-approved independent consultant of facilities, records, personnel, equipment, methodology, and quality assurance practices for compliance with these rules.

"International Electrotechnical Commission" or *"IEC"* means an independent, nongovernmental membership organization that prepares and publishes international standards for all electrical, electronic, and related technologies.

"International Organization for Standardization" or *"ISO"* means an independent, nongovernmental membership organization and the largest developer of voluntary international standards.

"Laboratory" means the state hygienic laboratory at the University of Iowa or other independent medical cannabidiol testing facility accredited to Standard ISO/IEC 17025 by an ISO-approved accrediting body, with a controlled substance registration certificate from the Drug Enforcement Administration of the U.S. Department of Justice and a certificate of registration from the Iowa board of pharmacy, and approved by the department to examine, analyze, or test samples of medical cannabidiol or any substance used in the manufacture of medical cannabidiol.

"Limit of detection" or *"LOD"* means the lowest quantity of a substance or analyte that can be distinguished from the absence of that substance within a stated confidence limit.

"Limit of quantitation" or *"LOQ"* means the minimum concentration of an analyte in a specific matrix that can be reliably quantified while also meeting predefined goals for bias and imprecision.

"Lot" means a specific quantity of medical cannabidiol that is uniform and intended to meet specifications for identity, strength, purity, and composition, and that is manufactured, packaged, and labeled during a specified time period according to a single manufacturing, packaging, and labeling record.

"Lot number" means a unique numeric or alphanumeric identifier assigned to a lot by a manufacturer when medical cannabidiol is produced. The lot number shall contain the manufacturer's number and a sequence to allow for inventory, traceability, and identification of the plant batches used in the production of a lot of medical cannabidiol.

"Manufacture" or *"manufacturing"* means the process of converting harvested cannabis plant material into medical cannabidiol.

"Manufacturer" means an individual or entity licensed by the department to produce medical cannabidiol and distribute it to dispensaries pursuant to Iowa Code chapter 124E and these rules. "Manufacturer" includes the employees and agents of the manufacturer.

"Manufacturing facility" means any secured building, space, grounds, and physical structure of a manufacturer for the cultivation, harvesting, packaging, processing, storage, and distribution of cannabis or medical cannabidiol and where access is restricted to designated employees of a manufacturer and escorted visitors.

"Market withdrawal" means the voluntary removal of medical cannabidiol from dispensaries and patients by a manufacturer for minor issues that do not pose a serious health threat.

"Mass spectrometry" means an analytical technique that ionizes chemical species and sorts the ions based on their mass-to-charge ratio.

"Matrix" means the component or substrate that contains the analyte of interest.

"Matrix spike duplicate" means a duplicate sample prepared by adding a known quantity of a target analyte to a field sample matrix or other matrix that is as closely representative of the matrix under analysis as possible.

"Matrix spike sample" means a sample prepared by adding a known quantity of the target analyte to a field sample matrix or to a matrix that is as closely representative of the matrix under analysis as possible.

"Medical assistance program" means IA Health Link, Medicaid Fee-for-Service, or HAWK-I, as administered by the Iowa Medicaid enterprise of the Iowa department of human services.

"Medical cannabidiol" means any pharmaceutical grade cannabinoid found in the plant *Cannabis sativa* L. or *Cannabis indica* or any other preparation thereof that has a tetrahydrocannabinol level of no more than 3 percent and that is delivered in a form recommended by the medical cannabidiol board, approved by the board of medicine, and designated in this chapter.

"Medical cannabidiol waste" means medical cannabidiol that is returned, damaged, defective, expired, or contaminated.

"Medical cannabis goods" means medical cannabidiol process lots, medical cannabidiol products, and cannabis plant material, including dried tissue.

"Method blank" means an analyte-free matrix to which all reagents are added in the same volumes or proportions as are used in sample preparation.

"Moisture content" means the percentage of water in a dry sample by weight.

"National criminal history background check" means fingerprint processing through the department of public safety and the Federal Bureau of Investigation (FBI) and review of records on file with national organizations, courts, and law enforcement agencies to the extent allowed by law.

"Non-target organism" means an organism that the test method or analytical procedure is not testing for. Non-target organisms are used in evaluating the specificity of a test method.

"Patient" means a person who is a permanent resident of the state of Iowa who suffers from a debilitating medical condition that qualifies for the use of medical cannabidiol pursuant to Iowa Code chapter 124E and these rules.

"Percent recovery" means the percentage of a measured concentration relative to the added (spiked) concentration in a reference material, matrix spike sample, or matrix spike duplicate.

"Permanent resident" means a natural person who physically resides in Iowa as the person's principal and primary residence and who establishes evidence of such residency by providing the department with one of the following:

1. A valid Iowa driver's license,
2. A valid Iowa nonoperator's identification card,
3. A valid Iowa voter registration card,
4. A current Iowa vehicle registration certificate,
5. A utility bill,
6. A statement from a financial institution,
7. A residential lease agreement,
8. A check or pay stub from an employer,
9. A child's school or child care enrollment documents,
10. Valid documentation establishing a filing for homestead or military tax exemption on property located in Iowa, or
11. Other valid documentation as deemed acceptable by the department to establish residency.

"Pharmaceutical grade" means medical cannabidiol that meets standards for content, contamination, and consistency set by the department as determined by testing conducted at a laboratory pursuant to Iowa Code chapter 124E and these rules.

"Plant material" means any cannabis plant, cutting, trimming, or clone that has roots or that is cultivated with the intention of growing roots.

"Plant material waste" means plant material that is not used in the production of medical cannabidiol in a form allowable under these rules.

"Primary caregiver" means a person who is a resident of this state or a bordering state, including but not limited to a parent or legal guardian, at least 18 years of age, who has been designated by a patient's health care practitioner as a necessary caretaker taking responsibility for managing the well-being of the patient with respect to the use of medical cannabidiol pursuant to the provisions of Iowa Code chapter 124E and these rules.

"Primary care provider" means any health care practitioner involved in the diagnosis and treatment of a patient's debilitating medical condition.

"Primary sample" means a portion of a batch, process lot, or lot that is used for testing for identity, strength, purity, and composition.

"Process lot" means any amount of cannabinoid concentrate or extract that is uniform, produced from one or more batches, and used for testing for identity, strength, purity, and composition prior to being packaged.

"Product expiration date" means the date after which a medical cannabidiol product may not be sold by a manufacturer or a dispensary.

"Production" or *"produce"* means:

1. Cultivating or harvesting plant material;
2. Processing or manufacturing; or
3. Packaging of medical cannabidiol.

"Proficiency test" means an evaluation of a laboratory's performance against preestablished criteria by means of interlaboratory comparisons of test measurements.

"Proficiency test sample" means a sample prepared by a party independent of the testing laboratory, with a concentration and identity of an analyte that is known to the independent party but is unknown to the testing laboratory and testing laboratory personnel.

"Public or private school" means any property operated by a school district, charter school, or accredited nonpublic school for purposes related to elementary, middle, or secondary schools or secondary vocation centers.

"Qualitative analysis" means identification of an analyte in a substance or mixture.

"Quality assurance" means a set of operating principles to produce data of known accuracy and precision. "Quality assurance" encompasses employee training, equipment preventative maintenance procedures, calibration procedures, and quality control testing, among other things.

"Quality control" means a set of measures implemented within an analytical procedure to ensure that the measurement system is operating in a state of statistical control in which errors have been reduced to acceptable levels.

"Quality control samples" means samples produced and used for the purpose of assuring quality control. Quality control samples include but are not limited to blank samples, spike samples, duplicate samples, and reference material samples.

"Quantitative analysis" means measurement of the quantities of chemical components present in a substance or mixture. Quantitative analysis typically uses a certified reference material, if available, to create a calibration curve.

"Reagent" means a compound or mixture added to a system to cause a chemical reaction or to test if a reaction occurs. A reagent may be used to tell whether or not a specific chemical substance is present by causing a reaction to occur with the chemical substance.

"Recall" means the return of medical cannabidiol from patients and dispensaries to a manufacturer because of the potential for serious health consequences from the use of the medical cannabidiol.

"Reference material" means a material containing a known concentration of an analyte of interest that is in solution or in a homogeneous matrix. Reference material is used to document the bias of the analytical process.

"Reference method" means a method by which the performance of an alternate method is measured or evaluated.

"Relative percent difference" or *"RPD"* means a comparative statistic used to calculate precision or random error. RPD is calculated using the following equation: RPD = absolute value (primary sample

measurement - duplicate sample measurement) / ([primary sample measurement + duplicate sample measurement] / 2) × 100.

"Relative standard deviation" or *"RSD"* means the standard deviation expressed as a percentage of the mean recovery. "RSD" is the coefficient of variation multiplied by 100. If any results are less than the limit of quantitation, then the absolute value of the limit of quantitation is used in the following equation: RSD = (s / x) × 100, where s = standard deviation and x = mean recovery.

"Requester" means a person who submits a request to a licensed testing laboratory for state-mandated testing of medical cannabis goods. The requester may be a licensed manufacturer or the department.

"Residual solvents and processing chemicals" means volatile organic chemicals that are used or produced in the manufacture or production of medical cannabidiol.

"Restricted access area" means a building, room, or other contiguous area on the premises where plant material is grown, cultivated, harvested, stored, packaged, or processed for sale under control of the manufacturer, and where no person under the age of 18 is permitted.

"Sample" means a representative part of or a single item from a larger whole or group.

"Sanitize" means to sterilize, disinfect, or make hygienic.

"Semiquantitative analysis" means less than quantitative precision and does not involve a full calibration. Analyte identification is based on a single-point reference or high-probability library match. The determination of amount uses the ratio of the unknown chemical analyte to that of a known analyte added to the sample before analysis. Uncertainty for semiquantitative results is higher than for quantitative results.

"Significant figures" means the number of digits used to express a measurement.

"Stability" or *"stable"* means that after storage of an unopened package of medical cannabidiol, the contents shall not vary in concentrations of THC and CBD by more or less than 15 percent by weight in milligrams per milliliter (mg/ml) for liquids and milligrams per gram (mg/g) for solids from the concentration indicated on the package label. Thus, after storage, a solid product labeled as containing a concentration of CBD of 10 milligrams per gram shall have a detected concentration of CBD that is no more than 11.50 milligrams per gram and no less than 8.50 milligrams per gram.

"Standard operating procedure" means a written document that provides detailed instructions for the performance of all aspects of an analysis, operation, or action.

"State" means a state of the United States, the District of Columbia, Puerto Rico, the Virgin Islands, Guam, American Samoa, and the Commonwealth of the Northern Mariana Islands.

"Synthetic cannabinoid" means a designed compound with structural features that allow binding to the known cannabinoid receptors present in human cells and that produce biological effects similar to those of natural cannabinoids.

"Tamper-evident" means that one or more one-time-use seals are affixed to the opening of a package, allowing a person to recognize whether or not the package has been opened.

"Target organism" means an organism that is being tested for in an analytical procedure or test method.

"Testing laboratory record" means information relating to the testing laboratory and the analyses it performs that is prepared, owned, used, or retained by the laboratory and includes electronic files and video footage.

"THC" or *"delta-9 THC"* means tetrahydrocannabinol, Chemical Abstracts Service number 1972-08-3.

"THCA" means tetrahydrocannabinolic acid, Chemical Abstracts Service number 23978-85-0.

"Untreatable pain" means any pain whose cause cannot be removed and, according to generally accepted medical practice, the full range of pain management modalities appropriate for the patient has been used without adequate result or with intolerable side effects.

"Validation" means the confirmation by examination and objective evidence that the particular requirements for a specific intended use are fulfilled.

"Written certification" means a document signed by a health care practitioner, with whom the patient has established a patient-provider relationship, which states that the patient has a debilitating medical condition and identifies that condition and provides any other relevant information.
[**ARC 1640C**, IAB 10/1/14, effective 1/30/15; **ARC 3150C**, IAB 7/5/17, effective 6/13/17; **ARC 3606C**, IAB 1/31/18, effective 3/7/18; **ARC 3836C**, IAB 6/6/18, effective 7/11/18]

REGISTRATION CARDS

641—154.2(124E) Health care practitioner certification—duties.

154.2(1) Prior to a patient's submission of an application for a medical cannabidiol registration card pursuant to this rule, a health care practitioner shall do all of the following:

a. Determine, in the health care practitioner's medical judgment, whether the patient whom the health care practitioner has examined and treated suffers from a debilitating medical condition that qualifies for the use of medical cannabidiol as defined by this chapter, and if so determined, provide the patient with a written certification of that diagnosis by completing the health care practitioner section of the application form provided for this purpose on the department's website (www.idph.iowa.gov).

b. Provide explanatory information to the patient as provided on the department's website (www.idph.iowa.gov) about the therapeutic use of medical cannabidiol and the possible risks, benefits, and side effects of the proposed treatment.

154.2(2) Subsequently, the health care practitioner shall do the following:

a. Determine, on an annual basis, if the patient continues to suffer from a debilitating medical condition and, if so, issue the patient a new certification of that diagnosis.

b. Otherwise comply with all requirements in this chapter and requests from the department for more information.

154.2(3) A health care practitioner may provide, but has no duty to provide, a written certification pursuant to this rule.
[**ARC 1640C**, IAB 10/1/14, effective 1/30/15; **ARC 3150C**, IAB 7/5/17, effective 6/13/17]

641—154.3(124E) Medical cannabidiol registration card—application and issuance to patient.

154.3(1) Subject to subrule 154.3(7), the department may approve the issuance of a medical cannabidiol registration card by the department of transportation to a patient who:

a. Is at least 18 years of age.

b. Is a permanent resident of Iowa.

c. Submits a written certification to the department, provided to the patient pursuant to rule 641—154.2(124E) and signed by the patient's health care practitioner certifying that the patient is suffering from a debilitating medical condition.

d. Submits an application to the department, on a form created by the department in consultation with the department of transportation and available at the department's website (www.idph.iowa.gov), that contains all of the following:

(1) The patient's full legal name, Iowa residence address, mailing address (if different from the patient's residence address), telephone number, date of birth, and sex designation. The patient shall not provide as a mailing address an address for which a forwarding order is in place.

(2) A copy of the patient's valid photo identification. Acceptable photo identification includes:

1. A valid Iowa driver's license,

2. A valid Iowa nonoperator's identification card, or

3. An alternative form of valid photo identification. A patient who possesses or is eligible for an Iowa driver's license or an Iowa nonoperator's identification card shall present such document as valid photo identification. A patient who is ineligible to obtain an Iowa driver's license or an Iowa nonoperator's identification card may apply for an exemption and request submission of an alternative form of valid photo identification. A patient who applies for an exemption is subject to verification of the patient's identity through a process established by the department and the department of transportation to ensure the genuineness, regularity, and legality of the alternative form of valid photo identification.

(3) Full name, address, and telephone number of the patient's health care practitioner.

(4) Full legal name, residence address, date of birth, and telephone number of each primary caregiver of the patient, if any.

(5) An attestation as to the truthfulness and accuracy of the information provided by the patient on the application.

e. Has not been convicted of a disqualifying felony offense.

f. Submits the required fee, as described in subrule 154.12(1).

154.3(2) Upon the completion, verification, and approval of the patient's application and the receipt of the required fee, the department shall notify the department of transportation that the patient may be issued a medical cannabidiol registration card.

154.3(3) A medical cannabidiol registration card issued to a patient by the department of transportation shall contain all of the following:

a. The patient's full legal name, Iowa residence address, date of birth, and sex designation, as shown on the patient's Iowa driver's license, nonoperator's identification card, or alternative form of valid photo identification provided pursuant to paragraph 154.3(1)*"d"*(2)"3." If the patient's name, Iowa residence address, date of birth, or sex designation has changed since the issuance of the patient's Iowa driver's license, nonoperator's identification card, or alternative form of valid photo identification, the patient shall first update the patient's Iowa driver's license or nonoperator's identification card to reflect the current information, according to the procedures set forth in 761—subrule 605.11(2), 761—subrule 605.25(4), or rule 761—630.3(321), or shall update the alternative form of valid photo identification in accordance with the process of the issuing agency.

b. The date of issuance and the date of expiration, which shall be one year from the date of issuance.

c. A distinguishing registration number that is not the patient's social security number.

d. The patient's signature. The signature shall be without qualification and shall contain only the patient's usual signature without any other titles, characters, or symbols. The patient's signature certifies, under penalty of perjury and pursuant to the laws of the state of Iowa, that the statements made and information provided in the patient's application for a medical cannabidiol registration card are true and correct. The patient's signature shall be captured electronically.

e. A color photograph of the patient.

f. A statement that the medical cannabidiol registration card is not valid for identification purposes.

154.3(4) Every patient 18 years of age or older must obtain a valid medical cannabidiol registration card to use medical cannabidiol in Iowa.

154.3(5) An authorization to use medical cannabidiol or marijuana for medicinal purposes issued by another state, territory, or jurisdiction does not satisfy the requirements of Iowa Code chapter 124E or these rules for the issuance of a medical cannabidiol registration card.

154.3(6) A valid medical cannabidiol registration card, or its equivalent, issued under the laws of another state that allow an out-of-state patient to possess or use medical cannabidiol in the jurisdiction of issuance shall have the same force and effect as a valid medical cannabidiol registration card issued pursuant to Iowa Code chapter 124E, except that an out-of-state patient in Iowa shall not obtain medical cannabidiol from a medical cannabidiol dispensary in Iowa.

154.3(7) The department shall not approve the issuance of a medical cannabidiol registration card for a patient who is enrolled in a federally approved clinical trial for the treatment of a debilitating medical condition with medical cannabidiol.

[**ARC 1640C**, IAB 10/1/14, effective 1/30/15; **ARC 3150C**, IAB 7/5/17, effective 6/13/17]

641—154.4(124E) Medical cannabidiol registration card—application and issuance to primary caregiver.

154.4(1) For a patient in a primary caregiver's care, the department may approve the issuance of a medical cannabidiol registration card by the department of transportation to a primary caregiver who:

a. Is at least 18 years of age.

b. Submits a written certification to the department, provided to the patient pursuant to rule 641—154.2(124E) and signed by the patient's health care practitioner certifying that the patient is suffering from a debilitating medical condition.

c. Submits an application as a primary caregiver for each patient for whom the person is the primary caregiver. The primary caregiver application must be on a form created by the department in consultation with the department of transportation and available at the department's website (www.idph.iowa.gov) that contains all of the following:

(1) The primary caregiver's full legal name, residence address, mailing address (if different from the primary caregiver's residence address), telephone number, date of birth, and sex designation. The primary caregiver shall not provide as a mailing address an address for which a forwarding order is in place.

(2) The patient's full legal name, date of birth, and parent or legal guardian's name if the patient is under the age of 18.

(3) A copy of the primary caregiver's valid photo identification. Acceptable photo identification includes:

1. A valid Iowa driver's license,

2. A valid Iowa nonoperator's identification card,

3. If the primary caregiver is not a resident of the state of Iowa, a valid state-issued driver's license or nonoperator's identification card issued by a state other than Iowa, or

4. An alternative form of valid photo identification. A primary caregiver who possesses or is eligible for a driver's license or a nonoperator's identification card shall present such document as valid photo identification. A primary caregiver who is ineligible to obtain a driver's license or a nonoperator's identification card may apply for an exemption and request submission of an alternative form of valid photo identification. A primary caregiver who applies for an exemption is subject to verification of the primary caregiver's identity through a process established by the department and the department of transportation to ensure the genuineness, regularity, and legality of the alternative form of valid photo identification.

(4) Full name, address, and telephone number of the patient's health care practitioner.

(5) An attestation as to the truthfulness and accuracy of the information provided by the primary caregiver on the application.

d. Has not been convicted of a disqualifying felony offense.

e. Submits the required fee, as described in subrule 154.12(2).

154.4(2) Upon the completion, verification, and approval of the primary caregiver's application, the department shall notify the department of transportation that the primary caregiver may be issued a medical cannabidiol registration card.

154.4(3) A medical cannabidiol registration card issued to a primary caregiver by the department of transportation shall contain all of the following:

a. The primary caregiver's full legal name, current residence address, date of birth, and sex designation, as shown on the primary caregiver's state-issued driver's license, nonoperator's identification card, or alternative form of valid photo identification provided pursuant to paragraph 154.4(1)*"c"*(3)"4." If the primary caregiver's name, current residence address, date of birth, or sex designation has changed since issuance of the primary caregiver's Iowa-issued driver's license, nonoperator's identification card, or other form of valid photo identification, the primary caregiver shall first update the primary caregiver's Iowa-issued driver's license or nonoperator's identification card according to the procedures set forth in 761—subrule 605.11(2), 761—subrule 605.25(4), or rule 761—630.3(321) or update the alternative form of valid photo identification in accordance with the process of the issuing agency.

b. The date of issuance and the date of expiration, which shall be one year from the date of issuance.

c. A distinguishing registration number that is not the primary caregiver's social security number.

d. The medical cannabidiol registration number for each patient in the primary caregiver's care. This number shall not be the primary caregiver's or patient's social security number. If the patient in the

primary caregiver's care is under the age of 18, the full name of the patient's parent or legal guardian shall be printed on the primary caregiver's registration card in lieu of the patient's medical cannabidiol registration number.

e. The primary caregiver's signature. The signature shall be without qualification and shall contain only the primary caregiver's usual signature without any other titles, characters, or symbols. The primary caregiver's signature certifies, under penalty of perjury and pursuant to the laws of the state of Iowa, that the statements made and information provided in the primary caregiver's application for a medical cannabidiol registration card are true and correct. The primary caregiver's signature shall be captured electronically.

f. A color photograph of the primary caregiver.

g. A statement that the medical cannabidiol registration card is not valid for identification purposes.

h. A statement distinguishing the medical cannabidiol registration cardholder as a primary caregiver.

154.4(4) A patient who is 18 years of age or older must have an approved application and a distinguishing medical cannabidiol registration number that is not the patient's social security number prior to the issuance of a medical cannabidiol registration card to the patient's primary caregiver.

154.4(5) An authorization to use, or to act as a primary caregiver for a patient authorized to use, cannabidiol or marijuana for medicinal purposes issued by another state, territory, or jurisdiction does not satisfy the requirements of Iowa Code chapter 124E or these rules for the issuance of a medical cannabidiol registration card.

[**ARC 1640C**, IAB 10/1/14, effective 1/30/15; **ARC 3150C**, IAB 7/5/17, effective 6/13/17]

641—154.5(124E) Tamperproofing. The department of transportation shall issue a medical cannabidiol registration card by a method or process which prevents as nearly as possible the alteration, reproduction, or superimposition of a photograph on the cannabidiol registration card without ready detection.

[**ARC 1640C**, IAB 10/1/14, effective 1/30/15; **ARC 3150C**, IAB 7/5/17, effective 6/13/17]

641—154.6(124E) Denial and cancellation. The department may deny an application for a medical cannabidiol registration card, or may cancel or direct the department of transportation to cancel a medical cannabidiol registration card, for any of the following reasons:

1. Information contained in the application is illegible, incomplete, falsified, misleading, deceptive, or untrue.

2. The department or the department of transportation is unable to verify the identity of the applicant from the photo identification or other documentation presented pursuant to paragraph 154.3(1)*"d"*(2)"3" or 154.4(1)*"c"*(3)"4."

3. The applicant violates or fails to satisfy any of the provisions of Iowa Code chapter 124E or these rules.

[**ARC 1640C**, IAB 10/1/14, effective 1/30/15; **ARC 3150C**, IAB 7/5/17, effective 6/13/17]

641—154.7(124E) Appeal. If the department denies an application for or cancels a medical cannabidiol registration card, the department shall inform the applicant or cardholder of the denial or cancellation and state the reasons for the denial or cancellation in writing. An applicant or cardholder may appeal the denial or cancellation of a medical cannabidiol registration card by submitting a request for appeal to the department by certified mail, return receipt requested, within 20 days of receipt of the notice of denial or cancellation. The department's address is Iowa Department of Public Health, Lucas State Office Building, 321 E. 12th Street, Des Moines, Iowa 50319-0075. Upon receipt of a request for appeal, the department shall forward the request within five working days to the department of inspections and appeals. A contested case hearing shall be conducted in accordance with 641—Chapter 173.

[**ARC 1640C**, IAB 10/1/14, effective 1/30/15; **ARC 3150C**, IAB 7/5/17, effective 6/13/17]

641—154.8(124E) Duplicate card.

154.8(1) *Lost, stolen, or destroyed card.* To replace a medical cannabidiol registration card that is lost, stolen, or destroyed, a cardholder shall present to the department of transportation the cardholder's valid state-issued driver's license, nonoperator's identification card, or alternative form of valid photo identification provided pursuant to paragraph 154.3(1)*"d"*(2)"3" or 154.4(1)*"c"*(3)"4."

154.8(2) *Change in card information and voluntary replacement.*

a. To replace a medical cannabidiol registration card that is damaged, the cardholder shall surrender to the department of transportation the card to be replaced and present the cardholder's valid state-issued driver's license, nonoperator's identification card, or alternative form of valid photo identification provided pursuant to paragraph 154.3(1)*"d"*(2)"3" or 154.4(1)*"c"*(3)"4."

b. A patient or primary caregiver to whom a medical cannabidiol registration card is issued shall notify the department of a change in current residence address, name, or sex designation listed on the card, within ten calendar days of the change. To replace a medical cannabidiol registration card to change the current residence address, name, or sex designation listed on the card, the cardholder shall surrender to the department of transportation the card to be replaced and present a valid state-issued driver's license, nonoperator's identification card, or alternative form of valid photo identification provided pursuant to paragraph 154.3(1)*"d"*(2)"3" or 154.4(1)*"c"*(3)"4" that has been updated according to the procedures established by the state or agency of issuance to reflect the requested residence address, name, or sex designation.

c. To replace a medical cannabidiol registration card held by a primary caregiver to change, add, or remove a patient's medical cannabidiol registration number or the name of a patient's parent or legal guardian listed on the primary caregiver's card, the primary caregiver shall submit a new application to the department pursuant to rule 641—154.4(124E). A medical cannabidiol registration card issued pursuant to this paragraph shall not be considered a duplicate card.

154.8(3) *Expiration date.* A duplicate medical cannabidiol registration card shall have the same expiration date as the medical cannabidiol registration card being replaced, changed, or amended.

[**ARC 1640C**, IAB 10/1/14, effective 1/30/15; **ARC 3150C**, IAB 7/5/17, effective 6/13/17]

641—154.9(124E) Renewal. A medical cannabidiol registration card shall be valid for one year from the date of issuance unless canceled pursuant to rule 641—154.6(124E).

154.9(1) A cardholder seeking renewal of a medical cannabidiol registration card shall submit a renewal application and fee to the department at least 60 days prior to the date of expiration.

a. A patient applying for renewal of a medical cannabidiol registration card shall submit a renewal application and fee to the department on a form approved by the department.

b. A primary caregiver applying for a renewal of a medical cannabidiol registration card shall submit a renewal application and fee to the department on a form approved by the department.

154.9(2) A cardholder who fails to renew the medical cannabidiol registration card may not lawfully possess medical cannabidiol pursuant to this chapter.

[**ARC 1640C**, IAB 10/1/14, effective 1/30/15; **ARC 3150C**, IAB 7/5/17, effective 6/13/17]

641—154.10(124E) Confidentiality. The department shall maintain a confidential file of the names of each patient to or for whom the department approves the issuance of a medical cannabidiol registration card and the name of each primary caregiver to whom the department issues a medical cannabidiol registration card under Iowa Code section 124E.4.

154.10(1) Personally identifiable information of patients and primary caregivers shall be maintained as confidential and is not accessible to the public. The department and the department of transportation shall release aggregate and statistical information regarding the medical cannabidiol act registration card program in a manner which prevents the identification of any patient or primary caregiver.

154.10(2) Personally identifiable information of patients and primary caregivers may be disclosed under the following limited circumstances:

a. To authorized employees or agents of the department and the department of transportation as necessary to perform the duties of the department and the department of transportation pursuant to Iowa Code chapter 124E.

b. To authorized employees of state or local law enforcement agencies located in Iowa, solely for the purpose of verifying that a person is lawfully in possession of a medical cannabidiol registration card issued pursuant to Iowa Code chapter 124E.

c. To a patient, primary caregiver, or health care practitioner, upon written authorization of the patient or primary caregiver.

[**ARC 1640C**, IAB 10/1/14, effective 1/30/15; **ARC 3150C**, IAB 7/5/17, effective 6/13/17]

641—154.11(124E) Agreement with department of transportation. The department may enter into a chapter 28E agreement with the department of transportation to facilitate the issuance of medical cannabidiol registration cards. The agreement may include provisions which govern the issuance, denial, and cancellation of medical cannabidiol registration cards, the sharing of information between the department and the department of transportation, and reimbursement for costs incurred by the department of transportation for issuing the card.

[**ARC 1640C**, IAB 10/1/14, effective 1/30/15; **ARC 3150C**, IAB 7/5/17, effective 6/13/17]

641—154.12(124E) Fees. All fees are nonrefundable.

154.12(1) *Patient medical cannabidiol registration card fee.*

a. Each application fee is $100 unless the patient qualifies for a reduced fee as described in paragraph 154.12(1)*"b."*

b. Each reduced application fee is $25 if the patient attests to receiving social security disability benefits, supplemental security income payments, or is enrolled in the medical assistance program as defined in rule 641—154.1(124E).

c. Each renewal fee is the same as the initial card application fee.

154.12(2) *Primary caregiver medical cannabidiol registration card fee.*

a. Each application fee is $25.

b. Each renewal fee is $25.

[**ARC 3150C**, IAB 7/5/17, effective 6/13/17]

641—154.13(124E) Use of medical cannabidiol—smoking prohibited. A patient shall not consume medical cannabidiol possessed or used pursuant to Iowa Code chapter 124E by smoking medical cannabidiol.

[**ARC 3150C**, IAB 7/5/17, effective 6/13/17]

641—154.14(124E) Form and quantity of medical cannabidiol. The form and quantity of medical cannabidiol authorized in this rule may be modified pursuant to recommendations by the medical cannabidiol board, subsequent approval of the recommendations by the board of medicine and adoption of the recommendations by the department by rule.

154.14(1) *Quantity.* A 90-day supply is the maximum amount of each product that shall be dispensed by a dispensary at one time.

154.14(2) *Form.*

a. A manufacturer may only manufacture medical cannabidiol in the following forms:

(1) Oral forms, including but not limited to:

1. Tablet.
2. Capsule.
3. Liquid.
4. Tincture.
5. Sublingual.

(2) Topical forms, including but not limited to:

1. Gel.
2. Ointment, cream or lotion.
3. Transdermal patch.

(3) Inhaled forms, limited to:

1. Nebulizable.

2. Vaporizable.

(4) Rectal/vaginal forms, including but not limited to suppository.

b. A manufacturer may not produce medical cannabidiol in any form that may be smoked.

c. A manufacturer may not produce medical cannabidiol in an edible form as defined in rule 641—154.1(124E).

[**ARC 3150C**, IAB 7/5/17, effective 6/13/17; **ARC 3836C**, IAB 6/6/18, effective 7/11/18; **ARC 4399C**, IAB 4/10/19, effective 5/15/19]

641—154.15 Reserved.

MANUFACTURING

641—154.16(124E) Duties of the department.

154.16(1) *Interagency agreements.* The department may enter into any interagency agreements with other state agencies for technical services or other assistance related to the regulation or inspection of manufacturers.

154.16(2) *Notice to law enforcement.* The department shall notify local law enforcement agencies and the department of public safety of the locations of manufacturers. If the department determines there is a threat to public safety, the department shall notify local law enforcement agencies and the department of public safety of any conditions that pose a threat to public safety, including but not limited to:

a. Loss or theft of medical cannabidiol or plant material;

b. Diversion or potential diversion of medical cannabidiol or plant material;

c. Unauthorized access to the secure sales and inventory tracking system or other patient and caregiver information system or file; or

d. Other violations of law.

154.16(3) *Inspection of manufacturers.* The department or its agents shall conduct regular inspections of manufacturers and manufacturing facilities as described in rule 641—154.28(124E).

154.16(4) *Establishment and maintenance of a secure sales and inventory tracking system.* The department shall establish and maintain a secure, electronic system that is available 24 hours a day, seven days a week to track:

a. Inventory of plant material, medical cannabidiol, and waste material;

b. Transport of plant material, waste material, and laboratory samples;

c. Application and use of crop inputs and other solvents and chemicals;

d. Sales of medical cannabidiol to dispensaries;

e. Sales of medical cannabidiol from dispensaries to patients and primary caregivers.

154.16(5) *Licensure and licensure renewal of manufacturers.* The department shall issue a request for proposals to select and license by December 1, 2017, up to two manufacturers to manufacture and to possess, cultivate, harvest, transport, package, process, and supply medical cannabidiol within the state consistent with the provisions of Iowa Code chapter 124E and these rules.

a. To be eligible for licensure, an applicant manufacturer shall provide information on forms and in a manner required by the department of public safety for the completion of a background investigation. In addition, the applicant manufacturer shall submit to the department of public safety necessary funds to satisfy the full reimbursement of costs associated with completing the background investigations. If an applicant manufacturer is not found suitable for licensure as a result of the background investigation, a license shall not be issued by the department.

b. As a condition for licensure, an applicant manufacturer shall agree to begin supplying medical cannabidiol to licensed medical cannabidiol dispensaries in Iowa no later than December 1, 2018.

c. The initial license to manufacture medical cannabidiol shall be valid from December 1, 2017, through November 30, 2018. The license shall be renewed annually unless a manufacturer relinquishes the license, there is a change in state law prohibiting the department from renewing the license, or the license is revoked pursuant to Iowa Code chapter 124E or these rules.

d. A license to manufacture issued by the department pursuant to these rules is not assignable or transferable.

e. The department shall consider the following factors in determining whether to select and license a medical cannabidiol manufacturer:

(1) The technical expertise of an applicant manufacturer regarding medical cannabidiol;

(2) The qualifications of an applicant manufacturer's employees;

(3) The long-term financial stability of an applicant manufacturer;

(4) The ability to provide appropriate security measures on the premises of an applicant manufacturer;

(5) Whether an applicant manufacturer has demonstrated an ability to meet certain medical cannabidiol production needs for medical use regarding the range of recommended dosages for each debilitating medical condition, the range of chemical compositions of any plant of the genus cannabis that will likely be medically beneficial for each of the debilitating medical conditions, and the form or forms of medical cannabidiol that may be appropriate for the approved debilitating medical conditions;

(6) An applicant manufacturer's projection of and ongoing assessment of wholesale product costs.

f. Pursuant to Iowa Code section 124E.6(1)*"b,"* information submitted during the application process shall be confidential until the licensure process is completed unless otherwise protected from disclosure under state or federal law.

g. A licensed manufacturer shall submit an application to renew its license with the department at least six months before the license expires. The application shall be submitted on a form created by the department.

h. The department shall notify a manufacturer of the decision to approve or deny the manufacturer's license by August 1 of the year in which the renewal application is submitted.

154.16(6) *Collection of fees from manufacturers.* Except as provided in this rule, all fees are nonrefundable, shall be retained by the department, and shall be considered repayment receipts as defined in Iowa Code section 8.2.

a. Fees to the department.

(1) Each application for licensure as a manufacturer shall include a nonrefundable application fee of $7,500.

(2) Licensed manufacturers shall pay an annual fee to the department to cover costs associated with regulating and inspecting manufacturers and for other expenses necessary for the administration of the medical cannabidiol program. The department shall assess the fee with the notice of approval of license renewal each year by August 1, payable by the manufacturer to the department no later than December 1.

b. Fees to the department of public safety.

(1) An applicant manufacturer shall be responsible to reimburse the department of public safety the full cost of conducting background investigations related to an application for licensure and operation as a licensed manufacturer. The department of public safety shall retain the right to bill a manufacturer for additional background investigations, as needed.

(2) Each manufacturer submitting an application for licensure shall, at the time of application, submit to the department of public safety a deposit of $10,000 for each business owner subject to a background investigation and a national criminal history background check. Background investigation costs shall be deducted from the funds deposited. If the background investigation fees exceed the funds deposited, the applicant shall submit additional funds as required by the department of public safety. If the background investigation fees are less than the funds deposited, the department of public safety may refund or retain the fees as mutually agreed with the manufacturer.

(3) A licensed manufacturer shall pay a deposit of $200 per employee to the department of public safety for a background investigation and a national criminal history background check on any person being considered for hire as an employee of the manufacturer. Background investigation costs shall be deducted from the funds deposited. If the background investigation fees exceed the funds deposited, the manufacturer shall submit additional funds as required by the department of public safety. If the background investigation fees are less than the funds deposited, the department of public safety may refund or retain the fees as mutually agreed with the manufacturer. The department shall retain the right

to preclude a potential employee from hire based upon the results of the background investigation and national criminal history background check.
[**ARC 3606C**, IAB 1/31/18, effective 3/7/18]

641—154.17(124E) Manufacturer operations.

154.17(1) *Operating documents.* The operating documents of a manufacturer shall include all of the following:

a. Procedures for the oversight of the manufacturer, including descriptions of operational and management practices regarding:

(1) The forms and quantities of medical cannabidiol products that are produced at the manufacturing facility;

(2) The methods of planting, harvesting, drying, and storing cannabis;

(3) The estimated types and amounts of all crop inputs used in the production of medical cannabidiol;

(4) The estimated types and amounts of medical cannabidiol waste and plant material waste to be generated;

(5) The disposal methods for all waste materials;

(6) Employee training methods for the specific phases of production;

(7) Biosecurity measures used in the production and manufacturing of medical cannabidiol;

(8) Strategies for identifying and reconciling discrepancies in inventory of plant material or medical cannabidiol;

(9) Sampling strategy and quality testing for labeling purposes;

(10) Medical cannabidiol packaging and labeling procedures;

(11) Procedures for recall and market withdrawal of medical cannabidiol;

(12) Plans for responding to a security breach at a manufacturing facility or while medical cannabidiol is in transit to a dispensary;

(13) A business continuity plan;

(14) Records relating to all transport activities; and

(15) Other information requested by the department.

b. Procedures to ensure accurate record keeping.

c. Procedures for the implementation of appropriate security measures to deter and prevent the theft of medical cannabidiol and unauthorized entrance into areas containing medical cannabidiol.

154.17(2) *Prohibited activities.* A manufacturer shall not:

a. Own or operate a medical cannabidiol manufacturing facility unless the manufacturer is licensed by the department pursuant to Iowa Code chapter 124E and these rules;

b. Produce or manufacture medical cannabidiol in any location except in those areas approved by the department;

c. Sell, deliver, transport, or distribute medical cannabidiol from any location except its manufacturing facility or a dispensary facility;

d. Produce or manufacture medical cannabidiol in Iowa for sales or distribution outside of Iowa;

e. Sell or distribute medical cannabidiol to any person or business other than a dispensary;

f. Refuse to sell, deliver, transport, or distribute medical cannabidiol in any form or quantity produced by the manufacturer to a dispensary, unless deemed appropriate in the manufacturer's reasonable business judgment and approved by the department in writing;

g. Transport or deliver medical cannabidiol to any location except as allowed in subrule 154.22(1);

h. Sell medical cannabidiol that is not packaged and labeled in accordance with rule 641—154.21(124E);

i. Sell medical cannabidiol in any form or quantity other than a form or quantity approved by the department, subject to recommendation by the medical cannabidiol board and approval by the board of medicine;

j. Permit any person to consume medical cannabidiol on the property of the manufacturer;

k. Employ a person who is under 18 years of age or who has been convicted of a disqualifying felony offense;

l. Manufacture edible medical cannabidiol products.

154.17(3) *Criminal background investigations.*

a. A manufacturer shall not have been convicted of a disqualifying felony offense and shall be subject to a background investigation conducted by the department of public safety, including but not limited to a national criminal history record check.

b. An employee of a manufacturer shall not have been convicted of a disqualifying felony offense and shall be subject to a background investigation conducted by the department of public safety, including but not limited to a national criminal history background check.

154.17(4) *Relationship to health care practitioners.* A manufacturer shall not share office space with, refer patients to, or have any financial relationship with a health care practitioner.

[**ARC 3606C**, IAB 1/31/18, effective 3/7/18; **ARC 3836C**, IAB 6/6/18, effective 7/11/18]

641—154.18(124E) Security requirements. The department may request assistance from the department of public safety in ensuring manufacturers meet the security requirements in this rule.

154.18(1) *Visitor logs.* Visitors to the manufacturing facility shall sign visitor manifests with name, date, and times of entry and exit, and shall wear badges that are visible at all times and that identify them as visitors.

154.18(2) *Restricted access.* A manufacturer shall use a controlled access system and written manifests to limit entrance to all restricted access areas of its manufacturing facility and shall retain a record of all persons who entered the restricted access areas.

a. The controlled access system shall do all of the following:

(1) Limit access to authorized individuals;

(2) Maintain a log of individuals with approved access, including dates of approvals and revocations;

(3) Track times of personnel entry to and exit from the facility;

(4) Store data for retrieval for a minimum of one year; and

(5) Limit access to authorized individuals in the event of a power failure.

b. Separate written manifests of visitors to restricted access areas shall be kept and stored for a minimum of one year if the controlled access system does not include electronic records of visitors to the restricted access areas.

c. A manufacturer shall promptly, but no later than five business days after receipt of request, submit stored controlled access system data to the department.

d. Restricted access areas shall be identified with signs that state: "Do Not Enter – Restricted Access Area – Access Limited to Authorized Personnel Only."

154.18(3) *Perimeter intrusion detection system.*

a. *Computer-controlled video surveillance system.* A manufacturer shall operate and maintain in good working order a computer-controlled, closed-circuit television surveillance system on its premises that operates 24 hours per day, seven days a week, and visually records:

(1) All phases of medical cannabidiol production;

(2) All areas that might contain plant material and medical cannabidiol, including all safes and vaults;

(3) All points of entry and exit;

(4) The entrance to the video surveillance control room; and

(5) Parking areas, which shall have appropriate lighting for the normal conditions of the area under surveillance.

b. *Camera specifications.* Cameras shall:

(1) Capture clear and certain identification of any person entering or exiting a manufacturing facility or its parking areas to the extent identification is technologically feasible with generally accepted commercial security cameras;

(2) Have the ability to produce a clear, color still photograph live or from a recording;

(3) Have on all recordings an embedded date-and-time stamp that is synchronized to the recording and does not obscure the picture; and

(4) Continue to operate during a power outage.

c. *Video recording specifications.*

(1) A video recording shall export still images in an industry standard image format, such as .jpg, .bmp, or .gif.

(2) Exported video shall be archived in a format that ensures authentication and guarantees that the recorded image has not been altered.

(3) Exported video shall also be saved in an industry standard file format that can be played on a standard computer operating system.

(4) All recordings shall be erased or destroyed at the end of the retention period and prior to disposal of any storage medium.

d. *Additional requirements.* A manufacturer shall maintain all security system equipment and recordings in a secure location to prevent theft, loss, destruction, corruption, and alterations.

e. *Retention.* A manufacturer shall ensure that recordings from all video cameras are:

(1) Available for viewing by the department upon request;

(2) Retained for at least 60 days;

(3) Maintained free of alteration or corruption; and

(4) Retained longer, as needed, if a manufacturer is given actual notice of a pending criminal, civil, or administrative investigation, or other legal proceeding for which the recording may contain relevant information.

f. *Required signage.* A manufacturer shall post a sign in capital letters in a conspicuous location at every entrance to the manufacturing facility that reads, "THESE PREMISES ARE UNDER CONSTANT VIDEO SURVEILLANCE."

154.18(4) *Security alarm system requirements.*

a. A manufacturer shall install and maintain a professionally monitored security alarm system that provides intrusion and fire detection of all:

(1) Facility entrances and exits;

(2) Rooms with exterior windows;

(3) Rooms with exterior walls;

(4) Roof hatches;

(5) Skylights; and

(6) Storage rooms.

b. For the purposes of this subrule, a security alarm system means a device or series of devices that summons law enforcement personnel during, or as a result of, an alarm condition. Devices may include:

(1) Hardwired systems and systems interconnected with a radio frequency method such as cellular or private radio signals that emit or transmit a remote or local audio, visual, or electronic signal;

(2) Motion detectors;

(3) Pressure switches;

(4) A duress alarm;

(5) A panic alarm;

(6) A holdup alarm;

(7) An automatic voice dialer; and

(8) A failure notification system that provides an audio, text, or visual notification of any failure in the surveillance system.

c. A manufacturer's security alarm system and all devices shall continue to operate during a power outage.

d. A manufacturer's security alarm system shall be inspected and all devices tested annually by a qualified alarm vendor. A manufacturer shall provide documentation of the annual inspection and device testing to the department upon request.

154.18(5) *Personnel identification system.* A manufacturer shall use a personnel identification system that controls and monitors individual employee access to restricted access areas within the manufacturing facility and that meets the requirements of this subrule and subrule 154.18(1).

a. Requirement for employee identification card. An employee identification card shall contain:

(1) The name of the employee;

(2) The date of issuance and expiration;

(3) An alphanumeric identification number that is unique to the employee; and

(4) A photographic image of the employee.

b. A manufacturer's employee shall keep the identification card visible at all times when the employee is in a manufacturing facility, a dispensary, or a vehicle transporting medical cannabidiol.

c. Upon termination or resignation of an employee, a manufacturer shall immediately:

(1) Revoke the employee's access to the manufacturing facility; and

(2) Obtain and destroy the employee's identification card, if possible.

[**ARC 3606C**, IAB 1/31/18, effective 3/7/18]

641—154.19(124E) Location. All of a manufacturer's manufacturing, cultivating, harvesting, packaging, processing, and storage of medical cannabidiol shall take place in one secured manufacturing facility location at a physical address provided to the department during the licensure and application processes.

154.19(1) *Proximity to dispensary.* A manufacturer shall not operate a manufacturing facility at the same physical location as a medical cannabidiol dispensary.

154.19(2) *Proximity to school.* A manufacturer shall not operate a manufacturing facility in any location, whether for manufacturing, possessing, cultivating, harvesting, transporting, packaging, processing, storing, or supplying, within 1,000 feet of a public or private school existing before the date of the manufacturer's licensure by the department.

[**ARC 3606C**, IAB 1/31/18, effective 3/7/18]

641—154.20(124E) Advertising and marketing.

154.20(1) *Permitted marketing and advertising activities.*

a. A manufacturer may:

(1) Display the manufacturer's business name and logo on medical cannabidiol labels, signs, website, and informational material provided to patients. The name or logo shall not include:

1. Images of cannabis or cannabis-use paraphernalia;
2. Colloquial references to cannabis;
3. Names of cannabis plant strains or varieties;
4. Unsubstantiated medical claims; or
5. Medical symbols that bear a reasonable resemblance to established medical associations. Examples of established medical organizations include the American Medical Association or American Academy of Pediatrics. The use of medical symbols is subject to approval by the department;

(2) Display signs on the manufacturing facility; and

(3) Maintain a business website that contains the following information:

1. The manufacturer's name and contact information;
2. The medical cannabidiol forms and quantities manufactured in Iowa; and
3. Other information as approved by the department.

b. The business website shall not include any false, misleading, or unsubstantiated statements regarding health or physical benefits to the patient.

c. The department reserves the right to review a manufacturer's marketing and advertising materials and to require a manufacturer to make changes to the content. The department has 30 calendar days following submission to approve or deny marketing and advertising materials of a manufacturer.

154.20(2) *Other marketing and advertising activities.* A manufacturer shall request and receive the department's written approval before beginning marketing or advertising activities that are not specified in subrule 154.20(1). The department has 30 calendar days to approve, deny, or request additional information regarding marketing and advertising activity requests from a manufacturer. In the event the department fails to respond to a manufacturer within 30 days with an approval, denial, or request for additional information, the manufacturer's marketing and advertising activity requests shall be deemed approved.

154.20(3) *Inconspicuous display.* A manufacturer shall arrange displays of medical cannabidiol, interior signs, and other exhibits to reasonably prevent public viewing from outside the manufacturing facility.

[**ARC 3606C**, IAB 1/31/18, effective 3/7/18]

641—154.21(124E) Packaging and labeling.

154.21(1) *Medical cannabidiol packaging.* A manufacturer shall package all medical cannabidiol intended for distribution according to the following standards:

a. The manufacturer shall properly package medical cannabidiol in compliance with the United States Poison Prevention Packing Act regarding child-resistant packaging and exemptions for packaging for elderly patients.

b. The manufacturer shall label packaged medical cannabidiol as described in subrule 154.21(3).

c. The manufacturer shall use medical containers that are:

(1) Of sufficient size to accommodate a separate dispensary label containing the information described in rule 641—154.46(124E);

(2) Designed to maximize the shelf life of the contained medical cannabidiol;

(3) Tamper-evident; and

(4) Child-resistant.

d. Medical cannabidiol packaging shall not bear a reasonable resemblance to commonly available nonmedical commercial products.

e. The manufacturer shall package medical cannabidiol in a manner that minimizes the package's appeal to children.

f. The manufacturer shall not depict images other than the manufacturer's business name or logo on the packaging.

154.21(2) *Trade names.* A manufacturer's medical cannabidiol trade names shall comply with the following:

a. Names shall be limited to those that clearly reflect the form's medical cannabidiol nature;

b. Any name that is identical to, or similar to, the name of an existing nonmedical cannabidiol product is prohibited;

c. Any name that is identical to, or similar to, the name of an unlawful product or substance is prohibited; and

d. Any name that contains language that suggests using medical cannabidiol for recreational purposes or for a condition other than a qualifying debilitating medical condition is prohibited.

154.21(3) *Package labeling.*

a. A manufacturer shall ensure that all medical cannabidiol packaging is labeled with the following information:

(1) The name and address of the manufacturer where the medical cannabidiol was manufactured;

(2) The medical cannabidiol's primary active ingredients, including concentrations of tetrahydrocannabinol, tetrahydrocannabinolic acid, cannabidiol, and cannabidiolic acid;

(3) Directions for use of the product, including recommended and maximum amount by age and weight, if applicable;

(4) All ingredients of the product shown with common or usual names, including any colors, artificial flavors, and preservatives, listed in descending order by predominance of weight;

(5) Instructions for storage, including light and temperature requirements, if any;

(6) Product expiration date;

(7) The date of manufacture and lot number;

(8) A notice with the statement, including capitalization: "This product has not been analyzed or approved by the United States Food and Drug Administration. There is limited information on the side effects of using this product, and there may be associated health risks and medication interactions. This product is not recommended for use by pregnant or breastfeeding women. KEEP THIS PRODUCT OUT OF REACH OF CHILDREN.";

(9) The universal warning symbol provided by the department; and

(10) A notice with the statement: "This medical cannabidiol is for therapeutic use only. Use of this product by a person other than the patient listed on the label is unlawful and may result in the cancellation of the patient's medical cannabidiol registration card. Return unused medical cannabidiol to a dispensary for disposal."

b. Labeling text shall not include any false or misleading statements.

c. A package may contain multiple labels if the information required by this rule is not obstructed.

d. Labeling text font size shall be no smaller than 6 point.

[**ARC 3606C**, IAB 1/31/18, effective 3/7/18; **ARC 3836C**, IAB 6/6/18, effective 7/11/18]

641—154.22(124E) Transportation of medical cannabidiol and plant material.

154.22(1) *Transport of medical cannabidiol.* A manufacturer is authorized to transport medical cannabidiol to and from:

a. Dispensaries;

b. A laboratory for testing;

c. A waste facility for disposal;

d. Other sites only with departmental approval.

154.22(2) *Transport of plant material.* A manufacturer is authorized to transport cannabis plant material from its manufacturing facility to:

a. A waste disposal site;

b. Other sites only with departmental approval.

154.22(3) *Chain-of-custody tracking system.*

a. A manufacturer shall use the secure sales and inventory tracking system, if available, or a department-approved manifest system to track shipping of medical cannabidiol. The system shall include a chain of custody that records:

(1) The name and address of the destination;

(2) The weight and description of each individual package that is part of the shipment, and the total number of individual packages;

(3) The date and time the medical cannabidiol shipment is placed into the transport vehicle;

(4) The date and time the shipment is accepted at the delivery destination;

(5) The person's identity, and the circumstances, duration, and disposition of any other person who had custody or control of the shipment; and

(6) Any handling or storage instructions.

b. Before transporting medical cannabidiol, a manufacturer shall:

(1) Record in the secure sales and inventory tracking system or on the manifest information about the material to be transported; and

(2) Notify the dispensary, laboratory, or waste facility, as applicable, of the expected arrival time and transmit a copy of the manifest to the dispensary, laboratory, or waste facility, if applicable.

c. Each transport shall be approved electronically or in writing by:

(1) An authorized manufacturer employee when the transport vehicle is departing the manufacturing facility; and

(2) An authorized employee of the receiving dispensary, laboratory, or waste facility.

d. An authorized employee at the dispensary, laboratory, or waste facility receiving medical cannabidiol shall:

(1) Verify and document the type and quantity of the transported medical cannabidiol against the information in the secure sales and inventory tracking system or written manifest;

(2) Approve the transport electronically or return a signed copy of the manifest to the manufacturing facility; and

(3) Record the medical cannabidiol that is received as inventory in the secure sales and inventory tracking system, if available. If a manifest system is being used, the dispensary, laboratory, or waste facility shall also maintain a signed copy of manifest, and shall maintain records of the inventory received consistent with these rules.

e. A manufacturer shall maintain all manifests for at least five years and make them available upon request of the department.

154.22(4) *Vehicle requirements for transport.*

a. A manufacturer shall ensure that all medical cannabidiol transported on public roadways is:

(1) Packaged in tamper-evident, bulk containers;

(2) Transported so it is not visible or recognizable from outside the vehicle; and

(3) Transported in a vehicle that does not bear any markings to indicate that the vehicle contains medical cannabidiol or bears the name or logo of the manufacturer.

b. When the motor vehicle contains medical cannabidiol, manufacturer employees who are transporting the medical cannabidiol on public roadways shall:

(1) Travel directly to a dispensary or other department-approved locations; and

(2) Document refueling and all other stops in transit, including:

1. The reason for the stop;
2. The duration of the stop; and
3. The location of the stop.

c. If the vehicle must be stopped due to an emergency situation, the employee shall notify 911 and complete an incident report on a form approved by the department.

d. Under no circumstance shall any person other than a designated manufacturer employee have actual physical control of the motor vehicle that is transporting the medical cannabidiol.

e. A manufacturer shall staff all motor vehicles with a minimum of two employees when transporting medical cannabidiol between a manufacturing facility and a dispensary. At least one employee shall remain with the motor vehicle at all times that the motor vehicle contains medical cannabidiol. A single employee may transport medical cannabidiol to the laboratory.

f. Each employee in a transport motor vehicle shall have telephone or other communication access with the manufacturer's personnel and have the ability to contact law enforcement via telephone or other method at all times that the motor vehicle contains medical cannabidiol.

g. An employee shall carry the employee's identification card at all times when transporting or delivering medical cannabidiol and, upon request, produce the identification card to the department or to a law enforcement officer acting in the course of official duties.

h. A manufacturer shall not leave a vehicle that is transporting medical cannabidiol unattended overnight.

[**ARC 3606C**, IAB 1/31/18, effective 3/7/18]

641—154.23(124E) Disposal of medical cannabidiol and plant material.

154.23(1) *Return of medical cannabidiol from dispensaries and laboratory.* A manufacturer shall collect at no charge unused, excess, or expired medical cannabidiol from dispensaries, including medical cannabidiol that was returned to a dispensary from a patient or primary caregiver, and from the laboratory that has tested samples submitted by the manufacturer. A manufacturer shall:

a. Collect waste medical cannabidiol from each dispensary on a schedule mutually agreed upon by the manufacturer and dispensary;

b. Collect waste medical cannabidiol from a laboratory on a schedule mutually agreed upon by the manufacturer and laboratory;

c. Dispose of the returned medical cannabidiol as provided in subrule 154.23(2); and

d. Maintain a written record of disposal that includes:

(1) The tracking number assigned at the time of the dispensing, if available, or the name of the patient, if the tracking number is unavailable, when the medical cannabidiol was returned to the dispensary from a patient or primary caregiver;

(2) The date the medical cannabidiol was returned;

(3) The quantity of medical cannabidiol returned; and

(4) The type and lot number of medical cannabidiol returned.

154.23(2) *Medical cannabidiol and plant material waste.* A manufacturer shall store, secure, and manage medical cannabidiol waste and plant material waste in accordance with all applicable federal, state, and local regulations.

a. The manufacturer shall dispose of medical cannabidiol waste at a waste facility according to federal and state law and in a manner which renders it unusable.

b. The manufacturer shall dispose of plant material waste at an approved solid waste disposal facility, according to federal and state law.

c. Before transport of plant material waste, the manufacturer shall render the plant material waste unusable and unrecognizable by grinding and incorporating the waste with a greater quantity of nonconsumable, solid wastes including:

(1) Paper waste;

(2) Cardboard waste;

(3) Food waste;

(4) Yard waste;

(5) Vegetative wastes generated from industrial or manufacturing processes that prepare food for human consumption;

(6) Soil; or

(7) Other waste approved by the department.

154.23(3) *Liquid and chemical waste disposal.* A manufacturer shall dispose of all liquid and chemical product waste generated in the process of cultivating, manufacturing, and distributing medical cannabidiol in accordance with all applicable federal, state, and local regulations.

154.23(4) *Waste-tracking requirements.* A manufacturer shall use forms approved by the department to maintain accurate and comprehensive records regarding waste material. The records shall account for, reconcile, and evidence all waste activity related to the disposal of medical cannabidiol waste and plant material waste.

[**ARC 3606C**, IAB 1/31/18, effective 3/7/18]

641—154.24(124E) Record-keeping requirements.

154.24(1) *Sales and distribution.* A manufacturer shall maintain complete and accurate electronic sales transaction records in the department's secure sales and inventory tracking system, including:

a. The date of each sale or distribution;

b. The item number, product name and description, and quantity of medical cannabidiol sold or otherwise distributed; and

c. The sale price.

154.24(2) *Financial transactions.* A manufacturer shall maintain records that reflect all financial transactions and the financial condition of the business. The following records shall be maintained for at least five years and made available for review, upon request of the department:

a. Purchase invoices, bills of lading, sales records, copies of bills of sale, and any supporting documents, to include the items or services purchased, from whom the items were purchased, and the date of purchase;

b. Bank statements and canceled checks for all business accounts;

c. Accounting and tax records;

d. Records of all financial transactions, including contracts and agreements for services performed or services received;

154.24(3) *Other records.*

a. A manufacturer shall maintain the following for at least five years, unless otherwise noted, and provide to the department upon request:

(1) All personnel records;

(2) Records of any theft, loss, or other unaccountability of any medical cannabidiol or plant material;

(3) Transport manifests and incident reports; and

(4) Records of all samples sent to a testing laboratory and the quality assurance test results.

b. A manufacturer shall maintain for at least one year and provide to the department upon request its controlled access system data and visitor manifests.

c. A manufacturer shall use the department's secure sales and inventory tracking system to maintain the following:

(1) Crop input records;

(2) Production records;

(3) Transportation records; and

(4) Inventory records, including disposal of waste.

[**ARC 3606C**, IAB 1/31/18, effective 3/7/18]

641—154.25(124E) Production requirements.

154.25(1) *Cultivation and processing.*

a. Only a licensed manufacturer is authorized to produce and manufacture medical cannabidiol.

b. All phases of production shall take place in designated, restricted access areas that are monitored by a surveillance camera system in accordance with rule 641—154.18(124E).

c. The production process shall be designed to limit contamination. Examples of contamination include mold, fungus, bacterial diseases, rot, pests, nonorganic pesticides, and mildew.

d. Each production area shall allow for access, observation, and inventory of each plant group.

e. Biosecurity measures shall be in effect as described in the operating documents pursuant to subrule 154.17(1).

154.25(2) *Record-keeping and tracking requirements.*

a. The manufacturer shall use the department's secure sales and inventory tracking system to maintain an electronic record of all crop inputs for at least five years. The record shall include the following:

(1) The date of input application;

(2) The name of the employee applying the crop input;

(3) The crop input that was applied;

(4) The plants that received the application;

(5) The amount of crop input that was applied; and

(6) A copy of or electronic link to the safety data sheet for the crop input applied.

b. At the time of planting, all plants shall be tracked in a batch process with a unique batch number that shall remain with the batch through final processing into medical cannabidiol.

c. A manufacturer shall record any removal of plants from the batch, including the reason for removal, on a record maintained at the manufacturing facility for at least five years.

d. Each batch or part of a batch of cannabis plants that contributes to a lot of medical cannabidiol shall be recorded in the department's secure sales and inventory tracking system or other manifest system.

154.25(3) *Production of medical cannabidiol.*

a. A manufacturer shall comply with all state and local building and fire code requirements.

b. A manufacturer shall obtain approval from the department for use of any hydrocarbon-based extraction process. Examples of a hydrocarbon-based extraction process include the use of butane, ethanol, hexane, and isopropyl alcohol.

c. Medical cannabidiol shall be prepared, handled, and stored in compliance with the sanitation requirements in this rule.

d. A manufacturer shall produce shelf-stable, nonperishable forms of medical cannabidiol.

e. A manufacturer shall ensure that the cannabinoid content of the medical cannabidiol it produces is homogenous.

f. Each lot of medical cannabidiol shall be assigned a unique lot number and recorded in the department's secure sales and inventory tracking system or other manifest system.

154.25(4) *General sanitation requirements.* A manufacturer shall take all reasonable measures and precautions to ensure that:

a. Any employee who has a communicable disease does not perform any tasks that might contaminate plant material or medical cannabidiol;

b. Hand-washing facilities are:

(1) Convenient and furnished with running water at a suitable temperature;

(2) Located in all production areas; and

(3) Equipped with effective hand-cleaning and -sanitizing preparations and sanitary towel service or electronic drying devices;

c. All employees working in direct contact with plant material and medical cannabidiol use hygienic practices while on duty, including:

(1) Maintaining personal cleanliness; and

(2) Washing hands thoroughly in a hand-washing area before starting work and at any other time when the hands may have become soiled or contaminated;

d. Litter and waste are routinely removed and the operating systems for waste disposal are routinely inspected;

e. Floors, walls, and ceilings are constructed with a surface that can be easily cleaned and maintained in good repair to inhibit microbial growth;

f. Lighting is adequate in all areas where plant material and medical cannabidiol are processed, stored, or sold;

g. Screening or other protection against the entry of pests is provided, including that rubbish is disposed of to minimize the development of odor and the potential for the waste becoming an attractant, harborage, or breeding place for pests;

h. Any buildings, fixtures, and other facilities are maintained in a sanitary condition;

i. Toxic cleaning compounds, sanitizing agents, and other potentially harmful chemicals are identified and stored in a separate location away from plant material and medical cannabidiol and in accordance with applicable local, state, or federal law;

j. All contact surfaces, utensils, and equipment used in the production of plant material and medical cannabidiol are maintained in a clean and sanitary condition;

k. The manufacturing facility water supply is sufficient for necessary operations;

l. Plumbing size and design meets operational needs and all applicable state and local laws;

m. Employees have accessible toilet facilities that are sanitary and in good repair; and

n. Plant material and medical cannabidiol that could support the rapid growth of undesirable microorganisms are isolated to prevent the growth of those microorganisms.

154.25(5) *Storage.*

a. A manufacturer shall store plant material and medical cannabidiol during production, transport, and testing to prevent diversion, theft, or loss, including ensuring that:

(1) Plant material and medical cannabidiol are returned to a secure location immediately after completion of the process or at the end of the scheduled business day; and

(2) The tanks, vessels, bins, or bulk containers containing plant material or medical cannabidiol are locked inside a secure area if a process is not completed at the end of a business day.

b. A manufacturer shall store all plant material and medical cannabidiol during production, transport, and testing, and all saleable medical cannabidiol:

(1) In areas that are maintained in a clean, orderly, and well-ventilated condition; and

(2) In storage areas that are free from infestation by insects, rodents, birds, and other pests of any kind.

c. To prevent degradation, a manufacturer shall store all plant material and medical cannabidiol in production, transport, and testing, and all saleable medical cannabidiol under conditions that will protect the product and its container against physical, chemical, and microbial contamination and deterioration.

d. A manufacturer shall maintain a separate secure storage area for medical cannabidiol that is returned from a dispensary, including medical cannabidiol that is outdated, damaged, deteriorated, mislabeled, or contaminated, or whose containers or packaging has been opened or breached, until the returned medical cannabidiol is destroyed. For purposes of this rule, a separate secure storage area includes a container, closet, or room that can be locked or secured.

[**ARC 3606C**, IAB 1/31/18, effective 3/7/18]

641—154.26(124E) Quality assurance and control.

154.26(1) *Quality control program.* A manufacturer shall develop and implement a written quality assurance program that assesses the chemical and microbiological composition of medical cannabidiol. Assessment includes a profile of the active ingredients, including shelf life, and the presence of inactive ingredients and contaminants. A manufacturer shall use these testing results to determine appropriate storage conditions and product expiration dates.

154.26(2) *Sampling protocols.* A manufacturer shall develop and follow written procedures for sampling medical cannabidiol that require the manufacturer to:

a. Conduct sample collection in a manner that provides analytically sound and representative samples;

b. Document every sampling event and provide this documentation to the department upon request;

c. Describe all sampling and testing plans in written procedures that include the sampling method and the number of units per lot to be tested;

d. Ensure that random samples from each lot are:

(1) Taken in an amount necessary to conduct the applicable test;

(2) Labeled with the lot number; and

(3) Submitted for testing;

e. Retain the results from the random samples for at least five years; and

f. Notify the department at least two business days prior to sample collection and allow the department or its designees to be present to observe the sampling procedures when the samples are to be sent to a laboratory for testing.

154.26(3) *Sampling and testing.* A manufacturer shall:

a. Work with the department and laboratory personnel to develop acceptance criteria for all potential contaminants based on the levels of metals, microbes, or other contaminants that the manufacturer uses in cultivating and producing medical cannabidiol;

b. Conduct sampling and testing of all medical cannabidiol lots using acceptance criteria that are protective of patient health. The sampling and testing results shall be approved by the department and laboratory personnel and shall ensure that lots of medical cannabidiol meet allowable health risk limits for contaminants. Testing of lots shall occur as follows:

(1) At a minimum, testing of lots for cannabinoid potency and all microbiological impurities except microbiological toxins shall occur after packaging but before transport or sale to a dispensary;

(2) At a minimum, testing of lots for residual solvents and processing chemicals, pesticides, and metals shall occur at the process lot stage. A packaged product that contains medical cannabidiol solely from process lots that passed laboratory testing for residual solvents and processing chemicals, pesticides, and metals does not need to be retested for these analytes provided that solvents and processing chemicals are not used during the processing into the packaged product;

(3) Testing of lots for residual solvents and processing chemicals shall also occur after packaging but before transport or sale to a dispensary if solvents or processing chemicals are used in the production process after the testing of the process lot has occurred;

c. Refrain from packaging or selling medical cannabidiol from a process lot that fails to meet established standards, specifications, and any other relevant quality control criteria. Medical cannabidiol from a process lot that fails quality assurance testing may be remixed and retested;

d. Reject and destroy medical cannabidiol from a lot that fails to meet established standards, specifications, and any other relevant quality control criteria when remixing and retesting are not warranted;

e. Develop and follow a written procedure for responding to results failing to meet established standards, specifications, and any other relevant quality control criteria, including:

(1) Criteria for when remixing and retesting are warranted;

(2) Instructions for destroying contaminated or substandard medical cannabidiol as provided in subrule 154.23(2) when remixing and retesting are not warranted; and

(3) Instructions for determining the source of contamination;

f. Retain documentation of test results, assessment, and destruction of medical cannabidiol for at least five years.

154.26(4) *Stability testing.*

a. The quality assurance program shall include procedures for performing stability testing of each product type produced to determine product expiration dates. The procedures shall describe:

(1) Sample size and test intervals based on statistical criteria and departmental guidance pursuant to subrule 154.69(1) for each attribute examined to ensure valid stability estimates;

(2) Storage conditions for samples retained for testing; and

(3) Reliable and specific test methods.

b. Stability studies shall include:

(1) Medical cannabidiol testing at appropriate intervals; and

(2) Medical cannabidiol testing in the same container-closure system in which the medical cannabidiol is marketed and dispensed.

c. If product-expiration-date studies have not been completed before December 1, 2018, a manufacturer shall assign a tentative product expiration date, not to exceed one year, based on any available stability information. A manufacturer shall concurrently conduct stability studies to determine the actual product expiration date.

d. After a manufacturer verifies the tentative product expiration date, or determines the appropriate product expiration date, a manufacturer shall include that product expiration date on each lot of medical cannabidiol.

e. Stability testing shall be repeated if the manufacturing process or the product's chemical composition is changed.

154.26(5) *Reserve samples.*

a. A manufacturer shall retain a uniquely labeled reserve sample that represents each lot of medical cannabidiol and store the reserve sample under conditions consistent with product labeling. The reserve sample shall be stored in the same immediate container-closure system in which the medical cannabidiol is marketed or in one that has similar characteristics. The reserve sample shall consist of at least twice the quantity necessary to perform all the required tests.

b. A manufacturer shall retain the reserve for at least two years from the date of manufacture.

c. After two years from the date of manufacture, reserve samples shall be destroyed as provided in subrule 154.23(2).

154.26(6) *Retesting.* If the department deems that public health may be at risk, the department may require the manufacturer to retest any sample of plant material or medical cannabidiol.

154.26(7) *Disposal of substandard product.* A manufacturer shall dispose of all medical cannabidiol as provided in subrule 154.23(2) when samples fail to meet established standards, specifications, and other relevant quality control criteria and when an adequate remedy for remixing and retesting as provided in paragraph 154.26(3)*"c"* is unavailable.

154.26(8) *Recall and market withdrawal procedures.* Each manufacturer shall establish a procedure for recalling or withdrawing from the market, as applicable, medical cannabidiol that has a reasonable

probability of causing an unexpected or harmful response in a patient population, despite appropriate use, that outweighs the potential benefit of the medical cannabidiol. This procedure shall include:

a. Factors that make a recall or market withdrawal necessary;

b. Manufacturer's personnel who are responsible for overseeing the recall or market withdrawal; and

c. How to notify affected parties of a recall or market withdrawal.

[**ARC 3606C**, IAB 1/31/18, effective 3/7/18; **ARC 3836C**, IAB 6/6/18, effective 7/11/18; **ARC 4078C**, IAB 10/10/18, effective 11/14/18]

641—154.27(124E) Supply and inventory.

154.27(1) *Reliable and ongoing supply.* A manufacturer shall provide a reliable and ongoing supply of medical cannabidiol to medical cannabidiol dispensaries.

154.27(2) *Inventory controls and procedures.* A manufacturer shall establish inventory controls and procedures for conducting inventory reviews to prevent and detect any diversion, theft, or loss in a timely manner.

154.27(3) *Real-time inventory required.* A manufacturer shall use the department-approved secure sales and inventory tracking system to track medical cannabidiol production from seed or plant cutting through distribution of medical cannabidiol to a dispensary. The manufacturer shall use the system to maintain a real-time record of the manufacturer's inventory of plant material and medical cannabidiol to include:

a. The quantity and form of medical cannabidiol maintained by the manufacturer at the manufacturing facility on a daily basis;

b. The amount of plants being grown at the manufacturing facility on a daily basis;

c. The names of the employees or employee conducting the inventory; and

d. Other information deemed necessary and requested by the department.

154.27(4) *Waste inventory.* A manufacturer shall maintain a record of its inventory of all medical cannabidiol waste and plant material waste for disposal.

154.27(5) *Reconciliation.* No less often than every two calendar weeks, a manufacturer shall reconcile its physical inventory with the inventory recorded in the department's secure sales and inventory tracking system.

a. Reconciliation shall include:

(1) Plant material at the manufacturing facility and in transit; and

(2) Medical cannabidiol at the manufacturing facility, at distribution and storage facilities, and in transit.

b. Discrepancies between the physical inventory of the manufacturer and the inventory recorded in the department's secure sales and inventory system shall be handled as follows:

(1) A manufacturer shall report suspected diversion of plant material or medical cannabidiol to the department and law enforcement within 72 hours of discovery.

(2) A manufacturer shall have up to 72 hours to reconcile discrepancies in the manufacturer's physical inventory with the inventory recorded in the secure sales and inventory tracking system. If the manufacturer cannot reconcile the manufacturer's physical inventory with the secure sales and inventory tracking system's inventory within 72 hours but diversion of plant material or medical cannabidiol is not suspected, the manufacturer shall immediately contact the department to report the discrepancy and to initiate a compliance action plan pursuant to paragraph 154.28(4)*"b."*

154.27(6) *Scales.* All scales used to weigh usable plant material for purposes of these rules shall be certified in accordance with ISO/IEC Standard 17025, which is incorporated herein by reference.

[**ARC 3606C**, IAB 1/31/18, effective 3/7/18; **ARC 4078C**, IAB 10/10/18, effective 11/14/18]

641—154.28(124E) Inspection by department or independent consultant. A manufacturer is subject to reasonable inspection by the department, a department-approved consultant, or other agency pursuant to Iowa Code chapter 124E and these rules and as authorized by laws and regulations.

154.28(1) *Types of inspections.* Inspections may include:

a. Aspects of the business operations;

b. The manufacturing facility;

c. Vehicles used for transport or delivery of medical cannabidiol or plant material;

d. Financial information and inventory documentation;

e. Physical and electronic security alarm systems; and

f. Other inspections as determined by the department.

154.28(2) *Local safety inspections.* A manufacturer may be subject to inspection of its manufacturing facility and grounds by the local fire department, building inspector, or code enforcement officer to confirm that no health or safety concerns are present. The inspection could result in additional specific standards to meet local licensing authority restrictions related to medical cannabidiol manufacturing or other local businesses. An annual fire safety inspection may result in the required installation of fire suppression devices, or other means necessary for adequate fire safety.

154.28(3) *Health and sanitary inspection.* The department has discretion to determine when an inspection by an independent consultant is necessary. The following is a nonexhaustive list of examples that may justify an independent inspection:

a. The department has reasonable grounds to believe that the manufacturer is in violation of one or more of the requirements set forth in these rules or other applicable public health or sanitary laws, rules or regulations; or

b. The department has reasonable grounds to believe that the manufacturer was the cause or source of contamination of medical cannabidiol.

154.28(4) *Compliance required.* A manufacturer shall respond to deficiencies found during inspections or inventory reconciliation as follows:

a. Deficiencies not related to inventory reconciliation.

(1) Upon written notification by the department of deficiencies that do not involve reconciliation of inventory, a manufacturer shall have up to 30 days to submit an action plan to the department with proposed remedies and timelines for completion of the remedies.

(2) The department shall have up to two weeks to accept or require revision of the action plan.

b. Deficiencies related to inventory reconciliation.

(1) Upon notifying the department that the manufacturer cannot reconcile the manufacturer's physical inventory with the inventory recorded in the department's secure sales and inventory tracking system, the manufacturer shall have up to two business days to submit an action plan to the department with proposed remedies and timelines for completion of the remedies.

(2) The department shall have up to two business days to accept or require revision of the action plan.

c. Failure to complete actions in the action plan within the timelines mutually agreed upon by the manufacturer and the department shall result in assessment of penalties or in suspension or revocation of a manufacturer license as authorized by these rules.

d. At the department's request and in a timely manner, a manufacturer shall pay for and undergo an independent health and sanitary inspection in accordance with this rule.

[**ARC 3606C**, IAB 1/31/18, effective 3/7/18; **ARC 4078C**, IAB 10/10/18, effective 11/14/18]

641—154.29(124E) Assessment of penalties. The department shall assess to a manufacturer a civil penalty of up to $1,000 per violation of Iowa Code chapter 124E or these rules in addition to other applicable penalties.

[**ARC 3606C**, IAB 1/31/18, effective 3/7/18]

641—154.30(124E) Suspension or revocation of a manufacturer license.

154.30(1) The department may suspend or revoke a manufacturer license upon any of the following grounds:

a. Submission of false, inaccurate, misleading, or fraudulent information to the department in the application or inspection processes.

b. Failure to submit required reports and documents.

c. Violation of Iowa Code chapter 124E or these rules, or violation of state or local law related to operation of the licensee.

d. Conduct or practices detrimental to the safety, health, or welfare of a patient, primary caregiver, or the public.

e. Criminal, civil, or administration action taken against a license or registration in this or another state or country related to manufacturing or dispensing medical cannabidiol.

f. False, misleading, or deceptive representations to the department, another state or federal agency, or a law enforcement agency.

g. Discontinuance of operation for more than 30 days, unless the department approves an extension of such period for good cause shown.

h. Failure to maintain effective controls against diversion, theft, or loss of medical cannabidiol.

i. Failure to correct a deficiency within the time frame required by the department.

j. Failure of a manufacturer's business owner to have a satisfactory result in a background investigation or national criminal history background check conducted by the department of public safety and as determined by the department.

154.30(2) The department shall notify the licensee of the proposed action pursuant to Iowa Code sections 17A.12 and 17A.18. Notice of issuance of a suspension or revocation shall be served by restricted certified mail, return receipt requested, or by personal service.

154.30(3) A request for appeal concerning the suspension or revocation of a license shall be submitted by the aggrieved party in writing to the department by certified mail, return receipt requested, within 20 days of the receipt of the department's notice. The address is: Iowa Department of Public Health, Office of Medical Cannabidiol, Lucas State Office Building, Des Moines, Iowa 50319-0075. If such a request is made within the 20-day time period, the notice shall be deemed to be suspended. Prior to or at the hearing, the department may rescind the notice upon satisfaction that the reason for the suspension or revocation has been or will be removed. After the hearing or upon default of the applicant or alleged violator, the administrative law judge shall affirm, modify or set aside the suspension or revocation. If no request for appeal is received within the 20-day time period, the department's notice of suspension or revocation shall become the department's final agency action.

154.30(4) Upon receipt of an appeal that meets contested case status, the appeal shall be forwarded within five working days to the department of inspections and appeals. The information upon which the adverse action is based and any additional information which may be provided by the aggrieved party shall also be provided to the department of inspections and appeals.

154.30(5) The hearing shall be conducted according to the procedural rules of the department of inspections and appeals found in 481—Chapter 10.

154.30(6) When the administrative law judge makes a proposed decision and order, it shall be served by restricted certified mail, return receipt requested, or delivered by personal service. That proposed decision and order then becomes the department's final agency action without further proceedings ten days after it is received by the aggrieved party unless an appeal to the director is taken.

154.30(7) Any appeal to the director for review of the proposed decision and order of the administrative law judge shall be filed in writing and mailed to the director by certified mail, return receipt requested, or delivered by personal service within ten days after the receipt of the administrative law judge's proposed decision and order by the aggrieved party. A copy of the appeal shall also be mailed to the administrative law judge. Any request for an appeal shall state the reason for appeal.

154.30(8) Upon receipt of an appeal request, the administrative law judge shall prepare the record of the hearing for submission to the director. The record shall include the following:

a. All pleadings, motions, and rules.

b. All evidence received or considered and all other submissions by recording or transcript.

c. A statement of all matters officially noticed.

d. All questions and offers of proof, objections, and rulings thereon.

e. All proposed findings and exceptions.

f. The proposed decision and order of the administrative law judge.

154.30(9) The decision and order of the director becomes the department's final agency action upon receipt by the aggrieved party and shall be delivered by restricted certified mail, return receipt requested, or by personal service.

154.30(10) It is not necessary to file an application for a rehearing to exhaust administrative remedies when appealing to the director or the district court as provided in Iowa Code section 17A.19. The aggrieved party to the final agency action of the department who has exhausted all administrative remedies may petition for judicial review of that action pursuant to Iowa Code chapter 17A.

154.30(11) Any petition for judicial review of a decision and order shall be filed in the district court within 30 days after the decision and order becomes final. A copy of the notice of appeal shall be sent to the department by certified mail, return receipt requested, or by personal service. The address is: Iowa Department of Public Health, Lucas State Office Building, Des Moines, Iowa 50319-0075.

154.30(12) The party who appeals a final agency action to the district court shall pay the cost of the preparation of a transcript of the contested case hearing for the district court.

154.30(13) Emergency adjudicative proceedings.

a. Necessary emergency action. To the extent necessary to prevent or avoid immediate danger to the public health, safety, or welfare, and consistent with the Constitution and other provisions of law, the department may issue a written order in compliance with Iowa Code section 17A.18A to suspend a license in whole or in part, order the cessation of any continuing activity, order affirmative action, or take other action within the jurisdiction of the department by emergency adjudicative order.

b. Before issuing an emergency adjudicative order, the department shall consider factors including, but not limited to, the following:

(1) Whether there has been a sufficient factual investigation to ensure that the department is proceeding on the basis of reliable information;

(2) Whether the specific circumstances which pose immediate danger to the public health, safety or welfare have been identified and determined to be continuing;

(3) Whether the licensee required to comply with the emergency adjudicative order may continue to engage in other activities without posing immediate danger to the public health, safety or welfare;

(4) Whether imposition of monitoring requirements or other interim safeguards would be sufficient to protect the public health, safety or welfare; and

(5) Whether the specific action contemplated by the department is necessary to avoid the immediate danger.

c. Issuance of order.

(1) An emergency adjudicative order shall contain findings of fact, conclusions of law, and policy reasons to justify the determination of an immediate danger in the department's decision to take immediate action. The order is a public record.

(2) The written emergency adjudicative order shall be immediately delivered to the licensee that is required to comply with the order. The order shall be delivered by one or more of the following methods:

1. Personal delivery.

2. Certified mail, return receipt requested, to the last address on file with the department.

3. Fax. Fax may be used as the sole method of delivery if the licensee required to comply with the order has filed a written request that agency orders be sent by fax and has provided a fax number for that purpose.

(3) To the degree practicable, the department shall select the procedure for providing written notice that best ensures prompt, reliable delivery.

(4) Unless the written emergency adjudicative order is provided by personal delivery on the same day that the order issues, the department shall make reasonable immediate efforts to contact by telephone the licensee that is required to comply with the order.

(5) After the issuance of an emergency adjudicative order, the department shall proceed as quickly as feasible to complete any proceedings that would be required if the matter did not involve an immediate danger.

(6) Issuance of a written emergency adjudicative order shall include notification of the date on which department proceedings are scheduled for completion. After issuance of an emergency adjudicative order, continuance of further department proceedings to a later date will be granted only

in compelling circumstances upon application in writing unless the licensee that is required to comply with the order is the party requesting the continuance.
[**ARC 3606C**, IAB 1/31/18, effective 3/7/18]

641—154.31(124E) Closure of operations.

154.31(1) *Notice.* A manufacturer shall notify the department at least six months before the closure of the manufacturing facility.

154.31(2) *Procedures.* If a manufacturer ceases operation, the manufacturer shall work with the department to verify the remaining inventory of the manufacturer and ensure that any plant material, plant material waste, and medical cannabidiol are destroyed at a waste facility as provided in subrule 154.23(2).
[**ARC 3606C**, IAB 1/31/18, effective 3/7/18]

641—154.32 to **154.39** Reserved.

DISPENSING

641—154.40(124E) Duties of the department.

154.40(1) *Interagency agreements.* The department may enter into any interagency agreements with other state agencies for technical services or other assistance related to the regulation or inspection of dispensaries.

154.40(2) *Notice to law enforcement.* The department shall notify local law enforcement agencies and the department of public safety of the locations of dispensaries. If the department has sufficient cause to believe that there is a threat to public safety, the department shall notify local law enforcement agencies and the department of public safety of any conditions that pose a threat to public safety including but not limited to:

a. Loss or theft of medical cannabidiol;

b. Diversion or potential diversion of medical cannabidiol;

c. Unauthorized access to the secure sales and inventory tracking system or other patient and caregiver information system or file; or

d. Other violations of law.

154.40(3) *Inspection of dispensaries.* The department or its agents shall conduct regular inspections of dispensaries and their facilities as described in rule 641—154.52(124E).

154.40(4) *Establishment and maintenance of a secure sales and inventory tracking system.* The department shall establish and maintain a secure, electronic system that is available 24 hours a day, seven days a week to track:

a. Inventory of medical cannabidiol and waste material;

b. Sales of medical cannabidiol from dispensaries to patients and primary caregivers.

154.40(5) *Licensure and licensure renewal of dispensaries.* The department shall issue a request for proposals to select and license by April 1, 2018, up to five dispensaries to dispense medical cannabidiol within the state consistent with the provisions of Iowa Code chapter 124E and these rules.

a. To be eligible for licensure, an applicant dispensary shall provide information on forms and in a manner required by the department of public safety for the completion of a background investigation. In addition, the applicant dispensary shall submit to the department of public safety necessary funds to satisfy the full reimbursement of costs associated with completing the background investigations. If the applicant dispensary is not found suitable for licensure as a result of the background investigation, a license shall not be issued by the department.

b. As a condition for licensure, an applicant dispensary shall agree to begin dispensing medical cannabidiol to patients and primary caregivers in Iowa no later than December 1, 2018.

c. The initial license to dispense medical cannabidiol shall be valid from April 1, 2018, through November 30, 2018. The license shall be renewed annually unless a dispensary relinquishes the license, there is a change in state law prohibiting the department from renewing the license, or the license is revoked pursuant to Iowa Code chapter 124E or these rules.

d. A license to dispense medical cannabidiol issued by the department pursuant to these rules is not assignable or transferable.

e. The department shall consider the following factors in determining whether to select and license a medical cannabidiol dispensary:

(1) Geographical location of the proposed dispensary facility;

(2) The technical expertise of an applicant dispensary's staff regarding medical cannabidiol;

(3) The qualifications of an applicant dispensary's employees;

(4) The long-term financial stability of an applicant dispensary;

(5) The ability of an applicant dispensary to provide appropriate security measures on the premises of the dispensary;

(6) An applicant dispensary's projection of and ongoing assessment of retail product costs, including any dispensing fees.

f. Pursuant to Iowa Code section 124E.8(1)*"b,"* information submitted during the application process shall be confidential until an applicant dispensary is licensed by the department unless otherwise protected from disclosure under state or federal law.

g. A licensed dispensary shall submit an application to renew its license with the department at least six months before the license expires. The application shall be submitted on a form created by the department.

h. The department shall notify a dispensary of the decision to approve or deny the dispensary's license by August 1 of the year in which the renewal application is submitted.

154.40(6) *Collection of fees from dispensaries.* Except as provided in this rule, all fees are nonrefundable, shall be retained by the department, and shall be considered repayment receipts as defined in Iowa Code section 8.2.

a. Fees to the department.

(1) One application is required for each dispensary location.

(2) Each application for licensure as a dispensary shall include a nonrefundable application fee of $5,000.

(3) Licensed dispensaries shall pay an annual fee to the department to cover costs associated with regulating and inspecting dispensaries and for other expenses necessary for the administration of the medical cannabidiol program. The department shall assess the fee with the notice of approval of license renewal each year on August 1, payable by the dispensary to the department no later than December 1.

b. Fees to the department of public safety.

(1) An applicant dispensary shall be responsible to reimburse the department of public safety the full cost of conducting background investigations related to an application for licensure and operation as a licensed dispensary. The department of public safety shall retain the right to bill a dispensary for additional background investigations, as needed.

(2) Each dispensary submitting an application for licensure shall, at time of application, submit to the department of public safety a deposit of $10,000 for each business owner subject to a background investigation and a national criminal history background check. Background investigation costs shall be deducted from the funds deposited. If the background investigation fees exceed the funds deposited, the applicant shall submit additional funds as required by the department of public safety. If the background investigation fees are less than the funds deposited, the department of public safety may refund or retain the fees as mutually agreed with the dispensary.

(3) A licensed dispensary shall pay a deposit of $200 per employee to the department of public safety for a background investigation and a national criminal history background check on any person being considered for hire as an employee of the dispensary. Background investigation costs shall be deducted from the funds deposited. If the background investigation fees exceed the funds deposited, the dispensary shall submit additional funds as required by the department of public safety. If the background investigation fees are less than the funds deposited, the department of public safety may refund or retain the fees as mutually agreed with the dispensary. The department shall retain the right to preclude a

potential employee from hire based upon the results of the background investigation and national criminal history background check.
[**ARC 3606C**, IAB 1/31/18, effective 3/7/18]

641—154.41(124E) Dispensary operations.

154.41(1) *Operating documents.* The operating documents of a dispensary shall include all of the following:

a. Procedures for the oversight of the dispensary, including descriptions of operational and management practices regarding:

(1) The forms and quantities of medical cannabidiol products that will be stored and dispensed at the dispensary;

(2) The estimated forms and quantities of medical cannabidiol waste to be generated or collected;

(3) The disposal methods for all waste materials;

(4) Employee training methods for the dispensary employees;

(5) Strategies for identifying and reconciling discrepancies in inventory of medical cannabidiol;

(6) Medical cannabidiol labeling procedures;

(7) Procedures for recall or market withdrawal of medical cannabidiol;

(8) Plans for responding to a security breach at the dispensary facility;

(9) A business continuity plan; and

(10) Other information requested by the department.

b. Procedures to ensure accurate record keeping.

c. Procedures for the implementation of appropriate security measures to deter and prevent the theft of medical cannabidiol and unauthorized entrance into areas of the dispensary facility containing medical cannabidiol.

154.41(2) *Prohibited activities.*

a. A person or entity shall not own or operate a dispensary unless the person or entity is licensed by the department pursuant to Iowa Code chapter 124E and these rules.

b. A dispensary shall not:

(1) Dispense medical cannabidiol in any location except in those areas approved by the department;

(2) Sell, receive, transport, or distribute medical cannabidiol from any location except its dispensary;

(3) Sell, receive, or distribute medical cannabidiol from any entity other than a manufacturer licensed by the department;

(4) Sell or distribute medical cannabidiol to any person other than an approved patient or primary caregiver;

(5) Transport or deliver medical cannabidiol to any location, unless approved by the department;

(6) Sell medical cannabidiol that is not packaged and labeled in accordance with rules 641—154.21(124E) and 641—154.46(124E);

(7) Repackage medical cannabidiol or remove the manufacturer's label;

(8) Sell medical cannabidiol in any form or quantity other than a form or quantity approved by the department and adopted by rule;

(9) Permit any person to consume medical cannabidiol on the property of the dispensary;

(10) Employ a person who is under 18 years of age or who has been convicted of a disqualifying felony offense.

154.41(3) *Criminal background checks.*

a. An owner of a dispensary shall not have been convicted of a disqualifying felony offense and shall be subject to a background investigation conducted by the department of public safety, including but not limited to a national criminal history background check.

b. An employee of a dispensary shall not have been convicted of a disqualifying felony offense and shall be subject to a background investigation conducted by the department of public safety, including but not limited to a national criminal history background check.

154.41(4) *Relationship to health care practitioners.* A dispensary shall not share office space with, refer patients to, or have any financial relationship with a health care practitioner.

[**ARC 3606C**, IAB 1/31/18, effective 3/7/18]

641—154.42(124E) Security requirements. The department may request assistance from the department of public safety in ensuring dispensaries meet the security requirements in this rule.

154.42(1) *Restricted access.* A dispensary shall have a controlled access system to limit entrance to all restricted access areas of the dispensary facility. Visitors to restricted access areas shall sign manifests with name, date, and times of entry and exit, if the controlled access system cannot electronically record visitors. Visitors shall wear badges that are visible at all times and identify them as visitors.

a. The controlled access system shall do all of the following:

(1) Limit access to authorized individuals;

(2) Maintain a log of individuals with approved access, including dates of approvals and revocations;

(3) Track times of personnel entry to and exit from restricted access areas;

(4) Store data for retrieval for a minimum of one year; and

(5) Limit access to authorized individuals in the event of a power failure.

b. A dispensary shall promptly, but no later than five business days after receipt of request, submit stored controlled access system data to the department.

c. Separate written manifests of visitors to restricted access areas shall be kept and stored for a minimum of one year if the controlled access system does not include electronic records of visitors to the restricted access areas.

d. Restricted access areas shall be identified with signs that state: "Do Not Enter – Restricted Access Area – Access Limited to Authorized Personnel Only."

154.42(2) *Perimeter intrusion detection system.*

a. *Computer-controlled video surveillance system.* A dispensary shall operate and maintain in good working order a computer-controlled, closed-circuit television surveillance system on its premises that operates 24 hours per day, seven days a week, and visually records:

(1) All areas that might contain medical cannabidiol, including all safes, vaults, and storage areas;

(2) All points of entry and exit;

(3) The entrance to the video surveillance control room; and

(4) Parking areas, which shall have appropriate lighting for the normal conditions of the area under surveillance.

b. *Camera specifications.* Cameras shall:

(1) Capture clear and certain identification of any person entering or exiting a dispensary or its parking areas to the extent identification is technologically feasible with generally accepted commercial security cameras;

(2) Have the ability to produce a clear, color still photograph live or from a recording;

(3) Have on all recordings an embedded date-and-time stamp that is synchronized to the recording and does not obscure the picture; and

(4) Continue to operate during a power outage.

c. *Video recording specifications.*

(1) A video recording shall export still images in an industry standard image format, such as .jpg, .bmp, or .gif.

(2) Exported video shall be archived in a format that ensures authentication and guarantees that the recorded image has not been altered.

(3) Exported video shall also be saved in an industry standard file format that can be played on a standard computer operating system.

(4) All recordings shall be erased or destroyed at the end of the retention period and prior to disposal of any storage medium.

d. *Additional requirements.* A dispensary shall maintain all security system equipment and recordings in a secure location to prevent theft, loss, destruction, corruption, and alterations.

e. *Retention.* A dispensary shall ensure that recordings from all video cameras are:

(1) Available for viewing by the department upon request;

(2) Retained for at least 60 days;

(3) Maintained free of alteration or corruption; and

(4) Retained longer, as needed, if a dispensary is given actual notice of a pending criminal, civil, or administrative investigation, or other legal proceeding for which the recording may contain relevant information.

f. *Required signage.* A dispensary shall post a sign in capital letters in a conspicuous location at every entrance to the dispensary that reads, "THESE PREMISES ARE UNDER CONSTANT VIDEO SURVEILLANCE."

154.42(3) *Security alarm system requirements.*

a. A dispensary shall install and maintain a professionally monitored security alarm system that provides intrusion and fire detection of all:

(1) Dispensary entrances and exits;

(2) Rooms with exterior windows;

(3) Rooms with exterior walls;

(4) Roof hatches;

(5) Skylights; and

(6) Storage rooms.

b. For the purposes of this subrule, a security alarm system means a device or series of devices that summons law enforcement personnel during, or as a result of, an alarm condition. Devices may include:

(1) Hardwired systems and systems interconnected with a radio frequency method such as cellular or private radio signals that emit or transmit a remote or local audio, visual, or electronic signal;

(2) Motion detectors;

(3) Pressure switches;

(4) A duress alarm;

(5) A panic alarm;

(6) A holdup alarm;

(7) An automatic voice dialer; and

(8) A failure notification system that provides an audio, text, or visual notification of any failure in the surveillance system.

c. A dispensary's security alarm system and all devices shall continue to operate during a power outage.

d. A dispensary's security alarm system shall be inspected and all devices tested annually by a qualified alarm vendor. A dispensary shall provide documentation of the annual inspection and device testing to the department upon request.

154.42(4) *Personnel identification system.* A dispensary shall use a personnel identification system that controls and monitors individual employee access to restricted access areas within the dispensary and that meets the requirements of this subrule and subrule 154.42(1).

a. Requirement for employee identification card. An employee identification card shall contain:

(1) The name of the employee;

(2) The date of issuance and expiration;

(3) An alphanumeric identification number that is unique to the employee; and

(4) A photographic image of the employee.

b. A dispensary's employees shall keep the identification card visible at all times when the employee is in a dispensary or a vehicle transporting medical cannabidiol.

c. Upon termination or resignation of an employee, a dispensary shall immediately:

(1) Revoke the employee's access to restricted access areas of the dispensary; and

(2) Obtain and destroy the employee's identification card, if possible.
[**ARC 3606C**, IAB 1/31/18, effective 3/7/18]

641—154.43(124E) Location. All dispensing of medical cannabidiol shall take place in an enclosed facility at one physical address provided to the department during the licensure process.

154.43(1) *Proximity to manufacturers.* A dispensary shall not operate at the same physical location as a manufacturer.

154.43(2) *Proximity to schools.* A dispensary shall not operate in any location within 1,000 feet of a public or private school existing before the date of the dispensary's licensure by the department.
[**ARC 3606C**, IAB 1/31/18, effective 3/7/18]

641—154.44(124E) Advertising and marketing.

154.44(1) *Permitted marketing and advertising activities.*

a. A dispensary may:

(1) Display the dispensary's business name and logo on medical cannabidiol labels, signs, website, and informational material provided to patients. The name or logo shall not include:

1. Images of cannabis or cannabis-use paraphernalia;
2. Colloquial references to cannabis;
3. Names of cannabis plant strains or varieties;
4. Unsubstantiated medical claims; or
5. Medical symbols that bear a reasonable resemblance to established medical associations. Examples of established medical organizations include the American Medical Association or American Academy of Pediatrics. The use of medical symbols is subject to approval by the department.

(2) Display signs on the dispensary; and

(3) Maintain a business website that contains the following information:

1. The dispensary's name and contact information;
2. The medical cannabidiol forms and quantities provided;
3. Medical cannabidiol pricing;
4. Hours of operation; and
5. Other information as approved by the department.

b. The business website shall not include any false, misleading, or unsubstantiated statements.

c. The department reserves the right to review a dispensary's marketing and advertising materials and to require a dispensary to make changes to the content. The department has 30 calendar days following submission to approve or deny marketing and advertising materials of a dispensary.

154.44(2) *Other marketing and advertising activities.* A dispensary shall request and receive the department's written approval before beginning marketing or advertising activities that are not specified in subrule 154.44(1). The department has 30 calendar days to approve, deny, or request additional information regarding marketing and advertising activity requests from a dispensary. In the event the department fails to respond to a dispensary within 30 days with an approval, denial, or request for additional information, the dispensary's marketing and advertising activity requests shall be deemed approved.

154.44(3) *Inconspicuous display.* A dispensary shall arrange displays of medical cannabidiol, interior signs, and other exhibits to reasonably prevent public viewing from outside the dispensary.
[**ARC 3606C**, IAB 1/31/18, effective 3/7/18]

641—154.45(124E) Storage.

154.45(1) *Storage of saleable medical cannabidiol.*

a. A dispensary shall store medical cannabidiol to prevent diversion, theft, or loss, including ensuring that:

(1) Medical cannabidiol is kept in a secure and monitored location within the dispensary; and

(2) Cabinets or storage containers inside the secure and monitored area are locked at the end of a business day.

b. A dispensary shall store all medical cannabidiol:

(1) In areas that are maintained in a clean, orderly, and well-ventilated condition;

(2) In areas that are free from infestation by insects, rodents, birds, and other pests of any kind;

(3) According to the manufacturer's requirements regarding temperature, light exposure, or other environmental conditions;

(4) Under conditions that will protect the product and its container against physical, chemical, and microbial contamination and deterioration.

154.45(2) *Storage of returned medical cannabidiol.* A dispensary shall maintain a separate secure storage area for medical cannabidiol that is to be returned to a manufacturer for disposal, including medical cannabidiol that is outdated, damaged, deteriorated, mislabeled, or contaminated, or whose containers or packaging has been opened or breached, until the medical cannabidiol is collected by a manufacturer. For purposes of this subrule, a separate secure storage area includes a container, closet, or room that can be locked or secured.

[**ARC 3606C**, IAB 1/31/18, effective 3/7/18]

641—154.46(124E) Dispensing.

154.46(1) *Access to all forms of product.* A dispensary shall provide access to all medical cannabidiol forms produced by each licensed manufacturer.

154.46(2) *Dispensing to a patient.*

a. Prior to dispensing any medical cannabidiol to a patient, a dispensary shall do all of the following:

(1) Verify the patient's identity;

(2) Verify that the patient is registered and listed in the secure sales and inventory tracking system and has a valid medical registration card;

(3) Assign a tracking number to any medical cannabidiol that is to be dispensed to the patient;

(4) Issue a label that contains the following information:

1. The medical cannabidiol tracking number;
2. The date and time the medication is being dispensed;
3. The name and address of the dispensary;
4. The patient's registry identification number, name, and date of birth;
5. The patient's address; and
6. Any specific instructions for use based upon manufacturer or departmental guidelines. Labeling text shall not include any false, misleading, or unsubstantiated statements regarding health or physical benefits to the patient.

b. The dispensary shall record the patient name, the amount dispensed, the price, the medical cannabidiol tracking number, the time and date, and other information required by the department in the secure sales and inventory tracking system within one business day.

154.46(3) *Dispensing to a primary caregiver.*

a. Prior to dispensing any medical cannabidiol to a primary caregiver, a dispensary shall do all of the following:

(1) Verify the primary caregiver's identity;

(2) Verify that the patient and the primary caregiver are registered and listed in the secure sales and inventory tracking system and have valid medical registration cards;

(3) Assign a medical cannabidiol tracking number to any medical cannabidiol that is to be dispensed to the primary caregiver;

(4) Issue a label that contains the following information:

1. The medical cannabidiol tracking number;
2. The date and time the medication is being dispensed;
3. The name and address of the dispensary;
4. The patient's registry identification number, name, and date of birth;
5. The primary caregiver's registry identification number, name, and date of birth;
6. The patient's address; and

7. Any specific instructions for use based upon manufacturer or departmental guidelines. Labeling text shall not include any false, misleading, or unsubstantiated statements regarding health or physical benefits to the patient.

b. The dispensary shall record the names of the patient and primary caregiver, the amount dispensed, the price, the medical cannabidiol tracking number, the time and date, and other information required by the department in the secure sales and inventory tracking system within one business day.

[**ARC 3606C**, IAB 1/31/18, effective 3/7/18]

641—154.47(124E) Transportation of medical cannabidiol. A dispensary is not authorized to transport medical cannabidiol, unless approved by the department. Any approved transport shall be logged in the secure sales and inventory tracking system.

[**ARC 3606C**, IAB 1/31/18, effective 3/7/18]

641—154.48(124E) Disposal of medical cannabidiol.

154.48(1) *Identification of excess, expired, or damaged medical cannabidiol.*

a. Dispensaries shall identify unused, excess, expired, or damaged medical cannabidiol for return to manufacturers.

b. Unused, excess, expired, or damaged medical cannabidiol shall be stored as described in subrule 154.45(2).

154.48(2) *Return of medical cannabidiol from a patient or primary caregiver to a dispensary.*

a. A dispensary shall accept at no charge unused, expired, or unwanted medical cannabidiol from any patient or primary caregiver.

b. The dispensary shall enter the following information into the secure sales and inventory tracking system for all medical cannabidiol returned from a patient or primary caregiver:

(1) The tracking number assigned at the time of the dispensing, if available, or the name of the patient, if the tracking number is unavailable, when the medical cannabidiol was returned to the dispensary from a patient or primary caregiver;

(2) The date the medical cannabidiol was returned;

(3) The quantity of medical cannabidiol returned; and

(4) The type and lot number of medical cannabidiol returned.

c. A dispensary shall store medical cannabidiol returned from patients and primary caregivers as described in subrule 154.45(2).

154.48(3) *Return of medical cannabidiol to a manufacturer.*

a. A manufacturer shall collect and dispose of medical cannabidiol from dispensaries as provided in rule 641—154.23(124E).

b. A dispensary shall record information on all medical cannabidiol collected by the manufacturer in the secure sales and inventory tracking system. Information shall include:

(1) The date the medical cannabidiol was collected by the manufacturer;

(2) The quantity of medical cannabidiol collected; and

(3) The type and lot number of medical cannabidiol collected.

[**ARC 3606C**, IAB 1/31/18, effective 3/7/18]

641—154.49(124E) Record-keeping requirements.

154.49(1) *Sales.* A dispensary shall maintain complete and accurate electronic sales transaction records in the department's secure sales and inventory tracking system, including:

a. The name of the patient and, if purchase is made by the primary caregiver, the name of the primary caregiver;

b. The date of each sale;

c. The item number, product name and description, and quantity of medical cannabidiol sold;

d. The sale price;

e. Other information required by the department.

154.49(2) *Financial transactions.* A dispensary shall maintain records that reflect all financial transactions and the financial condition of the business. The following records shall be maintained for at least five years and made available for review, upon request of the department:

a. Purchase invoices, bills of lading, sales records, copies of bills of sale, and any supporting documents, to include the items or services purchased, from whom the items were purchased, and the date of purchase;

b. Bank statements and canceled checks for all business accounts;

c. Accounting and tax records;

d. Records of all financial transactions, including contracts and agreements for services performed or services received.

154.49(3) *Other records.*

a. A dispensary shall maintain the following for at least five years, unless otherwise noted, and provide to the department upon request:

(1) All personnel records; and

(2) Records of any theft, loss, or other unaccountability of any medical cannabidiol.

b. A dispensary shall maintain for at least one year and provide to the department upon request its controlled access system data and visitor manifests.

c. A dispensary shall use the department's secure sales and inventory tracking system to maintain the following:

(1) Inventory records;

(2) Return of medical cannabidiol from a patient or primary caregiver; and

(3) Return of unused, excess, expired, or damaged medical cannabidiol to a manufacturer.

[**ARC 3606C**, IAB 1/31/18, effective 3/7/18]

641—154.50(124E) Quality assurance and control. A dispensary shall cooperate with manufacturers and the department on quality assurance and control procedures, including participating in stability-testing studies, developing sampling strategies, and returning medical cannabidiol that has been recalled or withdrawn from the market.

[**ARC 3606C**, IAB 1/31/18, effective 3/7/18]

641—154.51(124E) Inventory.

154.51(1) *Inventory controls and procedures.* A dispensary shall establish inventory controls and procedures for conducting inventory reviews to prevent and detect any diversion, theft, or loss in a timely manner.

154.51(2) *Real-time inventory required.* A dispensary shall use the department-approved secure sales and inventory tracking system to maintain a real-time record of the dispensary's inventory of medical cannabidiol to include:

a. The quantity and form of saleable medical cannabidiol maintained at the dispensary on a daily basis;

b. The amount of damaged, expired, or returned medical cannabidiol being held at the dispensary for return to a manufacturer; and

c. Other information deemed necessary and requested by the department.

154.51(3) *Reconciliation.* At least once a calendar week, a dispensary shall reconcile all medical cannabidiol at the dispensary with the inventory recorded in the department's secure sales and inventory tracking system. Discrepancies shall be handled as follows:

a. A dispensary shall report suspected diversion of medical cannabidiol to the department and law enforcement within 24 hours of discovery.

b. A dispensary shall have up to 24 hours to reconcile the dispensary's physical inventory with the inventory recorded in the secure sales and inventory tracking system. If the dispensary cannot reconcile the dispensary's physical inventory with the secure sales and inventory tracking system's inventory within 24 hours but diversion of product is not suspected, the dispensary shall immediately contact

the department to report the discrepancy and to initiate a compliance action plan pursuant to paragraph 154.52(4)*"b."*

[**ARC 3606C**, IAB 1/31/18, effective 3/7/18; **ARC 4078C**, IAB 10/10/18, effective 11/14/18]

641—154.52(124E) Inspection by department or independent consultant. A dispensary is subject to reasonable inspection by the department, a department-approved consultant, or other agency as authorized by Iowa Code chapter 124E and these rules or state or local laws and regulations.

154.52(1) *Types of inspections.* Inspections may include:

a. Aspects of the business operations;

b. The physical location of a dispensary, including any storage facilities;

c. Financial information and inventory documentation;

d. Physical and electronic security alarm systems; and

e. Other aspects or areas as determined by the department.

154.52(2) *Local safety inspections.* A dispensary may be subject to inspection of its dispensary by the local fire department, building inspector, or code enforcement officer to confirm that no health or safety concerns are present. The inspection could result in additional specific standards to meet local licensing authority restrictions related to medical cannabidiol dispensing or other local businesses. An annual fire safety inspection may result in the required installation of fire suppression devices, or other means necessary for adequate fire safety.

154.52(3) *Health and sanitary inspection.* The department has discretion to determine when an inspection by an independent consultant is necessary. The following is a nonexhaustive list of examples that may justify an independent inspection:

a. The department has reasonable grounds to believe that the dispensary is in violation of one or more of the requirements set forth in these rules or other applicable public health or sanitary laws, rules or regulations;

b. The department has reasonable grounds to believe that the dispensary was the cause or source of contamination of medical cannabidiol; or

c. The department has reasonable grounds to believe that the dispensary was the cause of loss of product quality or change in chemical composition due to improper storage and handling of medical cannabidiol.

154.52(4) *Compliance required.* A dispensary shall respond to deficiencies found during inspections or inventory reconciliation as follows:

a. Deficiencies not related to inventory reconciliation.

(1) Upon written notification by the department of deficiencies that do not involve reconciliation of inventory, a dispensary shall have up to 30 days to submit an action plan to the department with proposed remedies and timelines for completion of the remedies.

(2) The department shall have up to two weeks to accept or require revision of the action plan.

b. Deficiencies related to inventory reconciliation.

(1) Upon notifying the department that the dispensary cannot reconcile the dispensary's physical inventory with the inventory recorded in the department's secure sales and inventory tracking system, the dispensary shall have up to two business days to submit an action plan to the department with proposed remedies and timelines for completion of the remedies.

(2) The department shall have up to two business days to accept or require revision of the action plan.

c. Failure to complete actions in the action plan within the timelines mutually agreed upon by the dispensary and the department shall result in assessment of penalties or in suspension or revocation of a dispensary license as authorized by these rules.

d. At the department's request and in a timely manner, a dispensary shall pay for and undergo an independent health and sanitary inspection in accordance with this rule.

[**ARC 3606C**, IAB 1/31/18, effective 3/7/18; **ARC 4078C**, IAB 10/10/18, effective 11/14/18]

641—154.53(124E) Assessment of penalties. The department shall assess to a dispensary a civil penalty of up to $1,000 per violation of Iowa Code chapter 124E or these rules in addition to other applicable penalties.
[**ARC 3606C**, IAB 1/31/18, effective 3/7/18]

641—154.54(124E) Suspension or revocation of a dispensary license.

154.54(1) The department may suspend or revoke a dispensary license upon any of the following grounds:

a. Submission of false, inaccurate, misleading, or fraudulent information to the department in the application or inspection processes.

b. Failure to submit required reports and documents.

c. Violation of Iowa Code chapter 124E or these rules, or violation of state or local law related to operation of the licensee.

d. Conduct or practices detrimental to the safety, health, or welfare of a patient, primary caregiver, or the public.

e. Criminal, civil, or administration action taken against a license or registration in this or another state or country related to manufacturing or dispensing medical cannabidiol.

f. False, misleading, or deceptive representations to the department, another state or federal agency, or a law enforcement agency.

g. Discontinuance of operation for more than 30 days, unless the department approves an extension of such period for good cause shown.

h. Failure to maintain effective controls against diversion, theft, or loss of medical cannabidiol.

i. Failure to correct a deficiency within the time frame required by the department.

j. Failure of a dispensary's business owner to have a satisfactory result in a background investigation or national criminal history background check conducted by the department of public safety and as determined by the department.

154.54(2) The department shall notify the licensee of the proposed action pursuant to Iowa Code sections 17A.12 and 17A.18. Notice of issuance of a suspension or revocation shall be served by restricted certified mail, return receipt requested, or by personal service.

154.54(3) A request for appeal concerning the suspension or revocation of a license shall be submitted by the aggrieved party in writing to the department by certified mail, return receipt requested, within 20 days of the receipt of the department's notice. The address is: Iowa Department of Public Health, Office of Medical Cannabidiol, Lucas State Office Building, Des Moines, Iowa 50319-0075. If such a request is made within the 20-day time period, the notice shall be deemed to be suspended. Prior to or at the hearing, the department may rescind the notice upon satisfaction that the reason for the suspension or revocation has been or will be removed. After the hearing or upon default of the applicant or alleged violator, the administrative law judge shall affirm, modify or set aside the suspension or revocation. If no request for appeal is received within the 20-day time period, the department's notice of suspension or revocation shall become the department's final agency action.

154.54(4) Upon receipt of an appeal that meets contested case status, the appeal shall be forwarded within five working days to the department of inspections and appeals. The information upon which the adverse action is based and any additional information which may be provided by the aggrieved party shall also be provided to the department of inspections and appeals.

154.54(5) The hearing shall be conducted according to the procedural rules of the department of inspections and appeals found in 481—Chapter 10.

154.54(6) When the administrative law judge makes a proposed decision and order, it shall be served by restricted certified mail, return receipt requested, or delivered by personal service. That proposed decision and order then becomes the department's final agency action without further proceedings ten days after it is received by the aggrieved party unless an appeal to the director is taken.

154.54(7) Any appeal to the director for review of the proposed decision and order of the administrative law judge shall be filed in writing and mailed to the director by certified mail, return receipt requested, or delivered by personal service within ten days after the receipt of the administrative

law judge's proposed decision and order by the aggrieved party. A copy of the appeal shall also be mailed to the administrative law judge. Any request for an appeal shall state the reason for appeal.

154.54(8) Upon receipt of an appeal request, the administrative law judge shall prepare the record of the hearing for submission to the director. The record shall include the following:

a. All pleadings, motions, and rules.

b. All evidence received or considered and all other submissions by recording or transcript.

c. A statement of all matters officially noticed.

d. All questions and offers of proof, objections, and rulings thereon.

e. All proposed findings and exceptions.

f. The proposed decision and order of the administrative law judge.

154.54(9) The decision and order of the director becomes the department's final agency action upon receipt by the aggrieved party and shall be delivered by restricted certified mail, return receipt requested, or by personal service.

154.54(10) It is not necessary to file an application for a rehearing to exhaust administrative remedies when appealing to the director or the district court as provided in Iowa Code section 17A.19. The aggrieved party to the final agency action of the department who has exhausted all administrative remedies may petition for judicial review of that action pursuant to Iowa Code chapter 17A.

154.54(11) Any petition for judicial review of a decision and order shall be filed in the district court within 30 days after the decision and order becomes final. A copy of the notice of appeal shall be sent to the department by certified mail, return receipt requested, or by personal service. The address is: Iowa Department of Public Health, Lucas State Office Building, Des Moines, Iowa 50319-0075.

154.54(12) The party who appeals a final agency action to the district court shall pay the cost of the preparation of a transcript of the contested case hearing for the district court.

154.54(13) Emergency adjudicative proceedings.

a. Necessary emergency action. To the extent necessary to prevent or avoid immediate danger to the public health, safety, or welfare, and consistent with the Constitution and other provisions of law, the department may issue a written order in compliance with Iowa Code section 17A.18A to suspend a license in whole or in part, order the cessation of any continuing activity, order affirmative action, or take other action within the jurisdiction of the department by emergency adjudicative order.

b. Before issuing an emergency adjudicative order, the department shall consider factors including, but not limited to, the following:

(1) Whether there has been a sufficient factual investigation to ensure that the department is proceeding on the basis of reliable information;

(2) Whether the specific circumstances which pose immediate danger to the public health, safety or welfare have been identified and determined to be continuing;

(3) Whether the licensee required to comply with the emergency adjudicative order may continue to engage in other activities without posing immediate danger to the public health, safety or welfare;

(4) Whether imposition of monitoring requirements or other interim safeguards would be sufficient to protect the public health, safety or welfare; and

(5) Whether the specific action contemplated by the department is necessary to avoid the immediate danger.

c. Issuance of order.

(1) An emergency adjudicative order shall contain findings of fact, conclusions of law, and policy reasons to justify the determination of an immediate danger in the department's decision to take immediate action. The order is a public record.

(2) The written emergency adjudicative order shall be immediately delivered to the licensee that is required to comply with the order. The order shall be delivered by one or more of the following methods:

1. Personal delivery.

2. Certified mail, return receipt requested, to the last address on file with the department.

3. Fax. Fax may be used as the sole method of delivery if the licensee required to comply with the order has filed a written request that agency orders be sent by fax and has provided a fax number for that purpose.

(3) To the degree practicable, the department shall select the procedure for providing written notice that best ensures prompt, reliable delivery.

(4) Unless the written emergency adjudicative order is provided by personal delivery on the same day that the order issues, the department shall make reasonable immediate efforts to contact by telephone the licensee that is required to comply with the order.

(5) After the issuance of an emergency adjudicative order, the department shall proceed as quickly as feasible to complete any proceedings that would be required if the matter did not involve an immediate danger.

(6) Issuance of a written emergency adjudicative order shall include notification of the date on which department proceedings are scheduled for completion. After issuance of an emergency adjudicative order, continuance of further department proceedings to a later date will be granted only in compelling circumstances upon application in writing unless the licensee that is required to comply with the order is the party requesting the continuance.

[**ARC 3606C**, IAB 1/31/18, effective 3/7/18]

641—154.55(124E) Closure of operations.

154.55(1) *Notice.* A dispensary shall notify the department at least six months before the closure of the dispensary.

154.55(2) *Procedures.* If a dispensary ceases operation, the dispensary shall work with the department to verify the remaining inventory of the dispensary and ensure that any medical cannabidiol is returned to a manufacturer.

[**ARC 3606C**, IAB 1/31/18, effective 3/7/18]

641—154.56 to **154.59** Reserved.

MEDICAL CANNABIDIOL BOARD

641—154.60(124E) Purpose and duties of board.

154.60(1) The purpose of the board is to administer the provisions of Iowa Code section 124E.5.

154.60(2) Responsibilities of the board include but are not limited to:

a. Accepting and reviewing petitions to add medical conditions, medical treatments, or debilitating diseases to the list of debilitating medical conditions for which the medical use of cannabidiol would be medically beneficial under Iowa Code chapter 124E.

b. Making recommendations to the board of medicine relating to the removal or addition of debilitating medical conditions to the list of allowable debilitating medical conditions for which the medical use of cannabidiol under Iowa Code chapter 124E would be medically beneficial.

c. Working with the department regarding the requirements for the licensure of manufacturers and dispensaries, including licensure procedures.

d. Advising the department regarding the location of manufacturers and dispensaries throughout the state.

e. Making recommendations to the board of medicine relating to the form and quantity of allowable medical uses of cannabidiol.

f. Considering recommendations to the general assembly for statutory revisions to the definition of medical cannabidiol to increase the tetrahydrocannabinol (THC) level to more than 3 percent.

g. Submitting an annual report to the general assembly detailing the activities of the board no later than January 1.

[**ARC 3606C**, IAB 1/31/18, effective 3/7/18]

641—154.61(124E) Organization of board and proceedings.

154.61(1) *Membership.* The board shall be composed of nine members appointed by the governor pursuant to Iowa Code section 124E.5. The appointments, unless provided otherwise by law, shall be for three-year staggered terms which shall expire on June 30. Board members shall be knowledgeable

about the use of medical cannabidiol. The medical practitioners appointed to the board shall be licensed in Iowa and be nationally board-certified in their area of specialty.

154.61(2) *Vacancies.* Vacancies shall be filled in the same manner in which the original appointments were made for the balance of the unexpired term.

154.61(3) *Absences.* Three consecutive unexcused absences shall be grounds for the governor to consider dismissal of a board member and to appoint another. Department staff is charged with providing notification of absences to the governor's office.

154.61(4) *Board meetings.*

a. The board shall convene at least twice but no more than four times a year.

b. Board meetings shall be conducted in accordance with the open meetings requirements of Iowa Code chapter 21.

c. The department's office of medical cannabidiol shall schedule the time, date and location of meetings.

d. A majority of the members shall constitute a quorum for conducting business of the board.

e. An affirmative vote of a majority of the board members present at a meeting is required for a motion to pass.

154.61(5) *Facilities and staffing.* The department shall furnish the board with the necessary facilities and employees to perform the duties required by this chapter but shall be reimbursed for all costs incurred by fee revenue generated from licensing activities and registration card applications.

154.61(6) *Subcommittees.* The board may designate one or more subcommittees to perform such duties as may be deemed necessary.

[**ARC 3606C**, IAB 1/31/18, effective 3/7/18]

641—154.62(124E) Official communications. All official communications, including submissions, petitions and requests, may be addressed to the Medical Cannabidiol Board, Office of Medical Cannabidiol, Lucas State Office Building, 321 E. 12th Street, Des Moines, Iowa 50319-0075.

[**ARC 3606C**, IAB 1/31/18, effective 3/7/18]

641—154.63(124E) Office hours. The board office is open for public business from 8 a.m. to 4:30 p.m., Monday to Friday of each week, except holidays.

[**ARC 3606C**, IAB 1/31/18, effective 3/7/18]

641—154.64(124E) Public meetings. Members of the public may be present during board meetings unless the board votes to hold a closed session. Dates and location of board meetings may be obtained through the Iowa department of public health's website (idph.iowa.gov/mcarcp) or directly from the board office.

154.64(1) *Exclusion of participants.* The person presiding at a meeting of the board may exclude a person from an open meeting for behavior that obstructs the meeting.

154.64(2) *Recording of meetings.* Cameras and recording devices may be used at open meetings, provided the cameras or recording devices do not obstruct the meeting. If the user of a camera or recording device obstructs the meeting by the use of such device, the presiding department staff member at the meeting may request the user to discontinue use of the camera or device.

[**ARC 3606C**, IAB 1/31/18, effective 3/7/18]

641—154.65(124E) Petitions for the addition or removal of medical conditions, medical treatments or debilitating diseases. Petitions for the addition or removal of medical conditions, medical treatments, or debilitating conditions for which the medical use of cannabidiol would be medically beneficial under Iowa Code chapter 124E may be submitted to the board pursuant to this rule.

154.65(1) *Petition form.* Any person or entity may file a petition to add or remove medical conditions, medical treatments or debilitating diseases with the board. A petition is deemed filed when it is received by the medical cannabidiol office. The board must provide the petitioner with a file-stamped copy of the petition if the petitioner provides the board an extra copy for this purpose. The petition must be typewritten or legibly handwritten in ink and must substantially conform to the following form:

BEFORE THE MEDICAL CANNABIDIOL BOARD

Petition by (Name of Petitioner) for the (addition or removal) of (medical conditions, medical treatments or debilitating diseases) to the list of debilitating medical conditions for which the medical use of cannabidiol would be medically beneficial.	PETITION FOR (ADDITION or REMOVAL)

The petition must provide the following information:

a. A statement of the specific medical condition, medical treatment or debilitating disease the petitioner is seeking to add to or remove from the list of debilitating medical conditions for which the medical use of cannabidiol would be medically beneficial.

b. A brief summary of the petitioner's arguments in support of the action urged in the petition.

c. A brief summary of any data or scientific evidence supporting the action urged in the petition.

d. A list of reference material supporting the petition.

e. A list of subject matter experts who are willing to testify in support of the petition. The list of subject matter experts must contain names, credentials (if applicable), email addresses, telephone numbers, and mailing addresses.

f. The names and addresses of other persons, or a description of any class of persons, known by petitioner to be affected by, or interested in, the proposed action which is the subject of the petition.

154.65(2) *Signature and address.* The petition must be dated and signed by the petitioner or the petitioner's representative. It must also include the name, mailing address, telephone number and email address of the petitioner and petitioner's representative, and a statement indicating the person to whom communications concerning the petition should be directed.

154.65(3) *Denial for format.* The board may deny a petition because it does not substantially conform to the required form.

154.65(4) *Briefs.* The petitioner may attach a brief to the petition in support of the action urged in the petition. The board may request a brief from the petitioner or from any other person or entity concerning the substance of the petition.

154.65(5) *Inquiries.* Inquiries concerning the status of a petition may be made to the Office of Medical Cannabidiol, Department of Public Health, Lucas State Office Building, Des Moines, Iowa 50319-0075.

154.65(6) *Additional information.* The board may request the petitioner to submit additional information concerning the petition. The board may also solicit comments from any person on the substance of the petition. Comments on the substance of the petition may be submitted to the board by any person.

154.65(7) *Presentation to the board.* The board may request or allow the petitioner to make an oral presentation of the contents of a petition at a board meeting following submission of the petition.

154.65(8) *Board response.* Within six months after the filing of the petition, or within any longer period agreed to by the petitioner, the board must, in writing, either deny the petition and notify the petitioner of the board's action and the reasons therefore, or grant the petition and notify the petitioner that the board has recommended addition or removal of the medical condition, medical treatment, or debilitating disease to the board of medicine. A petitioner shall be deemed notified of the denial or recommendation on the date when the board mails the required notification to the petitioner.

154.65(9) *Denials.* Denial of a petition because it does not substantially conform to the required form does not preclude the filing of a new petition on the same subject that seeks to eliminate the grounds for the agency's rejection of the petition.

[**ARC 3606C**, IAB 1/31/18, effective 3/7/18]

641—154.66 to **154.68** Reserved.

LABORATORY TESTING

641—154.69(124E) Requirements of the department.

154.69(1) *Laboratory testing requirements and acceptance criteria.* The department shall work with manufacturers and laboratories to create and maintain a document describing required sampling methodology, acceptance criteria, stability-testing procedures, and other guidance for manufacturers and laboratories on testing procedures. The document shall:

a. Describe the minimum number of sample units and reserve samples required for testing by the laboratory;

b. Describe an option for manufacturers to reduce the amount of testing conducted by allowing compositing of sample units or other techniques that reduce the number of tests required without compromising the safety of the products once a manufacturer has satisfactorily completed a control study for a specific extraction or production process;

c. Describe the minimum requirements for sample size and testing intervals for stability testing;

d. Be available on the department's website (www.idph.iowa.gov).

154.69(2) *Review and approval of manufacturer sampling protocols.* The department shall have up to two weeks to review and approve or request revisions to a manufacturer's sampling protocols required pursuant to subrules 154.26(2) and 154.26(3).

154.69(3) *Review and approval of manufacturer stability-testing procedures.* The department shall have up to two weeks to review and approve or request revisions to a manufacturer's stability-testing procedures required pursuant to subrule 154.26(4).

[**ARC 4078C**, IAB 10/10/18, effective 11/14/18]

641—154.70(124E) Requirements of a laboratory.

154.70(1) *Minimum testing requirements.* A laboratory shall establish and implement test methods and corresponding standard operating procedures for the analyses of cannabinoids, residual solvents and processing chemicals, pesticides, microbiological impurities, and metals.

154.70(2) *Additional tests upon request.* A laboratory shall establish and implement test methods and corresponding standard operating procedures for other analyses as requested by the department.

154.70(3) *Level of quantitation.* A laboratory shall be able to demonstrate that its LOQ is below any action level established by the department.

154.70(4) *Inventory tracking.*

a. A laboratory shall use the department's secure sales and inventory tracking system, if available, or a manifest system to record the receipt of medical cannabis goods from a manufacturer for testing.

b. A laboratory shall use the department's secure sales and inventory tracking system, if available, or a manifest system to record the return of medical cannabis goods or waste to a manufacturer.

154.70(5) *Hazardous waste disposal.*

a. A laboratory shall discard hazardous waste, including hazardous waste containing medical cannabis goods, in accordance with federal and state hazardous waste laws.

b. A laboratory shall document the waste disposal procedures followed for each sample.

[**ARC 3836C**, IAB 6/6/18, effective 7/11/18]

641—154.71(124E) Requirements of a manufacturer.

154.71(1) *Assuming costs.* A manufacturer shall assume the costs for all laboratory testing requested by the department or laboratory for medical cannabis goods produced by the manufacturer.

154.71(2) *Sample waste retrieval.* A manufacturer shall retrieve analyzed samples and waste containing medical cannabis goods from the laboratory at a duration and frequency approved by the department.

154.71(3) *Obtaining approval for sampling protocols.* A manufacturer shall obtain approval from the department for the manufacturer's sampling protocols pursuant to subrule 154.26(2) prior to submitting samples for laboratory testing related to content and contamination.

154.71(4) *Obtaining approval for stability-testing procedures.* A manufacturer shall obtain approval from the department for the manufacturer's stability-testing procedures pursuant to subrule 154.26(4)

prior to submitting samples for laboratory testing related to stability testing and product-expiration-date studies.

[**ARC 3836C**, IAB 6/6/18, effective 7/11/18; **ARC 4078C**, IAB 10/10/18, effective 11/14/18]

641—154.72(124E) Content testing.

154.72(1) *Cannabinoids.*

a. For each unique lot of medical cannabidiol, and if asked to do so by a requester for other medical cannabis goods, a laboratory shall, at minimum, test for and report measurements for the following cannabinoid analytes:

(1) THC;

(2) THCA;

(3) CBD;

(4) CBDA;

(5) CBG; and

(6) CBN.

b. A laboratory shall report that the primary sample passed THC potency testing if the detected concentration of THC does not exceed 3 percent by weight in milligrams per milliliter (mg/ml) for liquids and milligrams per gram (mg/g) for solids and if the detected concentration of THC does not vary from the manufacturer's labeled concentration by more than 15 percent by weight in mg/ml for liquids and mg/g for solids. Thus, a solid product labeled as containing a concentration of THC of 10 mg/g shall have a detected concentration of THC that is no more than 11.50 mg/g and no less than 8.50 mg/g.

c. A laboratory shall report that the primary sample failed THC potency testing if the detected concentration of THC exceeds 3 percent by weight in mg/ml for liquids and mg/g for solids or if the detected concentration of THC varies from the labeled concentration of THC by more than 15 percent by weight in mg/ml for liquids and mg/g for solids.

d. A laboratory shall report that the primary sample passed CBD potency testing if the detected concentration of CBD does not vary from the manufacturer's labeled concentration by more than 15 percent by weight in mg/ml for liquids and mg/g for solids. Thus, a solid product labeled as containing a concentration of CBD of 10 mg/g shall have a detected concentration of CBD that is no more than 11.50 mg/g and no less than 8.50 mg/g.

e. A laboratory shall report that the primary sample failed potency testing if the detected concentration of CBD varies from the labeled concentration of CBD by more than 15 percent by weight in mg/ml for liquids and mg/g for solids.

f. For each cannabinoid analyte test, a laboratory shall issue a certificate of analysis that contains the following:

(1) Concentrations of cannabinoid analytes in mg/ml for liquids and mg/g for solids, or other measures approved by the department.

(2) Whether the primary sample passed or failed the test in accordance with paragraphs 154.72(1)*"b"* and 154.72(1)*"c."*

g. The laboratory may test for and provide test results for additional cannabinoid analytes if asked to do so by a requester.

154.72(2) *Contaminants—residual solvents and processing chemicals.*

a. For each unique lot of medical cannabidiol, and if asked to do so by a requester for other medical cannabis goods, a laboratory shall analyze primary samples for residual solvents and processing chemicals.

b. The department shall provide a list of residual solvents and processing chemicals for which primary samples are to be tested with corresponding action levels on the department's website (www.idph.iowa.gov).

c. For each residual solvent or processing chemical for which a primary sample is tested, a laboratory shall report that the primary sample passed the testing if the concentration of residual solvent or processing chemical is at or below the action level approved by the department.

d. For each residual solvent or processing chemical for which a laboratory tests, the laboratory shall report that the primary sample failed the testing if the concentration of residual solvent or processing chemical is above the action level approved by the department.

e. If a laboratory is using mass spectrometry instrumentation to analyze primary samples for residual solvents and processing chemicals and the laboratory determines that a primary sample contains residual solvent or processing chemical analytes that are not included in the department-approved list of required tests, the laboratory shall attempt to achieve tentative identification and semiquantitative results of the residual solvent or processing chemical analytes.

f. The laboratory may test for and provide test results for additional residual solvents or processing chemicals if asked to do so by a requester.

g. For each primary sample tested, a laboratory shall issue a certificate of analysis that contains the following:

(1) The name and concentration of each residual solvent or processing chemical for which the primary sample was tested.

1. The concentrations shall be listed in parts per million (ppm) or other units as determined by the department.

2. The laboratory shall report a result of "detected but not quantified" for any target residual solvent or processing chemical that falls below the LOQ, has a signal-to-noise ratio of greater than 3:1, and meets identification criteria.

(2) Whether the primary sample passed or failed the test in accordance with paragraphs 154.72(2)*"c"* and 154.72(2)*"d."*

(3) The names and amounts of any additional residual solvents and processing chemicals identified by the laboratory.

h. If the primary sample fails testing for residual solvents and processing chemicals, the lot fails laboratory testing.

i. When a laboratory identifies additional residual solvents and processing chemicals in a primary sample, the laboratory shall:

(1) Notify the department of the additional residual solvents and processing chemicals and the amounts detected.

(2) Refrain from issuing a final certificate of analysis to a manufacturer until given approval to do so by the department.

154.72(3) *Contaminants—pesticides.*

a. For each unique lot of medical cannabidiol, and if asked to do so by a requester for other medical cannabis goods, the laboratory shall analyze primary samples for pesticides.

b. The department shall provide a list of pesticides for which primary samples are to be tested with corresponding action levels on the department's website (www.idph.iowa.gov).

c. For each pesticide for which a laboratory tests, the laboratory shall report that the primary sample passed the testing if the concentration of pesticide is at or below the action level approved by the department.

d. For each pesticide for which a laboratory tests, the laboratory shall report that the primary sample failed the testing if the concentration of pesticide is above the action level approved by the department.

e. If a laboratory is using mass spectrometry instrumentation to analyze primary samples for pesticides and the laboratory determines that a primary sample contains pesticide analytes that are not included in the department-approved list of required tests, the laboratory shall attempt to achieve tentative identification and semiquantitative results of the pesticide analytes.

f. The laboratory may test for and provide test results for additional pesticides if asked to do so by a requester.

g. For each primary sample tested, a laboratory shall issue a certificate of analysis that contains the following:

(1) The name and concentration of each pesticide for which the primary sample was tested.

1. The concentrations shall be listed in parts per million (ppm) or other units as determined by the department.

2. The laboratory shall report a result of "detected but not quantified" for any pesticide that falls below the LOQ, has a signal-to-noise ratio of greater than 3:1, and meets identification criteria.

(2) Whether the primary sample passed or failed the test in accordance with paragraphs 154.72(3)*"c"* and 154.72(3)*"d."*

(3) The names and amounts of any additional pesticides identified by the laboratory.

h. If the primary sample fails testing for pesticides, the lot fails laboratory testing.

i. When a laboratory identifies additional pesticides in a primary sample, the laboratory shall:

(1) Notify the department of the additional pesticides and the amounts detected.

(2) Refrain from issuing a final certificate of analysis to a manufacturer until given approval to do so by the department.

154.72(4) *Contaminants—metals.*

a. For each unique lot of medical cannabidiol, and if asked to do so by a requester for other medical cannabis goods, the laboratory shall analyze primary samples for metals.

b. The department shall provide a list of metals for which primary samples are to be tested with corresponding action levels on the department's website (www.idph.iowa.gov).

c. For each metal for which a laboratory tests, the laboratory shall report that the primary sample passed the testing if the concentration of metal is at or below the action level approved by the department.

d. For each metal for which a laboratory tests, the laboratory shall report that the primary sample failed the testing if the concentration of metal is above the action level approved by the department.

e. If a laboratory is using mass spectrometry instrumentation to analyze primary samples for metals and the laboratory determines that a primary sample contains metal analytes that are not included in the department-approved list of required tests, the laboratory shall attempt to achieve tentative identification and semiquantitative results of the metal analytes.

f. The laboratory may test for and provide test results for additional metals if asked to do so by a requester.

g. For each primary sample tested, a laboratory shall issue a certificate of analysis that contains the following:

(1) The name and concentration of each metal for which the primary sample was tested.

1. The concentrations shall be listed in micrograms per gram or other units as determined by the department.

2. The laboratory shall report a result of "detected but not quantified" for any metal that falls below the LOQ, has a signal-to-noise ratio of greater than 3:1, and meets identification criteria.

(2) Whether the primary sample passed or failed the test in accordance with paragraphs 154.72(4)*"c"* and 154.72(4)*"d."*

(3) The names and amounts of any additional metals identified by the laboratory.

h. If the primary sample fails testing for metals, the lot fails laboratory testing.

i. When a laboratory identifies additional metals in a primary sample, the laboratory shall:

(1) Notify the department of the additional metals and the amounts detected.

(2) Refrain from issuing a final certificate of analysis to a manufacturer until given approval to do so by the department.

154.72(5) *Contaminants—microbiological impurities.*

a. For each unique lot of medical cannabidiol, and if asked to do so by a requester for other medical cannabis goods, the laboratory shall analyze primary samples for microbiological impurities.

b. The department shall provide a list of microbiological impurities for which primary samples are to be tested on the department's website (www.idph.iowa.gov).

c. For each microbiological impurity for which a laboratory tests, the laboratory shall report that the primary sample passed the testing if the microbiological impurity is not detected in 1 gram of matrix or as approved by the department. A primary sample may be reported as passed if a screening procedure yields a negative result or if a presumptively positive result is not found to be positive on the confirmatory procedure.

d. For each microbiological impurity for which a laboratory tests, the laboratory shall report that the primary sample failed the testing if the microbiological impurity is detected in 1 gram of matrix or as approved by the department. Confirmatory procedures shall be conducted on all presumptively positive results.

e. If a laboratory is using methods to test primary samples for microbiological impurities and the laboratory determines that a primary sample contains microbiological impurities that are not included in the department-approved list of required tests, the laboratory shall attempt to achieve tentative identification of the biological impurity.

f. The laboratory may test for and provide test results for additional microbiological impurities if asked to do so by a requester.

g. For each primary sample tested, a laboratory shall issue a certificate of analysis that contains the following:

(1) The name of each microbiological impurity for which the primary sample was tested.

(2) Whether the primary sample passed or failed the test in accordance with paragraphs 154.72(5)*"c"* and 154.72(5)*"d."*

(3) The names of any additional microbiological impurities identified by the laboratory.

h. If the primary sample fails testing for microbiological impurities, the lot fails laboratory testing.

i. When a laboratory identifies additional microbiological impurities in a primary sample, the laboratory shall:

(1) Notify the department of the additional microbiological impurities detected.

(2) Refrain from issuing a final certificate of analysis to a manufacturer until given approval to do so by the department.

154.72(6) *Additional tests.* The laboratory may perform additional tests if asked to do so by a requester.

[**ARC 3836C**, IAB 6/6/18, effective 7/11/18; **ARC 4078C**, IAB 10/10/18, effective 11/14/18]

641—154.73(124E) Reporting requirements.

154.73(1) *Reporting test results.* The laboratory shall generate a certificate of analysis for each primary sample that it tests and make the certificate of analysis available to the manufacturer who ordered the tests and the department through the department's secure sales and inventory tracking system, if available, or another laboratory information management system.

154.73(2) *Tentatively identified analytes.* A laboratory shall report on the certificate of analysis any tentatively identified analytes detected during the analysis of the primary sample. When a laboratory identifies additional analytes in a primary sample, the laboratory shall:

a. Notify the department of the additional analytes detected.

b. Refrain from issuing a final certificate of analysis to a manufacturer until given approval to do so by the department.

154.73(3) *Additional reporting requirements.*

a. In addition to the requirements described in rule 641—154.72(124E), the certificate of analysis shall contain, at a minimum, the following information:

(1) All requirements of Standard ISO/IEC 17025;

(2) Date of primary sample collection;

(3) Date the primary sample was received by the laboratory;

(4) Date of each analysis;

(5) The LOQ and action level for each analyte, as applicable;

(6) Whether the primary sample and lot passed or failed laboratory testing; and

(7) A signature by the laboratory quality officer and the date the certificate of analysis was validated as being accurate by the laboratory quality officer.

b. Any test result that is not covered under the laboratory's ISO/IEC 17025 scope of accreditation shall be clearly identified on the certificate of analysis.

c. Measurements below a method's limit of detection shall be reported as "<" (less than) or "not detected" and reference the reportable limit. The reporting of zero concentration is not permitted.

d. Measurements ≥ LOD but < LOQ shall be reported as "detected but not quantified."

e. The number of significant figures reported shall reflect the precision of the analysis.

[**ARC 3836C**, IAB 6/6/18, effective 7/11/18]

641—154.74(124E) Record-keeping requirements.

154.74(1) *Data package.* A laboratory shall create a data package for each analytical batch of primary samples that the laboratory analyzes. The data package shall contain at minimum the following information:

a. The name and address of the laboratory that performed the analytical procedures;

b. The names, functions, and signatures (electronic or handwritten) of the laboratory personnel that performed the primary sample preparation, analyzed the primary samples, and reviewed and approved the data;

c. All primary sample and analytical batch quality control sample results;

d. Raw data for each primary sample analyzed;

e. Instrument raw data, if any was produced;

f. Instrument test method with parameters;

g. Instrument tune report, if one was created;

h. All instrument standard calibration data;

i. Test-method worksheets or forms used for primary sample identification, characterization, and calculations, including chromatograms, sample-preparation worksheets, and final datasheets;

j. The quality control report with worksheets, forms, or copies of laboratory notebook pages containing pertinent information related to the identification and traceability of all reagents, reference materials, and standards used for analysis;

k. The analytical batch sample sequence;

l. The field sample log; and

m. The chain-of-custody form.

154.74(2) *Review of data package.* After the laboratory has compiled a data package, another individual at the laboratory shall independently review the data package. The reviewer shall:

a. Assess the analytical results for technical correctness and completeness;

b. Verify that the results of each analysis carried out by the laboratory are reported accurately, clearly, unambiguously, and objectively;

c. Verify that the measurements can be traced back; and

d. Approve the measurement results by signing and dating the data package prior to release of the certificate of analysis by the laboratory.

154.74(3) *Data package record retention.* The entire data package shall be stored by a laboratory for a minimum of five years and shall be made available upon request by the department or the requester of the laboratory testing.

154.74(4) *Other records.* A laboratory shall maintain all documents, forms, records, and standard operating procedures associated with the testing of medical cannabis goods.

a. A laboratory shall maintain analytical testing laboratory records in such a manner that the analyst, the date the analysis was performed, the approver of the certificate of analysis, the reviewer and approver of the data package, the test method, and the materials that were used can be determined by the department.

b. Records shall be stored in such a way that the data may be readily retrieved when requested by the department.

c. All testing laboratory records shall be kept for a minimum of five years, unless otherwise noted in these rules.

d. The department shall be allowed access to all electronic data, including standards records, calibration records, extraction logs, and laboratory notebooks.

e. A laboratory shall keep and make available to the department the following records related to the testing of medical cannabis goods:

(1) Personnel qualification, training, and competency documentation, including but not limited to résumés, training records, continuing education records, analytical proficiency testing records, and demonstration of competency records for laboratory work. These records shall be kept current.

(2) Method verification and validation records, including method modification records, method detection limit and quantitation limit determination records, ongoing verification records such as proficiency test records and reference material analysis records.

(3) Quality control and quality assurance records, including the laboratory's quality assurance manual and control charts with control limits.

(4) Chain-of-custody records, including chain-of-custody forms, field sample logs, sample-receipt records, sample-description records, sample-rejection records, laboratory information management system records, sample-storage records, sample-retention records, and disposal records.

(5) Purchasing and supply records, equipment-services records, and other equipment records, including purchase requisition records, packing slips, supplier records, and certificates of analysis.

(6) Laboratory equipment installation records, maintenance records, and calibration records. These records shall include the date and name of the person performing the installation of, calibration of, or maintenance on the equipment, with a description of the work performed, maintenance logs, pipette calibration records, balance calibration records, working and reference mass calibration records, and daily verification-of-calibration records.

(7) Customer service records, including customer contracts, customer requests, certificates of analysis, customer transactions, customer feedback, records related to the handling of complaints and nonconformities, and corrective action pertaining to complaints.

(8) Nonconforming work and corrective action records, including corrective action, nonconformance, nonconformities resolved by correction, customer notification of nonconformities, internal investigations, implementation of corrective action, and resumption-of-work records.

(9) Internal-audit and external-audit records, including audit checklists, standard operating procedures, and audit observation and findings reports. These records shall include the date and name of the person performing the audit.

(10) Management review records, including technical data review reports and final management-review reports. These records shall include the review date and the name of the reviewer.

(11) Laboratory data reports, data review, and data approval records, including instrument and equipment identification records, records with unique sample identifiers, analysts' laboratory notebooks and logbooks, traceability records, test-method worksheets and forms, instrumentation-calibration data, and test-method raw data. These records shall include the analysis date and the name of the analyst.

(12) Proficiency testing records, including the proficiency test schedule, proficiency tests, data-review records, data-reporting records, nonconforming work and corrective actions, and quality control and quality assurance records related to proficiency testing.

(13) Electronic data, backed-up data, records regarding the protection of data, including unprocessed instrument output data files and processed quantitation output files, electronic data protocols and records, and authorized personnel records.

(14) Security data, including laboratory-security records and laboratory-access records, surveillance-equipment records, and security-equipment records. These records shall be stored for at least one year.

(15) Traceability, raw data, standards records, calibration records, extraction logs, reference materials records, analysts' laboratory notebooks and logbooks, supplier records, and certificates of analysis, and all other data-related records.

(16) Laboratory contamination and cleaning records, including autoclave records, acid-wash logs and records, and general laboratory-safety and chemical-hygiene protocols.

[**ARC 3836C**, IAB 6/6/18, effective 7/11/18]

641—154.75(124E) Quality control. The laboratory shall have quality control protocols that include the following elements:

154.75(1) *Quality control samples required.*

a. The laboratory shall run quality control samples with every analytical batch of samples for chemical and microbiological analysis.

b. For microbiological analysis, the laboratory shall develop procedures for quality control requirements for each analytical batch of samples.

c. The laboratory shall analyze the quality control samples in exactly the same manner as the test samples to validate the laboratory testing results.

154.75(2) *Types of quality control samples.* At a minimum, a laboratory shall have the following quality control samples as part of every analytical batch tested for chemical analytes:

a. Negative control (method blank). A laboratory shall prepare and run at least one method blank sample with an analytical batch of 10 to 20 samples along with and under the same conditions, including all sample preparation steps, as the other samples in the analytical batch, to demonstrate that the analytical process did not introduce contamination.

b. Positive control (laboratory control sample). A laboratory shall prepare and run at least one laboratory control sample with an analytical batch of 10 to 20 samples along with and under the same conditions, including all sample preparation steps, as the other samples in the analytical batch.

c. Matrix spike sample. A laboratory shall prepare and run one or more matrix spike samples for each analytical batch.

(1) A laboratory shall calculate the percent recovery for quantitative chemical analysis by dividing the sample result by the expected result and multiplying that by 100. All quality control measures shall be assessed and evaluated on an ongoing basis, and quality control acceptance criteria shall be used. When necessary, the department may establish acceptance criteria on the department's website (www.idph.iowa.gov).

(2) If quality control acceptance criteria are not acceptable, a laboratory shall investigate the cause, correct the problem, and rerun the analytical batch of samples. If the problem persists, the laboratory shall reprepare the samples and run the analysis again, if possible.

d. Field duplicate sample. A laboratory shall prepare and run a duplicate sample with every 10 to 20 samples for each analytical method. The acceptance criterion between the primary sample and the duplicate sample is less than 20 percent relative percentage difference.

154.75(3) *Certified reference material for chemical analysis.* The laboratory shall use a reference material for each analytical batch in accordance with the following standards:

a. The reference material should be certified and obtained from an outside source, if possible. If a reference material is not available from an outside source, the laboratory shall make its own in-house reference material.

b. Reference material made in-house should be made from a different source of standards than the source from which the calibration standards are made.

c. The test result for the reference material shall fall within the quality control acceptance criteria. If it does not, the laboratory shall document and correct the problem and run the analytical batch again.

154.75(4) *Calibration standards.* The laboratory shall prepare calibration standards by serially diluting a standard solution to produce working standards used for calibration of an instrument and quantitation of analyses in samples.

154.75(5) *Quality control-sample report.* A laboratory shall generate a quality control-sample report that includes quality control parameters and measurements, analysis date, and type of matrix.

154.75(6) *Limit-of-detection and limit-of-quantitation calculations.* For chemical method analysis, a laboratory shall calculate the limit of detection and limit of quantitation using generally accepted methodology.

[**ARC 3836C**, IAB 6/6/18, effective 7/11/18]

641—154.76(124E) Security requirements. The department may request assistance from the department of public safety in ensuring a laboratory meets the security requirements in this rule.

154.76(1) *Security policy requirement.* A laboratory shall maintain a security policy to prevent the loss, theft, or diversion of medical cannabis goods and samples. The security policy shall apply to all staff and visitors at a laboratory facility.

154.76(2) *Visitor logs.* Visitors to a laboratory facility shall sign visitor manifests with name, date, and times of entry and exit, and shall wear badges that are visible at all times and that identify them as visitors.

154.76(3) *Restricted access.* A laboratory shall use a controlled access system and written manifests to limit entrance to all restricted access areas of its laboratory facility and shall retain a record of all persons who entered the restricted access areas.

a. The controlled access system shall do all of the following:

(1) Limit access to authorized individuals;

(2) Maintain a log of individuals with approved access, including dates of approvals and revocations;

(3) Track times of personnel entry;

(4) Track times of personnel movement between restricted access areas;

(5) Store data for retrieval for a minimum of one year; and

(6) Remain operable in the event of a power failure.

b. Separate written manifests of visitors to restricted areas shall be kept and stored for a minimum of one year if the controlled access system does not include electronic records of visitors to the restricted areas.

c. A laboratory shall promptly, but no later than five business days after receipt of request, submit stored controlled access system data to the department.

154.76(4) *Personnel identification system.* A laboratory shall use a personnel identification system that controls and monitors individual employee access to restricted access areas within the laboratory facility and that meets the requirements of this subrule and subrule 154.76(2).

a. Requirement for employee identification card. An employee identification card shall contain:

(1) The name of the employee;

(2) The date of issuance;

(3) An alphanumeric identification number that is unique to the employee; and

(4) A photographic image of the employee.

b. A laboratory employee shall keep the identification card visible at all times when the employee is in the laboratory.

c. Upon termination or resignation of an employee, a laboratory shall immediately:

(1) Revoke the employee's access to the laboratory; and

(2) Obtain and destroy the employee's identification card, if possible.

154.76(5) *Video monitoring and surveillance.*

a. *Video surveillance system.* A laboratory shall operate and maintain in good working order a video surveillance system for its premises that operates 24 hours per day, seven days a week, and visually records all areas where medical cannabis goods are stored or tested.

b. *Camera specifications.* Cameras shall:

(1) Capture clear and certain identification of any person entering or exiting a restricted access area containing medical cannabis goods;

(2) Have the ability to produce a clear, color still photograph live or from a recording;

(3) Have on all recordings an embedded date-and-time stamp that is synchronized to the recording and does not obscure the picture; and

(4) Continue to operate during a power outage.

c. *Video recording specifications.*

(1) A video recording shall export still images in an industry standard image format, such as .jpg, .bmp, or .gif.

(2) Exported video shall be archived in a format that ensures authentication and guarantees that the recorded image has not been altered.

(3) Exported video shall also be saved in an industry standard file format that can be played on a standard computer operating system.

(4) All recordings shall be erased or destroyed at the end of the retention period and prior to disposal of any storage medium.

d. Additional requirements. A laboratory shall maintain all security system equipment and recordings in a secure location to prevent theft, loss, destruction, corruption, and alterations.

e. Retention. A laboratory shall ensure that 24-hour recordings from all video cameras are:

(1) Available for viewing by the department upon request;

(2) Retained for a minimum of 60 days;

(3) Maintained free of alteration or corruption; and

(4) Retained longer, as needed, if a manufacturer is given actual notice of a pending criminal, civil, or administrative investigation, or other legal proceeding for which the recording may contain relevant information.

154.76(6) *Chain-of-custody policy and procedures.* A laboratory shall maintain a current chain-of-custody policy and procedures. The policy should ensure that:

a. Chain of custody is maintained for samples which may have probable forensic evidentiary value; and

b. Annual training is available for individuals who will be involved with testing medical cannabis goods.

154.76(7) *Information technology systems security.* A laboratory shall maintain information technology systems protection by employing comprehensive security controls that include security firewall protection, antivirus protection, network and desktop password protection, and security patch management procedures.

[**ARC 3836C**, IAB 6/6/18, effective 7/11/18]

These rules are intended to implement Iowa Code chapter 124E.

[Filed ARC 1640C (Notice ARC 1571C, IAB 8/6/14), IAB 10/1/14, effective 1/30/15]

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PROFESSIONAL LICENSURE DIVISION[645]

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Prior to 7/29/87, for Chs. 20 to 22 see Health Department[470] Chs. 152 to 154.

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645—5.1(147,152D) Athletic training license fees. All fees are nonrefundable.

5.1(1) License fee for license to practice athletic training is $120.

5.1(2) Temporary license fee for license to practice athletic training is $120.

5.1(3) Biennial license renewal fee for each biennium is $120.

5.1(4) Late fee for failure to renew before expiration is $60.

5.1(5) Reactivation fee is $180.

5.1(6) Duplicate or reissued license certificate or wallet card fee is $20.

5.1(7) Verification of license fee is $20.

5.1(8) Returned check fee is $25.

5.1(9) Disciplinary hearing fee is a maximum of $75.

This rule is intended to implement Iowa Code chapters 17A, 147, 152D and 272C.

645—5.2(147,158) Barbering license fees. All fees are nonrefundable.

5.2(1) License fee for an initial license to practice barbering, license by endorsement, license by reciprocity or an instructor's license is $60.

5.2(2) Biennial renewal fee for a barber license or barber instructor license is $60.

5.2(3) Temporary permit fee is $12.

5.2(4) Practical examination fee is $75.

5.2(5) Demonstrator permit fee is $45 for the first day and $12 for each day thereafter for which the permit is valid.

5.2(6) Barber school license fee is $600.

5.2(7) Barber school annual renewal fee is $300.

5.2(8) Barbershop license fee is $72.

5.2(9) Biennial renewal fee for a barbershop license is $72.

5.2(10) Late fee for failure to renew before expiration is $60.

5.2(11) Reactivation fee for a barber license is $120.

5.2(12) Reactivation fee for a barbershop license is $132.

5.2(13) Reactivation fee for a barber school license is $360.

5.2(14) Duplicate or reissued license certificate or wallet card fee is $20.

5.2(15) Verification of license fee is $20.

5.2(16) Returned check fee is $25.

5.2(17) Disciplinary hearing fee is a maximum of $75.

This rule is intended to implement Iowa Code section 147.80 and Iowa Code chapter 158.

[**ARC 8349B**, IAB 12/2/09, effective 1/6/10]

645—5.3(147,154D) Behavioral science license fees. All fees are nonrefundable.

5.3(1) License fee for license to practice marital and family therapy or mental health counseling is $120.

5.3(2) Temporary license fee for license to practice marital and family therapy or mental health counseling is $120.

5.3(3) Biennial license renewal fee for each biennium is $120.

5.3(4) Late fee for failure to renew before expiration is $60.

5.3(5) Reactivation fee is $180.

5.3(6) Duplicate or reissued license certificate or wallet card fee is $20.

5.3(7) Verification of license fee is $20.

5.3(8) Returned check fee is $25.

5.3(9) Disciplinary hearing fee is a maximum of $75.

5.3(10) License fee for license to practice as a behavior analyst or assistant behavior analyst is $300.

This rule is intended to implement Iowa Code section 147.8 and chapters 17A, 154D and 272C.

[**ARC 8152B**, IAB 9/23/09, effective 10/28/09; **ARC 4390C**, IAB 4/10/19, effective 3/22/19]

645—5.4(151) Chiropractic license fees. All fees are nonrefundable.

5.4(1) License fee for license to practice chiropractic is $270.

5.4(2) Fee for issuance of annual temporary certificate is $120.

5.4(3) Biennial license renewal fee is $120.

5.4(4) Late fee for failure to renew before the expiration date is $60.

5.4(5) Reactivation fee is $180.

5.4(6) Duplicate or reissued license certificate or wallet card fee is $20.

5.4(7) Fee for verification of license is $20.

5.4(8) Returned check fee is $25.

5.4(9) Disciplinary hearing fee is a maximum of $75.

This rule is intended to implement Iowa Code chapters 17A, 151 and 272C.

645—5.5(147,157) Cosmetology arts and sciences license fees. All fees are nonrefundable.

5.5(1) License fee for license to practice cosmetology arts and sciences, license by endorsement, license by reciprocity, or an instructor's license is $60.

5.5(2) Biennial license renewal fee for each license for each biennium is $60.

5.5(3) Late fee for failure to renew before expiration is $60.

5.5(4) Reactivation fee for applicants licensed to practice cosmetology is $120; for salons, $144; and for schools, $330.

5.5(5) Duplicate or reissued license certificate or wallet card fee is $20.

5.5(6) Fee for verification of license is $20.

5.5(7) Returned check fee is $25.

5.5(8) Disciplinary hearing fee is a maximum of $75.

5.5(9) Fee for license to conduct a school teaching cosmetology arts and sciences is $600.

5.5(10) Fee for renewal of a school license is $270 annually.

5.5(11) Salon license fee is $84.

5.5(12) Biennial license renewal fee for each salon license for each biennium is $84.

5.5(13) Demonstrator and not-for-profit temporary permit fee is $42 for the first day and $12 for each day thereafter that the permit is valid.

5.5(14) An initial fee or a reactivation fee for certification to administer microdermabrasion or utilize a certified laser product or an intense pulsed light (IPL) device is $25 for each type of procedure or certified laser product or IPL device.

5.5(15) An initial fee or a reactivation fee for certification of cosmetologists to administer chemical peels is $25.

This rule is intended to implement Iowa Code section 147.80 and chapter 157.

645—5.6(147,152A) Dietetics license fees. All fees are nonrefundable.

5.6(1) License fee for license to practice dietetics, license by endorsement, or license by reciprocity is $120.

5.6(2) Biennial license renewal fee for each biennium is $120.

5.6(3) Late fee for failure to renew before expiration is $60.

5.6(4) Reactivation fee is $180.

5.6(5) Duplicate or reissued license certificate or wallet card fee is $20.

5.6(6) Verification of license fee is $20.

5.6(7) Returned check fee is $25.

5.6(8) Disciplinary hearing fee is a maximum of $75.

This rule is intended to implement Iowa Code section 147.8 and Iowa Code chapters 17A, 152A and 272C.

645—5.7(147,154A) Hearing aid specialists license fees. All fees are nonrefundable.

5.7(1) Application fee for a license to practice by examination, endorsement, or reciprocity is $156.

5.7(2) Examination fee (check or money order made payable to the International Hearing Society) is $95.

5.7(3) Renewal of license fee is $60.

5.7(4) Temporary permit fee is $42.

5.7(5) Late fee is $60.

5.7(6) Reactivation fee is $120.

5.7(7) Duplicate or reissued license certificate or wallet card fee is $20.

5.7(8) Verification of license fee is $20.

5.7(9) Returned check fee is $25.

5.7(10) Disciplinary hearing fee is a maximum of $75.

This rule is intended to implement Iowa Code chapter 154A.

[**ARC 2151C**, IAB 9/16/15, effective 10/21/15]

645—5.8(147) Massage therapy license fees. All fees are nonrefundable.

5.8(1) License fee for license to practice massage therapy is $120.

5.8(2) Biennial license renewal fee for each biennium is $60.

5.8(3) Temporary license fee for up to one year is $120.

5.8(4) Late fee for failure to renew before expiration is $60.

5.8(5) Reactivation fee is $120.

5.8(6) Duplicate or reissued license certificate or wallet card fee is $20.

5.8(7) Verification of license fee is $20.

5.8(8) Returned check fee is $25.

5.8(9) Disciplinary hearing fee is a maximum of $75.

5.8(10) Initial application fee for approval of massage therapy education curriculum is $120.

This rule is intended to implement Iowa Code chapters 17A, 147 and 272C.

645—5.9(147,156) Mortuary science license fees. All fees are nonrefundable.

5.9(1) License fee for license to practice funeral directing is $120.

5.9(2) Biennial funeral director's license renewal fee for each biennium is $120.

5.9(3) Late fee for failure to renew before expiration is $60.

5.9(4) Reactivation fee for a funeral director is $180 and for a funeral establishment or cremation establishment is $150.

5.9(5) Duplicate or reissued license certificate or wallet card fee is $20.

5.9(6) Verification of license fee is $20.

5.9(7) Returned check fee is $25.

5.9(8) Disciplinary hearing fee is a maximum of $75.

5.9(9) Funeral establishment or cremation establishment fee is $90.

5.9(10) Three-year renewal fee of funeral establishment or cremation establishment is $90.

This rule is intended to implement Iowa Code section 147.8 and chapters 17A, 156 and 272C.

645—5.10(147,155) Nursing home administrators license fees. All fees are nonrefundable.

5.10(1) License fee for license to practice nursing home administration is $120.

5.10(2) Biennial license renewal fee for each license for each biennium is $60.

5.10(3) Late fee for failure to renew before expiration is $60.

5.10(4) Reactivation fee is $120.

5.10(5) Duplicate or reissued license certificate or wallet card fee is $20.

5.10(6) Verification of license fee is $20.

5.10(7) Returned check fee is $25.

5.10(8) Disciplinary hearing fee is a maximum of $75.

5.10(9) Provisional license fee is $120.

This rule is intended to implement Iowa Code section 147.80 and Iowa Code chapter 155.

645—5.11(147,148B) Occupational therapy license fees. All fees are nonrefundable.

5.11(1) License fee for an OT or OTA license to practice occupational therapy is $120.
5.11(2) Biennial license renewal fee to practice occupational therapy is $60.
5.11(3) Biennial license renewal fee for an occupational therapy assistant is $60.
5.11(4) Late fee for failure to renew before expiration is $60.
5.11(5) Reactivation fee is $120.
5.11(6) Duplicate or reissued license certificate or wallet card fee is $20.
5.11(7) Verification of license fee is $20.
5.11(8) Returned check fee is $25.
5.11(9) Disciplinary hearing fee is a maximum of $75.
This rule is intended to implement Iowa Code section 147.8 and chapters 17A, 148B and 272C.

645—5.12(147,154) Optometry license fees. All fees are nonrefundable.
5.12(1) License fee for license to practice optometry, license by endorsement, or license by reciprocity is $300.
5.12(2) Biennial license renewal fee for each biennium is $144.
5.12(3) Late fee for failure to renew before expiration date is $60.
5.12(4) Reactivation fee is $204.
5.12(5) Duplicate or reissued license certificate or wallet card fee is $20.
5.12(6) Verification of license fee is $20.
5.12(7) Returned check fee is $25.
5.12(8) Disciplinary hearing fee is a maximum of $75.
This rule is intended to implement Iowa Code chapters 17A, 147, 154 and 272C.

645—5.13(147,148A) Physical therapy license fees. All fees are nonrefundable.
5.13(1) License fee for license to practice physical therapy or as a physical therapist assistant is $120.
5.13(2) Biennial license renewal fee for a physical therapist is $60.
5.13(3) Biennial license renewal fee for a physical therapist assistant is $60.
5.13(4) Late fee for failure to renew before expiration is $60.
5.13(5) Reactivation fee is $120.
5.13(6) Duplicate or reissued license certificate or wallet card fee is $20.
5.13(7) Verification of license fee is $20.
5.13(8) Returned check fee is $25.
5.13(9) Disciplinary hearing fee is a maximum of $75.
This rule is intended to implement Iowa Code section 147.8 and chapters 17A, 148A and 272C.

645—5.14(148C) Physician assistants license fees. All fees are nonrefundable.
5.14(1) Application fee for a license is $120.
5.14(2) Fee for a temporary license is $120.
5.14(3) Renewal of license fee is $120.
5.14(4) Late fee for failure to renew before expiration is $60.
5.14(5) Reactivation fee is $180.
5.14(6) Duplicate or reissued license certificate or wallet card fee is $20.
5.14(7) Fee for verification of license is $20.
5.14(8) Returned check fee is $25.
5.14(9) Disciplinary hearing fee is a maximum of $75.
This rule is intended to implement Iowa Code section 147.8 and chapters 17A, 148C and 272C.

645—5.15(147,148F,149) Podiatry license fees. All fees are nonrefundable.
5.15(1) License fee for license to practice podiatry, license by endorsement, or license by reciprocity is $400.
5.15(2) License fee for temporary license to practice podiatry is $200.

5.15(3) The fee for a license to practice orthotics, prosthetics, or pedorthics received on or before July 1, 2015, shall be $600. The fee for a license to practice orthotics, prosthetics, or pedorthics received after July 1, 2015, shall be $400.

5.15(4) Biennial license renewal fee is $400 for each biennium.

5.15(5) Reactivation fee is $460.

5.15(6) Temporary license renewal fee is $200.

5.15(7) Late fee for failure to renew before expiration is $60.

5.15(8) Duplicate or reissued license certificate or wallet card fee is $20.

5.15(9) Verification of license fee is $20.

5.15(10) Returned check fee is $25.

5.15(11) Disciplinary hearing fee is a maximum of $75.

This rule is intended to implement Iowa Code section 147.8 and Iowa Code chapters 17A, 148F, 149 and 272C.

[**ARC 1192C**, IAB 11/27/13, effective 1/1/14]

645—5.16(147,154B) Psychology license fees. All fees are nonrefundable.

5.16(1) License fee for license to practice psychology is $120.

5.16(2) Biennial license renewal fee is $170.

5.16(3) Late fee for failure to renew before expiration is $60.

5.16(4) Reactivation fee is $230.

5.16(5) Duplicate or reissued license certificate or wallet card fee is $20.

5.16(6) Verification of license fee is $20.

5.16(7) Returned check fee is $25.

5.16(8) Disciplinary hearing fee is a maximum of $75.

5.16(9) Processing fee for exemption to licensure is $60.

5.16(10) Certification fee for a health service provider is $60.

5.16(11) Biennial renewal fee for certification as a certified health service provider in psychology is $60.

5.16(12) Reactivation fee for certification as a certified health service provider in psychology is $60.

5.16(13) Provisional license fee is $120.

5.16(14) Provisional license renewal fee is $170.

This rule is intended to implement Iowa Code section 147.80 and chapters 17A, 154B and 272C and 2014 Iowa Acts, chapter 1043.

[**ARC 1834C**, IAB 1/21/15, effective 2/25/15]

645—5.17(147,152B) Respiratory care license fees. All fees are nonrefundable.

5.17(1) Initial license fee.

a. The initial license fee for a respiratory care practitioner license is $75, plus the cost for evaluation of the fingerprint packet and the criminal history background checks by the Iowa division of criminal investigation (DCI) and the Federal Bureau of Investigation (FBI).

b. The initial license fee for a polysomnographic technologist license is $330, plus the cost for evaluation of the fingerprint packet and the criminal history background checks by the Iowa division of criminal investigation (DCI) and the Federal Bureau of Investigation (FBI).

c. The initial license fee for a respiratory care and polysomnography practitioner license is $90, plus the cost for evaluation of the fingerprint packet and the criminal history background checks by the Iowa division of criminal investigation (DCI) and the Federal Bureau of Investigation (FBI).

5.17(2) Biennial license renewal fee for each biennium.

a. The biennial license renewal fee for each biennium for a respiratory care practitioner license is $75.

b. The biennial license renewal fee for each biennium for a polysomnographic technologist license is $330.

c. The biennial license renewal fee for each biennium for a respiratory care and polysomnography practitioner license is $90.

5.17(3) Late fee for failure to renew before expiration is $60.

5.17(4) Reactivation fee.

a. The reactivation fee to practice respiratory care is $135, plus the cost for evaluation of the fingerprint packet and the criminal history background checks by the Iowa division of criminal investigation (DCI) and the Federal Bureau of Investigation (FBI) if the license has been on inactive status for two or more years.

b. The reactivation fee to practice as a polysomnographic technologist is $390, plus the cost for evaluation of the fingerprint packet and the criminal history background checks by the Iowa division of criminal investigation (DCI) and the Federal Bureau of Investigation (FBI) if the license has been on inactive status for two or more years.

c. The reactivation fee to practice respiratory care and polysomnography is $150, plus the cost for evaluation of the fingerprint packet and the criminal history background checks by the Iowa division of criminal investigation (DCI) and the Federal Bureau of Investigation (FBI) if the license has been on inactive status for two or more years.

5.17(5) Duplicate or reissued license certificate or wallet card fee is $20.

5.17(6) Verification of license fee is $20.

5.17(7) Returned check fee is $25.

5.17(8) Disciplinary hearing fee is a maximum of $75.

This rule is intended to implement Iowa Code section 147.8 and Iowa Code chapters 17A, 152B and 272C.

[**ARC 2717C**, IAB 9/14/16, effective 10/19/16]

645—5.18(147,154E) Sign language interpreters and transliterators license fees. All fees are nonrefundable.

5.18(1) License fee for license to practice interpreting or transliterating is $120.

5.18(2) License fee for temporary license to practice interpreting or transliterating is $120.

5.18(3) Biennial license renewal fee for each biennium is $120.

5.18(4) Late fee for failure to renew before expiration is $60.

5.18(5) Duplicate or reissued license certificate or wallet card fee is $20.

5.18(6) Verification of license fee is $20.

5.18(7) Returned check fee is $25.

5.18(8) Disciplinary hearing fee is a maximum of $75.

5.18(9) Reactivation fee is $180.

This rule is intended to implement Iowa Code chapters 17A, 147, 154E and 272C.

645—5.19(147,154C) Social work license fees. All fees are nonrefundable.

5.19(1) License fee for license to practice social work is $120.

5.19(2) Biennial license renewal fee for a license at the bachelor's level is $72; at the master's level, $120; and independent level, $144.

5.19(3) Late fee for failure to renew before expiration is $60.

5.19(4) Reactivation fee for the bachelor's level is $132; for the master's level, $180; and independent level, $204.

5.19(5) Duplicate or reissued license certificate or wallet card fee is $20.

5.19(6) Verification of license fee is $20.

5.19(7) Returned check fee is $25.

5.19(8) Disciplinary hearing fee is a maximum of $75.

This rule is intended to implement Iowa Code section 147.80 and chapters 17A, 154C and 272C.

645—5.20(147) Speech pathology and audiology license fees. All fees are nonrefundable.

5.20(1) License fee for license to practice speech pathology or audiology, temporary clinical license, license by endorsement, or license by reciprocity is $120.

5.20(2) Biennial license renewal fee for each biennium is $96.

5.20(3) Late fee for failure to renew before expiration is $60.
5.20(4) Reactivation fee is $156.
5.20(5) Duplicate or reissued license certificate or wallet card fee is $20.
5.20(6) Verification of license fee is $20.
5.20(7) Returned check fee is $25.
5.20(8) Disciplinary hearing fee is a maximum of $75.
5.20(9) Temporary clinical license renewal fee is $60.
5.20(10) Temporary permit fee is $30.
This rule is intended to implement Iowa Code chapters 17A, 147 and 272C.

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BEHAVIORAL SCIENTISTS

CHAPTER 31 LICENSURE OF MARITAL AND FAMILY THERAPISTS, MENTAL HEALTH COUNSELORS, BEHAVIOR ANALYSTS, AND ASSISTANT BEHAVIOR ANALYSTS

CHAPTER 32 CONTINUING EDUCATION FOR MARITAL AND FAMILY THERAPISTS AND MENTAL HEALTH COUNSELORS

CHAPTER 33 DISCIPLINE FOR MARITAL AND FAMILY THERAPISTS, MENTAL HEALTH COUNSELORS, BEHAVIOR ANALYSTS, AND ASSISTANT BEHAVIOR ANALYSTS

CHAPTER 31
LICENSURE OF MARITAL AND FAMILY THERAPISTS, MENTAL HEALTH COUNSELORS, BEHAVIOR ANALYSTS, AND ASSISTANT BEHAVIOR ANALYSTS

[Prior to 1/30/02, see 645—Chapter 30]

645—31.1(154D) Definitions. For purposes of these rules, the following definitions shall apply:

"ACA" means the American Counseling Association.

"Active license" means a license that is current and has not expired.

"AMFTRB" means the Association of Marital and Family Therapy Regulatory Boards.

"BACB" means the Behavior Analyst Certification Board.

"Board" means the board of behavioral science.

"CCE" means the Center for Credentialing and Education, Inc.

"Course" means three graduate semester credit hours.

"Department" means the department of public health.

"Grace period" means the 30-day period following expiration of a license when the license is still considered to be active. In order to renew a license during the grace period, a licensee is required to pay a late fee.

"Inactive license" means a license that has expired because it was not renewed by the end of the grace period. The category of "inactive license" may include licenses formerly known as lapsed, inactive, delinquent, closed, or retired.

"Licensee" means any person licensed to practice as a marital and family therapist, mental health counselor, behavior analyst, or assistant behavior analyst in the state of Iowa.

"License expiration date" means September 30 of even-numbered years for marital and family therapists and mental health counselors, and means the expiration date of the certification issued by the Behavior Analyst Certification Board for behavior analysts and assistant behavior analysts.

"Licensure by endorsement" means the issuance of an Iowa license to practice mental health counseling or marital and family therapy to an applicant who is or has been licensed in another state.

"Mandatory training" means training on identifying and reporting child abuse or dependent adult abuse required of marital and family therapists and mental health counselors who are mandatory reporters. The full requirements on mandatory reporting of child abuse and the training requirements are found in Iowa Code section 232.69. The full requirements on mandatory reporting of dependent adult abuse and the training requirements are found in Iowa Code section 235B.16.

"Mental health setting" means a behavioral health setting where an applicant is providing mental health services including the diagnosis, treatment, and assessment of emotional and mental health disorders and issues.

"NBCC" means the National Board for Certified Counselors.

"Reactivate" or *"reactivation"* means the process as outlined in rule 645—31.16(17A,147,272C) by which an inactive license is restored to active status.

"Reciprocal license" means the issuance of an Iowa license to practice mental health counseling or marital and family therapy to an applicant who is currently licensed in another state which has the same or similar qualifications to those required in Iowa.

"Reinstatement" means the process as outlined in 645—11.31(272C) by which a licensee who has had a license suspended or revoked or who has voluntarily surrendered a license may apply to have the

license reinstated, with or without conditions. Once the license is reinstated, the licensee may apply for active status.

"Temporary license" means a license to practice marital and family therapy or mental health counseling under direct supervision of a qualified supervisor as determined by the board by rule to fulfill the postgraduate supervised clinical experience requirement in accordance with this chapter.

[**ARC 9547B**, IAB 6/1/11, effective 7/6/11; **ARC 2845C**, IAB 12/7/16, effective 1/11/17; **ARC 4390C**, IAB 4/10/19, effective 3/22/19]

645—31.2(154D) Requirements for permanent and temporary licensure as a mental health counselor or marriage and family therapist. The following criteria shall apply to licensure:

31.2(1) The applicant shall complete a board-approved application. Application forms may be obtained from the board's website (www.idph.iowa.gov/licensure) or directly from the board office, or the applicant may complete the application online at ibplicense.iowa.gov. All paper applications shall be sent to the Board of Behavioral Science, Professional Licensure Division, Fifth Floor, Lucas State Office Building, Des Moines, Iowa 50319-0075.

31.2(2) The applicant shall complete the application form according to the instructions contained in the application. If the application is not completed according to the instructions, the application will not be reviewed by the board.

31.2(3) Each application shall be accompanied by the appropriate fees payable to the Board of Behavioral Science. The fees are nonrefundable.

31.2(4) No application will be considered by the board until official copies of academic transcripts sent directly from the school to the board of behavioral science have been received by the board or an equivalency evaluation completed by the Center for Credentialing and Education, Inc. (CCE) has been received by the board. The applicant shall present proof of meeting the educational requirements. Documentation of such proof shall be on file in the board office with the application and include one of the following:

a. For licensure as a marital and family therapist, an official transcript verifying completion of a marital and family therapy program accredited by the Commission on Accreditation for Marriage and Family Therapy Education (COAMFTE) as defined in subrule 31.4(1) or an equivalency evaluation of the applicant's educational credentials completed by CCE as defined in subrule 31.4(2).

b. For licensure as a mental health counselor, an official transcript verifying completion of a mental health counseling program accredited by the Council on Accreditation of Counseling and Related Educational Programs (CACREP) as defined in subrule 31.6(1) or an equivalency evaluation of the applicant's educational credentials completed by CCE as defined in subrule 31.6(2).

31.2(5) The candidate for permanent licensure shall have the examination score sent directly from the testing service to the board. The candidate for temporary licensure must successfully complete the examination before the temporary license is issued.

31.2(6) The candidate for permanent licensure shall submit the required attestation of supervision forms documenting clinical experience as required in rule 645—31.5(154D) for marital and family therapy and rule 645—31.7(154D) for mental health counseling.

31.2(7) The candidate for temporary licensure for the purpose of fulfilling the postgraduate supervised clinical experience requirement must submit the Supervised Clinical Experience: Approval and Attestation form to the board and receive approval of the candidate's supervisor(s) prior to licensure. The temporary licensee must notify the board immediately in writing of any proposed change in supervisor(s) and obtain approval of any change in supervisor(s). Within 30 days of completion of the supervised clinical experience, the attestation of the completed supervised experience must be submitted to the board office. The temporary licensee shall remain under supervision until a permanent license is issued.

31.2(8) A temporary license for the purpose of fulfilling the postgraduate supervised clinical experience requirement is valid for three years and may be renewed at the discretion of the board.

31.2(9) A licensee who was issued an initial permanent license within six months prior to the renewal shall not be required to renew the license until the renewal date two years later.

31.2(10) Submitting complete application materials. An application for a temporary or permanent license will be considered active for two years from the date the application is received. If the applicant does not submit all materials within this time period or if the applicant does not meet the requirements for the license, the application shall be considered incomplete. An applicant whose application is filed incomplete must submit a new application, supporting materials, and the application fee. The board shall destroy incomplete applications after two years.

[**ARC 8152B**, IAB 9/23/09, effective 10/28/09; **ARC 0777C**, IAB 6/12/13, effective 7/17/13; **ARC 1758C**, IAB 12/10/14, effective 1/14/15; **ARC 2845C**, IAB 12/7/16, effective 1/11/17; **ARC 4390C**, IAB 4/10/19, effective 3/22/19]

645—31.3(154D) Examination requirements for mental health counselors and marital and family therapists. The following criteria shall apply to the written examination(s):

31.3(1) In order to qualify for licensing, the applicant:

a. For a marital and family therapist license shall take and pass the Association of Marital and Family Therapy Regulatory Board (AMFTRB) Examination in Marital and Family Therapy.

b. For a mental health counselor license shall take and pass the National Counselor Examination of the NBCC or the National Clinical Mental Health Counselor Examination of the NBCC.

31.3(2) Examination information will be provided when the applicant has been approved to take the examination.

31.3(3) The board will notify the applicant in writing of examination results.

31.3(4) Persons determined by the board not to have performed satisfactorily may apply for reexamination.

31.3(5) The passing score on the written examination shall be the passing point criterion established by the appropriate national testing authority at the time the test was administered.

31.3(6) An applicant who is requesting approval to take the licensure examination prior to graduation shall:

a. Apply for licensure by creating an account and paying online at ibplicense.iowa.gov or by completing and returning a paper application with a check or money order payable to the Board of Behavioral Science.

b. Have a letter on official school letterhead sent directly from the program director to the board indicating that the applicant is in good academic standing; that the applicant will graduate from the program within three months of the date on the letter; and the applicant's anticipated date of graduation.

[**ARC 2845C**, IAB 12/7/16, effective 1/11/17; **ARC 4390C**, IAB 4/10/19, effective 3/22/19]

645—31.4(154D) Educational qualifications for marital and family therapists. The applicant must complete the required semester credit hours, or equivalent quarter hours, of graduate level coursework in each of the content areas identified in 31.4(2); no course may be used more than once. The applicant must present proof of completion of the following educational requirements for licensure as a marital and family therapist:

31.4(1) *Accredited program.* Applicants must present with the application an official transcript verifying completion of a master's degree of 60 semester hours (or 80 quarter hours or equivalent) or a doctoral degree in marital and family therapy from a program accredited by the Commission on Accreditation for Marriage and Family Therapy Education (COAMFTE) from a college or university accredited by an agency recognized by the United States Department of Education. Applicants who entered a program of study prior to July 1, 2010, must present with the application an official transcript verifying completion of a master's degree of 45 semester hours or the equivalent; or

31.4(2) *Content-equivalent program.* Applicants must present an official transcript verifying completion of a master's degree of 60 semester hours (or 80 quarter hours or equivalent) or a doctoral degree in marital and family therapy, behavioral science, or a counseling-related field from a college or university accredited by an agency recognized by the United States Department of Education, which is content-equivalent to a graduate degree in marital and family therapy. Applicants who entered a program of study prior to July 1, 2010, must present with the application an official transcript verifying completion of a master's degree of 45 semester hours or the equivalent. Graduates from non-COAMFTE-accredited marital and family therapy programs shall provide an equivalency

evaluation of the graduates' educational credentials by the Center for Credentialing and Education, Inc. (CCE), website cce-global.org. The professional curriculum must be equivalent to that stated in these rules. Applicants shall bear the expense of the curriculum evaluation. In order to qualify as a "content-equivalent" degree, a graduate transcript must document:

a. At least 9 semester hours or the equivalent in each of the three areas listed below:

(1) Theoretical foundations of marital and family therapy systems. Any course which deals primarily in areas such as family life cycle; theories of family development; marriage or the family; sociology of the family; families under stress; the contemporary family; family in a social context; the cross-cultural family; youth/adult/aging and the family; family subsystems; individual, interpersonal relationships (marital, parental, sibling).

(2) Assessment and treatment in family and marital therapy. Any course which deals primarily in areas such as family therapy methodology; family assessment; treatment and intervention methods; overview of major clinical theories of marital and family therapy, such as communications, contextual, experiential, object relations, strategic, structural, systemic, transgenerational.

(3) Human development. Any course which deals primarily in areas such as human development; personality theory; human sexuality. One course must be psychopathology.

b. At least 3 semester hours or the equivalent in each of the two areas listed below:

(1) Ethics and professional studies. Any course which deals primarily in areas such as professional socialization and the role of the professional organization; legal responsibilities and liabilities; independent practice and interprofessional cooperation; ethical issues in marital and family counseling; and family law.

(2) Research. Any course which deals primarily in areas such as research design, methods, statistics; research in marital and family studies and therapy.

If the applicant has taught a graduate-level course as outlined above at a college or university accredited by an agency recognized by the United States Department of Education or the Council on Professional Accreditation, that course will be credited toward the course requirements.

c. A graduate-level clinical practicum in marital and family therapy of at least 300 clock hours is required for all applicants.

[**ARC 7673B**, IAB 4/8/09, effective 4/30/09; **ARC 9547B**, IAB 6/1/11, effective 7/6/11; **ARC 2845C**, IAB 12/7/16, effective 1/11/17]

645—31.5(154D) Clinical experience requirements for marital and family therapists.

31.5(1) The supervised clinical experience shall:

a. Be a minimum of two years or the equivalent of full-time, postgraduate supervised professional work experience in marital and family therapy.

b. Be completed following completion of the practicum, internship, and all graduate coursework, with the exception of the thesis.

c. Include successful completion of at least 3,000 hours of marital and family therapy that shall include at least 1,500 hours of direct client contact and 200 hours of clinical supervision. Applicants who entered a program of study prior to July 1, 2010, shall include successful completion of 200 hours of clinical supervision concurrent with 1,000 hours of marital and family therapy conducted in person with couples, families and individuals.

d. Include a minimum of 25 percent of all clinical supervision in person.

(1) The first two meetings shall be face-to-face and in person.

(2) Up to 50 percent of all supervision may be completed by telephone.

(3) Up to 75 percent of all supervision may be completed by electronic means.

(4) Supervision by electronic means is acceptable if the system utilized is a confidential, interactive, secure, real-time system that provides for visual and audio interaction between the licensee and the supervisor.

e. Include in the 200 hours of clinical supervision at least 100 hours of individual supervision.

f. Follow and maintain a plan throughout the supervisory period established by the supervisor and the licensee. Such a plan must be kept by the licensee for a period of five years following receipt of

the permanent license and must be submitted to the board upon request. The plan for supervision shall include:

(1) The name, license number, date of licensure, address, telephone number, and email address (when available) of the supervisor;

(2) The name, license number, address, telephone number, and email address (when available) of supervisee;

(3) Employment setting in which experience will occur;

(4) The nature, duration and frequency of supervision;

(5) The number of hours of supervision per month;

(6) The supervisor/licensees type (individual/group) and mode (face-to-face/electronic) of supervision;

(7) The methodology for secure transmission of case information;

(8) The beginning date of supervised professional practice and estimated date of completion;

(9) The goals and objectives for the supervised professional practice; and

(10) The signatures of the supervisor and licensee, and the dates of signatures.

g. Have only supervised clinical contact credited for this requirement.

31.5(2) To meet the requirements of the supervised clinical experience:

a. The supervisee must:

(1) Meet with the supervisor for a minimum of four hours per month;

(2) Offer documentation of supervised hours signed by the supervisor;

(3) Compute part-time employment on a prorated basis for the supervised professional experience;

(4) Have the background, training, and experience that is appropriate to the functions performed;

(5) Have supervision that is clearly distinguishable from personal psychotherapy and is contracted in order to serve professional/vocational goals;

(6) Have individual supervision that shall be in person with no more than one supervisor to two supervisees;

(7) Have group supervision that may be completed with up to ten supervisees and a supervisor; and

(8) Not participate in the following activities which are deemed unacceptable for clinical supervision:

1. Peer supervision, i.e., supervision by a person of equivalent, but not superior, qualifications, status, and experience.

2. Supervision, by current or former family members, or any other person, in which the nature of the personal relationship prevents, or makes difficult, the establishment of a professional relationship.

3. Administrative supervision, e.g., clinical practice performed under administrative rather than clinical supervision of an institutional director or executive.

4. A primarily didactic process wherein techniques or procedures are taught in a group setting, classroom, workshop, or seminar.

5. Consultation, staff development, or orientation to a field or program, or role-playing of family interrelationships as a substitute for current clinical practice in an appropriate clinical situation.

b. The supervisor shall:

(1) Be an Iowa-licensed marital and family therapist with a minimum of three years of clinical experience following licensure; or

(2) Be a supervisor or supervisor candidate approved by the American Association for Marriage and Family Therapy Commission on Supervision; or

(3) Be licensed under Iowa Code chapter 147 and have a minimum of three years of full-time professional work experience, including experience in marital and family therapy, as approved by the board; and

(4) Meet a minimum of four hours per month with the supervisee; and

(5) Provide training that is appropriate to the functions to be performed; and

(6) Ensure that therapeutic work is completed under the professional supervision of a supervisor; and

(7) Not supervise any marital and family therapy or permit the supervisee to engage in any therapy which the supervisor cannot perform competently.

c. Effective October 1, 2020, the supervisor shall:

(1) Be an Iowa-licensed marital and family therapist with a minimum of three years of clinical experience following licensure or shall be a supervisor or supervisor candidate approved by the American Association for Marriage and Family Therapy Commission on Supervision; or

(2) Be an Iowa-licensed mental health counselor in Iowa with at least three years of clinical experience following licensure or shall be approved by the National Board for Certified Counselors (NBCC) as a supervisor; and

(3) Have completed at least a six-hour continuing education course in counseling supervision or one master's level course in counseling supervision; and

(4) Meet a minimum of four hours per month with the supervisee; and

(5) Provide training that is appropriate to the functions to be performed; and

(6) Ensure that therapeutic work is completed under the professional supervision of a supervisor; and

(7) Not supervise any marital and family therapy or permit the supervisee to engage in any therapy that the supervisor cannot perform competently.

d. Exceptions to paragraph 31.5(2)*"c"* shall be made on an individual basis. Requests for alternative supervisors must be submitted in writing, and the board must approve the supervisor prior to commencement of the supervision.

31.5(3) An applicant who has obtained American Association for Marriage and Family Therapy (AAMFT) clinical membership is considered to have met the clinical experience requirements of rule 645—31.5(154D). The applicant shall request that proof of current clinical membership be sent directly from AAMFT to the board.

[**ARC 7673B**, IAB 4/8/09, effective 4/30/09; **ARC 8152B**, IAB 9/23/09, effective 10/28/09; **ARC 9547B**, IAB 6/1/11, effective 7/6/11; **ARC 0777C**, IAB 6/12/13, effective 7/17/13; **ARC 2845C**, IAB 12/7/16, effective 1/11/17]

645—31.6(154D) Educational qualifications for mental health counselors. The applicant must complete three semester credit hours, or equivalent quarter hours, of graduate level coursework in each of the content areas identified in 31.6(2); no course may be used to fulfill more than one content area. The applicant must present proof of completion of the following educational requirements for licensure as a mental health counselor:

31.6(1) *Accredited program.* Applicants must present with the application an official transcript verifying completion of a master's degree of 60 semester hours (or equivalent quarter hours) or a doctoral degree in counseling with emphasis in mental health counseling from a mental health counseling program accredited by the Council on Accreditation of Counseling and Related Educational Programs (CACREP) from a college or university accredited by an agency recognized by the United States Department of Education. Applicants who entered a program of study prior to July 1, 2012, must present with the application an official transcript verifying completion of a master's degree of 45 semester hours or the equivalent; or

31.6(2) *Content-equivalent program.* Applicants must present an official transcript verifying completion of a master's degree or a doctoral degree from a college or university accredited by an agency recognized by the United States Department of Education which is content-equivalent to a master's degree in counseling with emphasis in mental health counseling. Graduates from non-CACREP accredited mental health counseling programs shall provide an equivalency evaluation of their educational credentials by the Center for Credentialing and Education, Inc. (CCE), website cce-global.org. The professional curriculum must be equivalent to that stated in these rules. Applicants shall bear the expense of the curriculum evaluation.

a. The degree of an applicant who entered a program of study prior to July 1, 2012, will be considered "content-equivalent" if the degree includes 45 semester hours (or equivalent quarter hours) and successful completion of graduate-level coursework in each of the areas in subparagraphs (1) to (12). If the applicant has taught a graduate-level course in any of the areas in subparagraphs (1) to (12) at a

college or university accredited by an agency recognized by the United States Department of Education, that course may be credited toward the coursework requirement.

(1) Counseling theories. Studies that provide an understanding of counseling theories, utilize personal and environmental data in the mental health counseling process, and investigate procedures that are appropriate to various counseling theories and specific settings.

(2) Supervised counseling practicum. A graduate-level clinical supervised counseling practicum in a mental health setting in which students must complete supervised practicum experiences that total a minimum of 100 clock hours over a minimum ten-week academic term. The practicum provides for the development of counseling skills under supervision. The student's practicum includes all of the following:

1. At least 40 hours of direct service with actual clients that contributes to the development of counseling skills;

2. Weekly interaction with an average of 1 hour per week of individual or triadic supervision throughout the practicum by a program faculty member, a student supervisor, or a site supervisor who is working in biweekly consultation with a program faculty member in accordance with the supervision contract;

3. An average of 1½ hours per week of group supervision that is provided on a regular schedule throughout the practicum by a program faculty member or a student supervisor; and

4. Evaluation of the student's counseling performance throughout the practicum, including documentation of a formal evaluation after the student completes the practicum.

(3) Human growth and development. Studies that provide an understanding of the nature and needs of individuals at all developmental levels. Studies in this area include, but are not limited to, the following:

1. Theories of human development across the life span;

2. Major theories of personality development; and

3. Human behavior, including an understanding of developmental crises, disability, psychopathology, and cultural factors as they affect both normal and abnormal behavior.

(4) Social and cultural foundations. Studies that provide an understanding of issues and trends in a multicultural and diverse society. Studies in this area include, but are not limited to, the following:

1. Multicultural and pluralistic trends, including characteristics and concerns of diverse groups;

2. Attitudes and behavior based on factors such as age, race, religious preference, physical disability, sexual orientation, ethnicity and culture, gender, socioeconomic status, and intellectual ability; and

3. Individual and group interventions with diverse populations.

(5) Helping relationships. Studies that provide an understanding of counseling and consultation processes. Studies in this area include, but are not limited to, the following:

1. Helping skills and counseling and consultation theories, including coverage of relevant research and factors considered in applications;

2. Counselor or consultant characteristics and behaviors that influence helping processes, including gender and ethnicity differences, verbal and nonverbal behaviors and personal characteristics, orientations, and skills; and

3. Client or consultee characteristics and behaviors that influence helping processes, including gender and ethnicity differences, verbal and nonverbal behaviors and personal characteristics, traits, capabilities, life circumstances, and developmental levels.

(6) Groups. Studies that provide an understanding of group development, dynamics, counseling theories, and group counseling methods and skills. Studies in this area include, but are not limited to, the following:

1. Principles of group dynamics, including group process components, developmental stage theories, and group members' roles and behaviors;

2. Group leadership styles and approaches, including characteristics of various types of group leaders and leadership styles;

3. Theories of group counseling, including commonalities, distinguishing characteristics, and pertinent research and literature; and

4. Group counseling methods, including group counselor orientations and behaviors, ethical considerations, appropriate selection criteria and methods, and methods of evaluation of effectiveness.

(7) Career and lifestyle development. Studies that provide an understanding of career development and the interrelationships among work, family, and other life factors. Studies in this area include, but are not limited to, the following:

1. Career development theories and decision-making models;

2. Career, avocational, educational and labor market sources, print media, computer-assisted career guidance, and computer-based career information;

3. Career development program planning;

4. Interrelationships among work, family, and other life factors such as multicultural and gender issues, as related to career development;

5. Career and educational placement, follow-up and evaluation; and

6. Assessment instruments relevant to career planning and decision making.

(8) Diagnosis and assessment treatment procedures. Studies that provide an understanding of individual and group approaches to assessment and evaluation. Studies in this area include, but are not limited to, the following:

1. Theoretical and historical bases for assessment techniques and methods of interpretation of appraisal data and information;

2. Types of educational and psychological appraisal as appropriate to the helping process;

3. Validity, including evidence for establishing content, construct, and empirical validity;

4. Reliability, including methods of establishing stability and internal and equivalence reliability;

5. Major appraisal methods, including environmental assessment, performance assessment, individual and group test and inventory methods, behavioral observations, and computer-managed and computer-assisted methods;

6. Psychometric statistics, including types of test scores, measures of central tendency, indices of variability, standard errors and correlations; and

7. Gender, ethnicity, language, disability, and cultural factors related to the assessment and evaluation of individuals and groups.

(9) Research and program evaluation. Studies that provide an understanding of types of research methods, basic statistics, and ethical and legal considerations in research. Studies in this area include, but are not limited to, the following:

1. Basic types of research methods, including qualitative, quantitative-descriptive, and quantitative-descriptive-experimental designs;

2. Basic statistics, including both univariate and bivariate hypothesis testing;

3. Uses of computers for data management and analyses; and

4. Ethical and legal considerations in research.

(10) Professional orientation. Studies that provide an understanding of all aspects of professional functioning, including history, roles, organizational structures, ethics, standards, and credentialing. Studies in this area include, but are not limited to, the following:

1. History of the helping professions, including significant factors and events;

2. Professional roles and functions, including similarities with and differences from other types of professionals;

3. Professional organizations (primarily ACA, its divisions, and its branches), including membership benefits, activities, services to members, and current emphases;

4. Ethical standards of the ACA and their evolution, legal issues, and applications to various professional activities (e.g., appraisal and group work);

5. Professional preparation standards and their evolution and current applications; and

6. Professional credentialing, including certification, licensure, and accreditation practices and standards, and the effects of public policy on these issues.

(11) Supervised counseling internship that provides an opportunity for the trainee to perform under supervision a variety of activities that a regularly employed staff member in a setting would be expected to perform. A regularly employed staff member is defined as a person occupying the professional role to which the trainee is aspiring. The internship follows a supervised practicum experience. A three-semester-hour internship includes the following:

1. A minimum of 120 hours of direct service with clientele appropriate to the program of study;
2. A minimum of 1 hour per week of individual supervision, throughout the internship, usually performed by the on-site supervisor; and
3. A minimum of 1½ hours per week of group supervision, throughout the internship, usually performed by a program faculty member supervisor.

(12) Psychopathology. Studies that provide an understanding of the description, classification and diagnosis of behavior disorders and dysfunction. Studies in this area include, but are not limited to, the following:

1. Study of cognitive, behavioral, physiological and interpersonal mechanisms for adapting to change and to stressors;
2. Role of genetic, physiological, cognitive, environmental and interpersonal factors and their interactions on development of the form, severity, course and persistence of the various types of disorders and dysfunction;
3. Research methods and findings pertinent to the description, classification, diagnosis, origin, and course of disorders and dysfunction;
4. Theoretical perspectives relevant to the origin, development, and course and outcome for the forms of behavior disorders and dysfunction; and
5. Methods of intervention or prevention used to minimize and modify maladaptive behaviors, disruptive and distressful cognition, or compromised interpersonal functioning associated with various forms of maladaptation.

b. The degree of an applicant who entered a program of study on or after July 1, 2012, will be considered "content-equivalent" if the degree includes 60 semester hours (or equivalent quarter hours) and successful completion of graduate-level coursework in each of the areas in subparagraphs (1) to (12). If the applicant has taught a graduate-level course in any of the areas in subparagraphs (1) to (12) at a college or university accredited by an agency recognized by the United States Department of Education, that course may be credited toward the coursework requirement.

(1) Professional orientation and ethical practice. Studies that provide an understanding of all of the following aspects of professional functioning:

1. History and philosophy of the counseling profession, including mental health counseling;
2. Professional roles, functions, and relationships of the mental health counselor with other human services providers, including strategies for interagency/interorganization collaboration and communication;
3. Counselors' roles and responsibilities as members of an interdisciplinary emergency management response team during a local, regional, or national crisis, disaster or other trauma-causing event;
4. Self-care strategies appropriate to the counselor role;
5. Counseling supervision models, practices, and processes;
6. Professional organizations (i.e., primarily ACA, its divisions, branches, and affiliates), including membership benefits, activities, services to members, and current emphases;
7. Professional credentialing, including certification, licensure, and accreditation practices and standards, and the effects of public policy on these issues;
8. The role and process of the professional mental health counselor advocating on behalf of the profession;
9. Advocacy processes needed to address institutional and social barriers that impede access, equity, and success for clients; and
10. Ethical standards of ACA and related entities, and applications of ethical and legal considerations in professional counseling.

(2) Social and cultural diversity. Studies that provide an understanding of the cultural context of relationships, issues, and trends in a multicultural and diverse society including all of the following:

1. Multicultural and pluralistic trends, including characteristics and concerns within and among diverse groups nationally and internationally;

2. Attitudes, beliefs, understandings, and acculturative experiences, including specific experiential learning activities designed to foster students' understanding of self and culturally diverse clients;

3. Theories of multicultural counseling, identity development, and social justice;

4. Individual, couple, family, group, and community strategies for working with and advocating for diverse populations, including multicultural competencies;

5. Counselors' roles in developing cultural self-awareness, promoting cultural social justice, advocacy, and conflict resolution and other culturally supported behaviors that promote optimal wellness and growth of the human spirit, mind or body; and

6. Counselors' roles in eliminating biases, prejudices, and processes of intentional and unintentional oppression and discrimination.

(3) Human growth and development. Studies that provide an understanding of the nature and needs of persons at all developmental levels and in multicultural contexts, including all of the following:

1. Theories of individual and family development and transitions across the life span;

2. Theories of learning and personality development including current understandings about neurobiological behavior;

3. Effects of crises, disasters, and other trauma-causing events on persons of all ages;

4. Theories and models of individual, cultural, couple, family, and community resilience;

5. A general framework for understanding exceptional abilities and strategies for differentiated interventions;

6. Human behavior, including an understanding of developmental crises, disability, psychopathology, and situational and environmental factors that affect both normal and abnormal behavior;

7. Theories and etiology of addictions and addictive behaviors, including strategies for prevention, intervention, and treatment; and

8. Strategies for facilitating optimum development over the life span.

(4) Career development. Studies that provide an understanding of career development and related life factors, including all of the following:

1. Career development theories and decision-making models;

2. Career, avocational, educational, occupational and labor market information resources and career information systems;

3. Career development program planning, organization, implementation, administration, and evaluation;

4. Interrelationships among and between work, family, and other life roles and factors including the role of multicultural issues in career development;

5. Career and educational planning, placement, follow-up, and evaluation;

6. Assessment instruments and techniques relevant to career planning and decision making; and

7. Career counseling processes, techniques, and resources, including those applicable to specific populations.

(5) Helping relationships. Studies that provide an understanding of counseling processes in a multicultural society, including all of the following:

1. An orientation to wellness and prevention as desired counseling goals;

2. Counselor characteristics and behaviors that influence helping processes;

3. An understanding of essential interviewing and counseling skills;

4. Counseling theories that provide the student with a model(s) to conceptualize client presentation and select appropriate counseling interventions. Students shall be exposed to models of counseling that are consistent with current professional research and practice in the field so that they can begin to develop a personal model of counseling;

5. A systems perspective that provides an understanding of family and other systems theories and major models of family and related interventions;

6. A general framework for understanding and practicing consultation; and

7. Crisis intervention and suicide prevention models, including the use of psychological first-aid strategies.

(6) Group work. Studies that provide both theoretical and experiential understanding of group purpose, development, dynamics, theories, methods, skills, and other group approaches in a multicultural society, including all of the following:

1. Principles of group dynamics, including group process components, developmental stage theories, group members' roles and behaviors, and therapeutic factors of group work;

2. Group leadership or facilitation styles and approaches, including characteristics of various types of group leaders and leadership styles;

3. Theories of group counseling, including commonalties, distinguishing characteristics, and pertinent research and literature;

4. Group counseling methods, including group counselor orientations and behaviors, appropriate selection criteria and methods, and methods of evaluation of effectiveness; and

5. Experiences in which students participate as group members in a small group activity, approved by the program, for a minimum of 10 clock hours over the course of one academic term.

(7) Assessment. Studies that provide an understanding of individual and group approaches to assessment and evaluation in a multicultural society, including the following:

1. Historical perspectives concerning the nature and meaning of assessment;

2. Basic concepts of standardized and nonstandardized testing and other assessment techniques including norm-referenced and criterion-referenced assessment, environmental assessment, performance assessment, individual and group test and inventory methods, and behavioral observations;

3. Statistical concepts, including scales of measurement, measures of central tendency, indices of variability, shapes and types of distributions, and correlations;

4. Reliability (i.e., theory of measurement error, models of reliability, and the use of reliability information);

5. Validity (i.e., evidence of validity, types of validity, and the relationship between reliability and validity);

6. Social and cultural factors related to the assessment and evaluation of individuals, groups, and specific populations;

7. Ethical strategies for selecting, administering, and interpreting assessment and evaluation instruments and techniques in counseling; and

8. An understanding of general principles and methods of case conceptualization, assessment, or diagnoses of mental and emotional status.

(8) Research and program evaluation. Studies that provide an understanding of research methods, statistical analysis, needs assessment, and program evaluation, including all of the following:

1. The importance of research in advancing the counseling profession;

2. Research methods such as qualitative, quantitative, single-case designs, action research, and outcome-based research;

3. Statistical methods used in conducting research and program evaluation;

4. Principles, models, and applications of needs assessment, program evaluation, and use of findings to effect program modifications;

5. Use of research to inform evidence-based practice; and

6. Ethical and culturally relevant strategies for interpreting and reporting the results of research and program evaluation studies.

(9) Diagnosis and treatment planning. Studies that provide an understanding of individual and group approaches to assessment and evaluation in a multicultural society. Studies in this area include, but are not limited to, the following:

1. The principles of the diagnostic process, including differential diagnosis, and the use of current diagnostic tools, such as the current edition of the Diagnostic and Statistical Manual;

2. The established diagnostic criteria for mental or emotional disorders that describe treatment modalities and placement criteria within the continuum of care;

3. The impact of co-occurring substance use disorders on medical and psychological disorders;

4. The relevance and potential biases of commonly used diagnostic tools as related to multicultural populations;

5. The appropriate use of diagnostic tools, including the current edition of the Diagnostic and Statistical Manual, to describe the symptoms and clinical presentation of clients with mental or emotional impairments;

6. The ability to conceptualize accurate multi-axial diagnoses of disorders presented by clients and discuss the differential diagnosis with collaborating professionals; and

7. The ability to differentiate between diagnosis and developmentally appropriate reactions during crises, disasters, and other trauma-causing events.

(10) Psychopathology. Studies that provide an understanding of emotional and mental disorders experienced by persons of all ages, characteristics of disorders, and common nosologies of emotional and mental disorders utilized within the U.S. health care system for diagnosis and treatment planning. Studies in this area include, but are not limited to, the following:

1. Study of cognitive, behavioral, physiological and interpersonal mechanisms for adapting to change and to stressors;

2. Role of genetic, physiological, cognitive, environmental and interpersonal factors and their interactions on development of the form, severity, course and persistence of the various types of disorders and dysfunction;

3. Research methods and findings pertinent to the description, classification, diagnosis, origin, and course of disorders and dysfunction;

4. Theoretical perspectives relevant to the origin, development, and course and outcome for the forms of behavior disorders and dysfunction; and

5. Methods of intervention or prevention used to minimize and modify maladaptive behaviors, disruptive and distressful cognition, or compromised interpersonal functioning associated with various forms of maladaptation.

(11) Practicum. A graduate-level clinical supervised counseling practicum in a mental health setting in which students must complete supervised practicum experiences that total a minimum of 100 clock hours over a minimum ten-week academic term. The practicum provides for the development of counseling skills under supervision. The student's practicum includes all of the following:

1. At least 40 hours of direct service with actual clients that contributes to the development of counseling skills;

2. Weekly interaction with an average of 1 hour per week of individual or triadic supervision throughout the practicum by a program faculty member, a student supervisor, or a site supervisor who is working in biweekly consultation with a program faculty member in accordance with the supervision contract;

3. An average of 1½ hours per week of group supervision that is provided on a regular schedule throughout the practicum by a program faculty member or a student supervisor; and

4. Evaluation of the student's counseling performance throughout the practicum including documentation of a formal evaluation after the student completes the practicum.

(12) Internship. A graduate-level clinical supervised counseling internship in a mental health setting that requires students to complete a supervised internship of 600 clock hours that is begun after the student's successful completion of the practicum. The internship is intended to reflect the comprehensive work experience of a professional counselor appropriate to clinical mental health counseling. The internship provides an opportunity for the student to perform, under supervision, a variety of counseling activities that a mental health counselor is expected to perform. The student's internship includes all of the following:

1. At least 240 hours of direct service with clientele, including experience leading groups;

2. Weekly interaction that averages 1 hour per week of individual supervision or triadic supervision throughout the internship, usually performed by the on-site supervisor;

3. An average of 1½ hours per week of group supervision, provided on a regular schedule throughout the internship, usually performed by a program faculty member supervisor;

4. The opportunity for the student to become familiar with a variety of professional activities in addition to direct service (e.g., record keeping, supervision, information and referral, in-service and staff meetings);

5. The opportunity for the student to develop program-appropriate audio/video recordings for use in supervision or to receive live supervision of the student's interactions with clients;

6. The opportunity for the student to gain supervised experience in the use of a variety of professional resources such as assessment instruments, technologies, print and nonprint media, professional literature, and research; and

7. Evaluation of the student's counseling performance throughout the internship including documentation of a formal evaluation by a program faculty member in consultation with the site supervisor after the student completes the internship.

31.6(3) *Foreign-trained marital and family therapists or mental health counselors.* Foreign-trained marital and family therapists or mental health counselors shall:

a. Provide an equivalency evaluation of their educational credentials by the following: International Educational Research Foundations, Inc., Credentials Evaluation Service, P.O. Box 3665, Culver City, CA 90231-3665; telephone (310)258-9451; website www.ierf.org or email at info@ierf.org. The professional curriculum must be equivalent to that stated in these rules. A candidate shall bear the expense of the curriculum evaluation.

b. Provide a notarized copy of the certificate or diploma awarded to the applicant from a mental health counselor program in the country in which the applicant was educated.

c. Receive a final determination from the board regarding the application for licensure.

[**ARC 7673B**, IAB 4/8/09, effective 4/30/09; **ARC 9547B**, IAB 6/1/11, effective 7/6/11; **ARC 1758C**, IAB 12/10/14, effective 1/14/15; **ARC 2845C**, IAB 12/7/16, effective 1/11/17]

645—31.7(154D) Clinical experience requirements for mental health counselors.

31.7(1) The supervised clinical experience shall:

a. Be a minimum of two years or the equivalent of full-time, postgraduate supervised professional work experience in mental health counseling.

b. Be completed following completion of the practicum, internship, and all graduate coursework, with the exception of the thesis.

c. Include successful completion of at least 3,000 hours of mental health counseling that shall include at least 1,500 hours of direct client contact and 200 hours of clinical supervision. Applicants who entered a program of study prior to July 1, 2010, shall include successful completion of 200 hours of clinical supervision concurrent with 1,000 hours of mental health counseling conducted in person with couples, families and individuals.

d. Include a minimum of 25 percent of all clinical supervision in person.

(1) The first two meetings shall be face-to-face and in person.

(2) Up to 50 percent of all supervision may be completed by telephone.

(3) Up to 75 percent of all supervision may be completed by electronic means.

(4) Supervision by electronic means is acceptable if the system utilized is a confidential, interactive, secure, real-time system that provides for visual and audio interaction between the licensee and the supervisor.

e. Include in the 200 hours of clinical supervision at least 100 hours of individual supervision.

f. Follow and maintain a plan throughout the supervisory period established by the supervisor and the licensee. Such a plan must be kept by the licensee for a period of five years following receipt of the permanent license and must be submitted to the board upon request. The plan for supervision shall include:

(1) The name, license number, date of licensure, address, telephone number, and email address (when available) of the supervisor;

(2) The name, license number, address, telephone number, and email address (when available) of supervisee;

(3) Employment setting in which experience will occur;

(4) The nature, duration and frequency of supervision;

(5) The number of hours of supervision per month;

(6) The supervisor/licensees type (individual/group) and mode (face-to-face/electronic) of supervision;

(7) The methodology for secure transmission of case information;

(8) The beginning date of supervised professional practice and estimated date of completion;

(9) The goals and objectives for the supervised professional practice; and

(10) The signatures of the supervisor and licensee, and the dates of signatures.

g. Have only supervised clinical contact credited for this requirement.

31.7(2) To meet the requirements of the supervised clinical experience:

a. The supervisee must:

(1) Meet with the supervisor a minimum of four hours per month;

(2) Offer documentation of supervised hours signed by the supervisor;

(3) Compute part-time employment on a prorated basis for the supervised professional experience;

(4) Have the background, training, and experience that are appropriate to the functions performed;

(5) Have supervision that is clearly distinguishable from personal counseling and is contracted in order to serve professional/vocational goals;

(6) Have individual supervision that shall be in person with no more than one supervisor to two supervisees;

(7) Have group supervision that may be completed with up to ten supervisees and a supervisor; and

(8) Not participate in the following activities which are deemed unacceptable for clinical supervision:

1. Peer supervision, i.e., supervision by a person of equivalent, but not superior, qualifications, status, and experience.

2. Supervision, by current or former family members, or any other person, in which the nature of the personal relationship prevents, or makes difficult, the establishment of a professional relationship.

3. Administrative supervision, e.g., clinical practice performed under administrative rather than clinical supervision of an institutional director or executive.

4. A primarily didactic process wherein techniques or procedures are taught in a group setting, classroom, workshop, or seminar.

5. Consultation, staff development, or orientation to a field or program, or role-playing of family interrelationships as a substitute for current clinical practice in an appropriate clinical situation.

b. The supervisor:

(1) May be a licensed mental health counselor in Iowa with at least three years of postlicensure clinical experience; or

(2) Shall be approved by the National Board for Certified Counselors (NBCC) as a supervisor; or

(3) May be an alternate supervisor who possesses qualifications equivalent to a licensed mental health counselor with at least three years of postlicensure clinical experience, including mental health professionals licensed to practice independently; and

(4) Shall meet a minimum of four hours per month with the supervisee; and

(5) Shall provide training that is appropriate to the functions to be performed; and

(6) Shall ensure that therapeutic work is done under the professional supervision of a supervisor; and

(7) Shall not supervise any mental health counselor or permit the supervisee to engage in any therapy which the supervisor cannot perform competently.

c. Effective October 1, 2020, the supervisor shall:

(1) Be an Iowa-licensed mental health counselor in Iowa with at least three years of clinical experience following licensure or shall be approved by the National Board for Certified Counselors (NBCC) as a supervisor; or

(2) Be an Iowa-licensed marital and family therapist with a minimum of three years of clinical experience following licensure or shall be a supervisor or supervisor candidate approved by the American Association for Marriage and Family Therapy Commission on Supervision; and

(3) Have completed at least a six-hour continuing education course in counseling supervision or one master's level course in counseling supervision; and

(4) Meet a minimum of four hours per month with the supervisee; and

(5) Provide training that is appropriate to the functions to be performed; and

(6) Ensure that therapeutic work is completed under the professional supervision of a supervisor; and

(7) Not supervise any mental health counselor or permit the supervisee to engage in any therapy that the supervisor cannot perform competently.

d. Exceptions to paragraph 31.7(2)*"c"* shall be made on an individual basis. Requests for alternative supervisors must be submitted in writing, and the board must approve the supervisor prior to commencement of the supervision.

31.7(3) Rescinded IAB 7/6/05, effective 8/10/05.

31.7(4) An applicant who has obtained Certified Clinical Mental Health Counselor status with the National Board for Certified Counselors (NBCC) is considered to have met the clinical experience requirements of rule 645—31.7(154D). The applicant shall ensure that proof of current certified clinical mental health counselor status be sent directly from NBCC to the board.

[**ARC 7673B**, IAB 4/8/09, effective 4/30/09; **ARC 8152B**, IAB 9/23/09, effective 10/28/09; **ARC 9547B**, IAB 6/1/11, effective 7/6/11; **ARC 0777C**, IAB 6/12/13, effective 7/17/13; **ARC 2845C**, IAB 12/7/16, effective 1/11/17]

645—31.8(154D) Licensure by endorsement for mental health counselors and marital and family therapists. An applicant who has been a licensed marriage and family therapist or mental health counselor under the laws of another jurisdiction may file an application for licensure by endorsement with the board office.

31.8(1) The board may receive by endorsement any applicant from the District of Columbia or another state, territory, province or foreign country who:

a. Submits to the board a completed application;

b. Pays the licensure fee;

c. Shows evidence of licensure requirements that are similar to those required in Iowa;

d. Provides official transcripts sent directly from the school to the board verifying completion of a master's degree of 45 hours or equivalent if the applicant entered a program of study prior to July 1, 2012, or verifying completion of a master's degree of 60 hours or equivalent if the applicant entered a program of study on or after July 1, 2012, or the appropriate doctoral degree. Graduates from a non-CACREP-accredited mental health counselor program or a non-COAMFTE-accredited marital and family therapy program shall provide an equivalency evaluation of their educational credentials by the Center for Credentialing and Education, Inc. (CCE), website cce-global.org. The professional curriculum must be equivalent to that stated in these rules. Applicants shall bear the expense of the curriculum evaluation;

e. Supplies satisfactory evidence of the candidate's qualifications in writing on the prescribed forms by the candidate's supervisors. If verification of clinical experience is not available, the board may consider submission of documentation from the state in which the applicant is currently licensed or equivalent documentation of supervision;

f. Provides verification(s) of license(s) from every jurisdiction in which the applicant has been licensed, sent directly from the jurisdiction(s) to the board office. Web-based verification may be substituted for verification direct from the jurisdiction's board office if the verification provides:

(1) Licensee's name;

(2) Date of initial licensure;

(3) Current licensure status; and

(4) Any disciplinary action taken against the license; and

g. Has the examination score sent directly from the testing service to the board.

31.8(2) In lieu of meeting the requirements of paragraphs 31.8(1)*"d"* and *"e,"* applicants who meet the qualifications below may instead submit documentation demonstrating how each of the qualifications below is satisfied:

a. The applicant has been licensed as a mental health counselor or a marital and family therapist in another state for at least five years at the independent level (independent level means the highest level of licensure in the field offered by the particular state);

b. The applicant has been practicing under the independent license in a clinical mental health or marital and family therapy counseling setting for at least five years;

c. The applicant possesses a master's degree or higher in mental health counseling or marital and family therapy or an equivalent counseling-related field; and

d. The applicant does not have any past or pending disciplinary action from any state licensing boards related to any mental health counseling or marital and family therapy license currently or previously held by the applicant.

[**ARC 7673B**, IAB 4/8/09, effective 4/30/09; **ARC 0777C**, IAB 6/12/13, effective 7/17/13; **ARC 1758C**, IAB 12/10/14, effective 1/14/15; **ARC 2845C**, IAB 12/7/16, effective 1/11/17; **ARC 4390C**, IAB 4/10/19, effective 3/22/19]

645—31.9(147) Licensure of behavior analysts and assistant behavior analysts.

31.9(1) The applicant shall complete a board-approved application. Application forms may be obtained from the board's website (www.idph.iowa.gov/licensure) or directly from the board office. All paper applications shall be sent to the Board of Behavioral Science, Professional Licensure Division, Fifth Floor, Lucas State Office Building, Des Moines, Iowa 50319-0075.

31.9(2) The applicant shall complete the application form according to the instructions contained in the application. If the application is not completed according to the instructions, the application will not be reviewed by the board.

31.9(3) Each application shall be accompanied by the appropriate fees payable to the board of behavioral science. The fees are nonrefundable.

31.9(4) For licensure as a behavior analyst, the applicant shall submit proof of current BACB certification as a board-certified behavior analyst or board-certified behavior analyst-doctoral. For licensure as an assistant behavior analyst, the applicant shall submit proof of current BACB certification as a board-certified assistant behavior analyst.

[**ARC 4390C**, IAB 4/10/19, effective 3/22/19]

645—31.10(147) License renewal for mental health counselors and marriage and family therapists.

31.10(1) The biennial license renewal period for a license to practice marital and family therapy or mental health counseling shall begin on October 1 of an even-numbered year and end on September 30 of the next even-numbered year. The licensee is responsible for renewing the license prior to its expiration. Failure of the licensee to receive notice from the board does not relieve the licensee of the responsibility for renewing the license.

31.10(2) An individual who was issued an initial license within six months of the license renewal date will not be required to renew the license until the subsequent renewal two years later.

31.10(3) A licensee seeking renewal shall:

a. Meet the continuing education requirements of rule 645—32.2(272C) and the mandatory reporting requirements of subrule 31.10(4). A licensee whose license was reactivated during the current renewal compliance period may use continuing education credit earned during the compliance period for the first renewal following reactivation; and

b. Submit the completed renewal application and renewal fee before the license expiration date.

c. An individual who was issued a license within six months of the license renewal date will not be required to renew the license until the next renewal two years later.

31.10(4) Mandatory reporter training requirements.

a. A licensee who, in the scope of professional practice or in the licensee's employment responsibilities, examines, attends, counsels or treats children in Iowa shall indicate on the renewal application completion of two hours of training in child abuse identification and reporting in the previous five years or condition(s) for waiver of this requirement as identified in paragraph *"e."*

b. A licensee who, in the course of employment, examines, attends, counsels or treats adults in Iowa shall indicate on the renewal application completion of two hours of training in dependent adult abuse identification and reporting in the previous five years or condition(s) for waiver of this requirement as identified in paragraph *"e."*

c. A licensee who, in the scope of professional practice or in the course of employment, examines, attends, counsels or treats both adults and children in Iowa shall indicate on the renewal application completion of training in abuse identification and reporting for dependent adults and children in the previous five years or condition(s) for waiver of this requirement as identified in paragraph *"e."*

Training may be completed through separate courses as identified in paragraphs *"a"* and *"b"* or in one combined two-hour course that includes curricula for identifying and reporting child abuse and dependent adult abuse. The course shall be a curriculum approved by the Iowa department of public health abuse education review panel.

d. The licensee shall maintain written documentation for five years after mandatory training as identified in paragraphs *"a"* to *"c,"* including program date(s), content, duration, and proof of participation.

e. The requirement for mandatory training for identifying and reporting child and dependent adult abuse shall be suspended if the board determines that suspension is in the public interest or that a person at the time of license renewal:

(1) Is engaged in active duty in the military service of this state or the United States.

(2) Holds a current waiver by the board based on evidence of significant hardship in complying with training requirements, including an exemption of continuing education requirements or extension of time in which to fulfill requirements due to a physical or mental disability or illness as identified in 645—Chapter 4.

f. The board may select licensees for audit of compliance with the requirements in paragraphs *"a"* to *"e."*

31.10(5) Upon receiving the information required by this rule and the required fee, board staff shall administratively issue a two-year license and shall send the licensee a wallet card by regular mail. In the event the board receives adverse information on the renewal application, the board shall issue the renewal license but may refer the adverse information for further consideration or disciplinary investigation.

31.10(6) A person licensed to practice as a marital and family therapist or mental health counselor shall keep the person's license certificate and wallet card displayed in a conspicuous public place at the primary site of practice.

31.10(7) Late renewal. The license shall become late when the license has not been renewed by the expiration date on the wallet card. The licensee shall be assessed a late fee as specified in 645—subrule 5.3(3). To renew a late license, the licensee shall complete the renewal requirements and submit the late fee within the grace period.

31.10(8) Inactive license. A licensee who fails to renew the license by the end of the grace period has an inactive license. A licensee whose license is inactive continues to hold the privilege of licensure in Iowa, but may not practice mental health counseling or marital and family therapy in Iowa until the license is reactivated. A licensee who practices mental health counseling or marital and family therapy in the state of Iowa with an inactive license may be subject to disciplinary action by the board, injunctive action pursuant to Iowa Code section 147.83, criminal sanctions pursuant to Iowa Code section 147.86, and other available legal remedies.

[**ARC 9547B**, IAB 6/1/11, effective 7/6/11; **ARC 4390C**, IAB 4/10/19, effective 3/22/19]

645—31.11(272C) Initial licensing, reactivation, and license renewal for behavior analysts and assistant behavior analysts.

31.11(1) An initial license for a behavior analyst or assistant behavior analyst shall be issued with the same expiration date as the applicant's current certification issued by BACB.

31.11(2) The biennial license renewal period for a behavior analyst or assistant behavior analyst shall run concurrent with the licensee's BACB certification. Each license renewed shall be given the expiration date that is on the licensee's current BACB certification. The licensee is responsible for renewing the

license prior to its expiration. Failure of the licensee to receive notice from the board does not relieve the licensee of the responsibility for renewing the license.

31.11(3) A licensee seeking renewal shall:

a. Meet the continuing education requirements required by BACB to renew a certification.

b. Maintain current certification as a board-certified behavior analyst, board-certified behavior analyst-doctoral, or board-certified assistant behavior analyst issued by BACB.

c. Submit the completed renewal application and renewal fee before the license expiration date.

31.11(4) Upon receiving the information required by this rule and the required fee, board staff shall administratively issue a license. In the event the board receives adverse information on the renewal application, the board shall issue the renewal license but may refer the adverse information for further consideration or disciplinary investigation.

31.11(5) A person licensed as a behavior analyst or assistant behavior analyst shall keep the person's license certificate and wallet card displayed in a conspicuous public place at the primary site of practice.

31.11(6) Late renewal. The license shall become late when the license has not been renewed by the expiration date on the wallet card. The licensee shall be assessed a late fee as specified in 645—subrule 5.3(4). To renew a late license, the licensee shall complete the renewal requirements and submit the late fee within the grace period.

31.11(7) Inactive license. A licensee who fails to renew the license by the end of the grace period has an inactive license. A licensee whose license is inactive continues to hold the privilege of licensure in Iowa, but may not engage in the practice of applied behavior analysis for which a license is required in Iowa until the license is reactivated. A licensee who practices applied behavior analysis in a capacity that requires licensure in the state of Iowa with an inactive license may be subject to disciplinary action by the board, injunctive action pursuant to Iowa Code section 147.83, criminal sanctions pursuant to Iowa Code section 147.86, and other available legal remedies.

31.11(8) Reactivation. To apply for reactivation of an inactive license, a licensee shall submit a completed renewal application and proof of current certification and shall be assessed a reactivation fee as specified in 645—subrule 5.3(5).

[**ARC 4390C**, IAB 4/10/19, effective 3/22/19]

645—31.12(147) Licensee record keeping.

31.12(1) A licensee shall maintain sufficient, timely, and accurate documentation in client records.

31.12(2) For purposes of this rule, "client" means the individual, couple, family, or group to whom a licensee provides direct clinical services.

31.12(3) A licensee's records shall reflect the services provided, facilitate the delivery of services, and ensure continuity of services in the future.

31.12(4) Clinical services. A licensee who provides clinical services in any employment setting, including private practice, shall:

a. Store records in accordance with state and federal statutes and regulations governing record retention and with the guidelines of the licensee's employer or agency, if applicable. If no other legal provisions govern record retention, a licensee shall store all client records for a minimum of seven years after the date of the client's discharge or death, or, in the case of a minor, for three years after the client reaches the age of majority under state law or seven years after the date of the client's discharge or death, whichever is longer.

b. Maintain timely records that include subjective and objective data, an assessment, a treatment plan, and any revisions to the assessment or plan made during the course of treatment.

c. Provide the client with reasonable access to records concerning the client. A licensee who is concerned that a client's access to the client's records could cause serious misunderstanding or harm to the client shall provide assistance in interpreting the records and consultation with the client regarding the records. A licensee may limit a client's access to the client's records, or portions of the records, only in exceptional circumstances when there is compelling evidence that such access would cause serious harm to the client. Both the client's request for access and the licensee's rationale for withholding some or all of a record shall be documented in the client's records.

d. Take steps to protect the confidentiality of other individuals identified or discussed in any records to which a client is provided access.

31.12(5) Electronic record keeping. The requirements of this rule apply to electronic records as well as to records kept by any other means. When electronic records are kept, the licensee shall ensure that a duplicate hard-copy record or a backup, unalterable electronic record is maintained.

31.12(6) Correction of records.

a. *Hard-copy records.* Original notations shall be legible, written in ink, and contain no erasures or whiteouts. If incorrect information is placed in the original record, it must be crossed out with a single, nondeleting line and be initialed and dated by the licensee.

b. *Electronic records.* If a record is stored in an electronic format, the record may be amended with a signed addendum attached to the record.

31.12(7) Confidentiality and transfer of records. Marital and family therapists or mental health counselors shall preserve the confidentiality of client records in accordance with their respective rules of conduct and with federal and state law. Upon receipt of a written release or authorization signed by the client, the licensee shall furnish such therapy records, or copies of the records, as will be beneficial for the future treatment of that client. A fee may be charged for duplication of records, but a licensee may not refuse to transfer records for nonpayment of any fees. A written request may be required before transferring the record(s).

31.12(8) Retirement, death or discontinuance of practice.

a. If a licensee is retiring or discontinuing practice and is the owner of a practice, the licensee shall notify in writing all active clients and, upon knowledge and agreement of the clients, shall make reasonable arrangements with those clients to transfer client records, or copies of those records, to the succeeding licensee.

b. Upon a licensee's death:

(1) The licensee's employer or representative must ensure that all client records are transferred to another licensee or entity that is held to the same standards of confidentiality and agrees to act as custodian of the records.

(2) The licensee's employer or representative shall notify each active client that the client's records will be transferred to another licensee or entity that will retain custody of the records and that, at the client's written request, the records will be sent to the licensee or entity of the client's choice.

31.12(9) Nothing stated in this rule shall prohibit a licensee from conveying or transferring the licensee's client records to another licensed individual who is assuming a practice, provided that written notice is furnished to all clients.

645—31.13(147) Duplicate certificate or wallet card. Rescinded IAB 1/14/09, effective 2/18/09.

645—31.14(147) Reissued certificate or wallet card. Rescinded IAB 1/14/09, effective 2/18/09.

645—31.15(17A,147,272C) License denial. Rescinded IAB 1/14/09, effective 2/18/09.

645—31.16(17A,147,272C) License reactivation for mental health counselors and marital and family therapists. To apply for reactivation of an inactive license, a licensee shall:

31.16(1) Submit a reactivation application on a form provided by the board.

31.16(2) Pay the reactivation fee that is due as specified in 645—Chapter 5.

31.16(3) Provide verification of current competence to practice mental health counseling or marital and family therapy by satisfying one of the following criteria:

a. If the license has been on inactive status for five years or less, an applicant must provide the following:

(1) Verification of the license(s) from every jurisdiction in which the applicant is or has been licensed and is or has been practicing during the time period the Iowa license was inactive, sent directly from the jurisdiction(s) to the board office. Web-based verification may be substituted for verification from a jurisdiction's board office if the verification includes:

1. Licensee's name;
2. Date of initial licensure;
3. Current licensure status; and
4. Any disciplinary action taken against the license; and

(2) Verification of completion of 40 hours of continuing education obtained within the two years immediately preceding the application for reactivation.

b. If the license has been on inactive status for more than five years, an applicant must provide the following:

(1) Verification of the license(s) from every jurisdiction in which the applicant is or has been licensed and is or has been practicing during the time period the Iowa license was inactive, sent directly from the jurisdiction(s) to the board office. Web-based verification may be substituted for verification from a jurisdiction's board office if the verification includes:

1. Licensee's name;
2. Date of initial licensure;
3. Current licensure status; and
4. Any disciplinary action taken against the license; and

(2) Verification of completion of 80 hours of continuing education obtained within the two years immediately preceding the application for reactivation.

[**ARC 0777C**, IAB 6/12/13, effective 7/17/13; **ARC 4390C**, IAB 4/10/19, effective 3/22/19]

645—31.17(17A,147,272C) License reinstatement. A licensee whose license has been revoked, suspended, or voluntarily surrendered must apply for and receive reinstatement of the license in accordance with 645—11.31(272C) and must apply for and be granted reactivation of the license in accordance with 645—31.16(17A,147,272C) or subrule 31.11(8) prior to practicing mental health counseling, marital and family therapy, or applied behavior analysis in this state.

[**ARC 4390C**, IAB 4/10/19, effective 3/22/19]

645—31.18(154D) Marital and family therapy and mental health counselor services subject to regulation. Marital and family therapy and mental health counselor services provided to an individual in this state through telephonic, electronic or other means, regardless of the location of the marital and family therapy and mental health counselor, shall constitute the practice of marital and family therapy and mental health counseling and shall be subject to regulation in Iowa.

These rules are intended to implement Iowa Code chapters 17A, 147, 154D and 272C.

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◊ Two or more ARCs

1 February 18, 2009, effective date of amendments to 645—31.4(154D) to 645—31.8(154D), **ARC 7476B**, Items 5 to 9, delayed 70 days by the Administrative Rules Review Committee at its meeting held February 6, 2009.

CHAPTER 33
DISCIPLINE FOR MARITAL AND FAMILY THERAPISTS, MENTAL HEALTH COUNSELORS, BEHAVIOR ANALYSTS, AND ASSISTANT BEHAVIOR ANALYSTS

[Prior to 1/30/02, see 645—Chapter 31]

645—33.1(154D) Definitions.

"Board" means the board of behavioral science.

"Discipline" means any sanction the board may impose upon licensees.

"Licensee" means a person licensed to practice as a marital and family therapist, mental health counselor, behavior analyst, or assistant behavior analyst in Iowa.

[**ARC 4390C**, IAB 4/10/19, effective 3/22/19]

645—33.2(154D,272C) Grounds for discipline. The board may impose any of the disciplinary sanctions provided in rule 645—33.3(147,272C) when the board determines that the licensee is guilty of any of the following acts or offenses:

33.2(1) Failure to comply with the national association's code of ethics.

a. *Marital and family therapists.* Failure to comply with the current American Association for Marriage and Family Therapy (AAMFT) Code of Ethics, which is hereby adopted by reference. Copies of the Code of Ethics may be obtained from the AAMFT's website.

b. *Mental health counselors.* Failure to comply with the current Code of Ethics of the American Counseling Association (ACA), which is hereby adopted by reference. Copies of the Code of Ethics may be obtained from the ACA website.

c. *Behavior analysts and assistant behavior analysts.* Failure to comply with the current Behavior Analyst Certification Board (BACB) Professional and Ethical Compliance Code for Behavior Analysts, which is hereby adopted by reference. Copies of the Professional and Ethical Compliance Code may be obtained from the BACB website.

33.2(2) Fraud in procuring a license. Fraud in procuring a license includes, but is not limited to, an intentional perversion of the truth in making application for a license to practice in this state, which includes the following:

a. False representations of a material fact, whether by word or by conduct, by false or misleading allegations, or by concealment of that which should have been disclosed when making application for a license in this state, or

b. Attempting to file or filing with the board or the department of public health any false or forged diploma or certificate or affidavit or identification or qualification in making an application for a license in this state.

33.2(3) Professional incompetency. Professional incompetency includes, but is not limited to:

a. A substantial lack of knowledge or ability to discharge professional obligations within the scope of practice.

b. A substantial deviation from the standards of learning or skill ordinarily possessed and applied by other practitioners in the state of Iowa acting in the same or similar circumstances.

c. A failure to exercise the degree of care which is ordinarily exercised by the average practitioner acting in the same or similar circumstances.

d. Failure to conform to the minimal standard of acceptable and prevailing practice of the licensed marital and family therapist or mental health counselor in this state.

e. Mental or physical inability reasonably related to and adversely affecting the licensee's ability to practice in a safe and competent manner.

f. Being adjudged mentally incompetent by a court of competent jurisdiction.

33.2(4) Knowingly making misleading, deceptive, untrue or fraudulent representations in the practice of the profession or engaging in unethical conduct or practice harmful or detrimental to the public. Proof of actual injury need not be established.

33.2(5) Practice outside the scope of the profession.

33.2(6) Use of untruthful or improbable statements in advertisements. Use of untruthful or improbable statements in advertisements includes, but is not limited to, an action by a licensee in

making information or intention known to the public which is false, deceptive, misleading or promoted through fraud or misrepresentation.

33.2(7) Habitual intoxication or addiction to the use of drugs.

a. The inability of a licensee to practice with reasonable skill and safety by reason of the excessive use of alcohol on a continuing basis.

b. The excessive use of drugs which may impair a licensee's ability to practice with reasonable skill or safety.

33.2(8) Obtaining, possessing, attempting to obtain or possess, or administering controlled substances without lawful authority.

33.2(9) Falsification of client records.

33.2(10) Acceptance of any fee by fraud or misrepresentation.

33.2(11) Negligence by the licensee in the practice of the profession. Negligence by the licensee in the practice of the profession includes a failure to exercise due care including negligent delegation of duties or supervision of employees or other individuals, whether or not injury results; or any conduct, practice or conditions which impair the ability to safely and skillfully practice the profession.

33.2(12) Conviction of a crime related to the profession or occupation of the licensee or the conviction of any crime that would affect the licensee's ability to practice within the profession, regardless of whether the judgment of conviction or sentence was deferred. A copy of the record of conviction or plea of guilty shall be conclusive evidence.

33.2(13) Violation of a regulation or law of this state, another state, or the United States, which relates to the practice of the profession.

33.2(14) Revocation, suspension, or other disciplinary action taken by a licensing authority or professional certifying entity of this state, another state, territory, or country; or failure by the licensee to report in writing to the board revocation, suspension, or other disciplinary action taken by a licensing authority or certifying entity within 30 days of the final action. A stay by an appellate court shall not negate this requirement; however, if such disciplinary action is overturned or reversed by a court of last resort, the report shall be expunged from the records of the board.

33.2(15) Failure of a licensee or an applicant for licensure in this state to report any voluntary agreements restricting the practice of the profession in another state, district, territory or country.

33.2(16) Failure to notify the board of a criminal conviction within 30 days of the action, regardless of the jurisdiction where it occurred.

33.2(17) Failure to notify the board within 30 days after the occurrence of any judgment or settlement of a malpractice claim or action.

33.2(18) Engaging in any conduct that subverts or attempts to subvert a board investigation.

33.2(19) Failure to comply with a subpoena issued by the board, or to otherwise fail to cooperate with an investigation of the board.

33.2(20) Failure to comply with the terms of a board order or the terms of a settlement agreement or consent order.

33.2(21) Failure to pay costs assessed in any disciplinary action.

33.2(22) Submission of a false report of continuing education or failure to submit the biennial report of continuing education.

33.2(23) Failure to report another licensee to the board for any violations listed in these rules, pursuant to Iowa Code section 272C.9.

33.2(24) Knowingly aiding, assisting, procuring, or advising a person to unlawfully practice as a marital and family therapist, mental health counselor, behavior analyst, or assistant behavior analyst.

33.2(25) Failure to report a change of name or address within 30 days after it occurs.

33.2(26) Representing oneself as a licensed marital and family therapist, mental health counselor, behavior analyst, or assistant behavior analyst when one's license has been suspended or revoked, or when one's license is on inactive status.

33.2(27) Permitting another person to use the licensee's license for any purpose.

33.2(28) Permitting an unlicensed employee or person under the licensee's control to perform activities requiring a license.

33.2(29) Unethical conduct. In accordance with Iowa Code section 147.55(3), behavior (i.e., acts, knowledge, and practices) which constitutes unethical conduct may include, but need not be limited to, the following:

a. Verbally or physically abusing a patient, client or coworker.

b. Improper sexual contact with, or making suggestive, lewd, lascivious or improper remarks or advances to a patient, client or coworker.

c. Betrayal of a professional confidence.

d. Engaging in a professional conflict of interest.

33.2(30) *Sexual relationships.*

a. Current clients. A licensee shall not engage in sexual activities or sexual contact with a client, regardless of whether such contact is consensual or nonconsensual.

b. Former clients. A licensee shall not engage in sexual activities or sexual contact with a former client within the five years following termination of the client relationship. A licensee shall not engage in sexual activities or sexual contact with a former client, regardless of the length of time elapsed since termination of the client relationship, if the client has a history of physical, emotional, or sexual abuse or if the client has ever been diagnosed with any form of psychosis or personality disorder or if the client is likely to remain in need of therapy due to the intensity or chronicity of a problem.

c. A licensee shall not engage in sexual activities or sexual contact with a client's or former client's spouse or significant other.

d. A licensee shall not engage in sexual activities or sexual contact with a client's or former client's relative within the second degree of consanguinity (client's parent, grandparent, child, grandchild, or sibling) when there is a risk of exploitation or potential harm to a client or former client.

e. A licensee shall not provide clinical services to an individual with whom the licensee has had prior sexual contact.

33.2(31) *Physical contact.* A licensee shall not engage in physical contact with a client when there is a possibility of psychological harm to the client as a result of the contact. A licensee who engages in appropriate physical contact with a client is responsible for setting clear, appropriate, and culturally and age-sensitive boundaries which govern such contact.

33.2(32) Failure to comply with universal precautions for preventing transmission of infectious diseases as issued by the Centers for Disease Control of the United States Department of Health and Human Services.

33.2(33) Violation of the terms of an initial agreement with the impaired practitioner review committee or violation of the terms of an impaired practitioner recovery contract with the impaired practitioner review committee.

[**ARC 9547B**, IAB 6/1/11, effective 7/6/11; **ARC 0777C**, IAB 6/12/13, effective 7/17/13; **ARC 4390C**, IAB 4/10/19, effective 3/22/19]

645—33.3(147,272C) Method of discipline. The board has the authority to impose the following disciplinary sanctions:

1. Revocation of license.
2. Suspension of license until further order of the board or for a specific period.
3. Prohibit permanently, until further order of the board, or for a specific period the engaging in specified procedures, methods, or acts.
4. Probation.
5. Require additional education or training.
6. Require a reexamination.
7. Order a physical or mental evaluation, or order alcohol and drug screening within a time specified by the board.
8. Impose civil penalties not to exceed $1000.
9. Issue a citation and warning.
10. Such other sanctions allowed by law as may be appropriate.

645—33.4(272C) Discretion of board. The following factors may be considered by the board in determining the nature and severity of the disciplinary sanction to be imposed:

1. The relative serious nature of the violation as it relates to ensuring a high standard of professional care to the citizens of this state;
2. The facts of the particular violation;
3. Any extenuating facts or other countervailing considerations;
4. The number of prior violations or complaints;
5. The seriousness of prior violations or complaints;
6. Whether remedial action has been taken; and
7. Such other factors as may reflect upon the competency, ethical standards, and professional conduct of the licensee.

645—33.5(154D) Order for mental, physical, or clinical competency examination or alcohol or drug screening. Rescinded IAB 1/14/09, effective 2/18/09.

These rules are intended to implement Iowa Code chapters 17A, 147, 154D and 272C.

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[Filed Emergency ARC 4390C, IAB 4/10/19, effective 3/22/19]

PHARMACY BOARD[657]

[Prior to 2/10/88, see Pharmacy Examiners, Board of [620], renamed Pharmacy Examiners Board[657] under the "umbrella" of Public Health Department by 1986 Iowa Acts, ch 1245; renamed by 2007 Iowa Acts, Senate File 74]

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CHAPTER 37
IOWA PRESCRIPTION MONITORING PROGRAM

657—37.1(124) Purpose and scope. These rules establish a prescription monitoring program (PMP) that compiles a central database of reportable prescriptions dispensed to patients in Iowa. An authorized health care practitioner shall access PMP information when mandated by the practitioner's licensing authority regarding the practitioner's patient to assist in determining appropriate treatment options and to improve the quality of patient care. The PMP is intended to provide a practitioner with a resource for information regarding a patient's use of controlled substances and to serve as a tool to assess a prescriber's prescribing practices. This database will assist the practitioner in identifying any potential diversion, misuse, or abuse of controlled substances without impeding the appropriate medical use of controlled substances.
[**ARC 4397C**, IAB 4/10/19, effective 5/15/19]

657—37.2(124) Definitions. For the purposes of this chapter, the following definitions shall apply.

"Administer" means to provide or apply a controlled substance to a patient for immediate use within the prescribing practitioner's practice location. Administration does not include dispensing.

"Board" means the Iowa board of pharmacy.

"Controlled substance" means a drug in Schedules II through IV set forth in Iowa Code chapter 124, division II.

"Council" means the PMP advisory council established pursuant to Iowa Code section 124.555 to provide oversight and to co-manage PMP activities with the board.

"CSA registration" means registration with the board under the Iowa uniform controlled substances Act pursuant to 657—Chapter 10.

"DEA number" means the registration number issued to an individual or pharmacy by the U.S. Department of Justice, Drug Enforcement Administration (DEA), authorizing the individual or pharmacy to engage in the prescribing, dispensing, distributing, or procuring of a controlled substance.

"Dispense" means to provide a controlled substance to a patient for self-use outside of the prescribing practitioner's practice location. Dispensing does not include administration.

"Dispenser" means a pharmacy or prescriber, regardless of location, who delivers to the ultimate user a substance required to be reported to the PMP. "Dispenser" does not include a person exempt from reporting pursuant to subrule 37.7(2).

"First responder" means an emergency medical care provider, a registered nurse staffing an authorized service program under Iowa Code section 147A.12, a physician assistant staffing an authorized service program under Iowa Code section 147A.13, a firefighter, or a peace officer as defined in Iowa Code section 801.4, who is trained and authorized to administer an opioid antagonist.

"Health care facility" means a residential care facility, a nursing facility, an intermediate care facility for persons with mental illness, or an intermediate care facility for persons with an intellectual disability.

"Health care professional" means a person who, by education, training, certification, or licensure, is qualified to provide and is engaged in providing health care to patients. "Health care professional" does not include clerical or administrative staff. A health care professional shall be licensed, registered, certified, or otherwise credentialed in a manner that permits verification of the health care professional's credentials.

"Health care system" means an organization that includes at least one hospital or at least one group of practitioners that provides comprehensive care that are connected with each other through common ownership or management.

"HIPAA" means the Health Insurance Portability and Accountability Act.

"Law enforcement" means an entity or agency with jurisdiction to investigate or prosecute violations of criminal law. "Law enforcement" includes, but is not limited to, such agencies as police departments, United States attorneys, the DEA, county attorneys, and the Medicaid fraud control unit.

"Licensing authority" means an agency that licenses or registers health care professionals and has jurisdiction to enforce governing laws over those individuals who are licensed or registered. "Licensing authority" includes, but is not limited to, professional licensing boards and the DEA.

"NarxCare" means an analytics tool and care management platform that helps practitioners analyze real-time data from the PMP. The platform analyzes patient data and history to provide a patient risk score and usage patterns to help practitioners identify potential risk factors.

"NDC number" means the universal product identifier used in the United States to identify a specific human drug.

"Opioid antagonist" means a drug that binds to opioid receptors and blocks or inhibits the effects of opioids acting on those receptors, including but not limited to naloxone hydrochloride or any other similarly acting drug approved by the United States Food and Drug Administration.

"PMP administrator" means staff persons designated to manage and administer the PMP under the direction and oversight of the board and the council.

"Practitioner" means a prescriber or a pharmacist.

"Practitioner's delegate" means a health care professional who is under the supervision of a PMP-registered practitioner and who is authorized by the practitioner to access PMP information on the practitioner's behalf.

"Prescriber" means an individual with an active CSA registration who has the authority to prescribe controlled substances. For the purposes of this chapter, "prescriber" does not include a licensed veterinarian.

"Prescription monitoring program" or *"PMP"* means the program established pursuant to these rules for the collection and maintenance of PMP information and for the provision of PMP information to authorized individuals.

"Reportable prescription" means the record of a controlled substance administered or dispensed by a practitioner and the record of an opioid antagonist dispensed by a practitioner or administered by a first responder. "Reportable prescription" shall not include records identified in subrule 37.7(1). "Reportable prescription" shall include, but not be limited to:

1. The dispensing of a controlled substance to an emergency department patient;
2. The administration of a controlled substance to a patient at the discretion of the treating practitioner;
3. The administration or dispensing of an opioid antagonist to an emergency department patient;
4. The dispensing of a controlled substance sample; and
5. The dispensing of a controlled substance or opioid antagonist to a patient upon discharge from a hospital or care facility.

[**ARC 4397C**, IAB 4/10/19, effective 5/15/19]

657—37.3(124) Registration. Registration for the PMP pursuant to this rule shall be via the Iowa PMP AWARxE website at iowa.pmpaware.net.

37.3(1) *Prescribers.* A prescriber shall register for the PMP at the same time the prescriber registers or renews a CSA registration pursuant to 657—Chapter 10. A licensed veterinarian with an active CSA registration may register for the PMP. Registration for the PMP shall also require the prescriber's DEA number.

37.3(2) *Pharmacists.* A pharmacist who is involved in patient care shall register for the PMP at the same time the pharmacist becomes licensed or renews a license pursuant to 657—Chapter 2.

37.3(3) *Practitioner's delegates.* A practitioner may authorize an adequate number of health care professionals who actively work with the practitioner to act as the practitioner's delegates for the purpose of requesting PMP information. A practitioner's delegate shall be licensed, registered, certified, or otherwise credentialed as a health care professional in a manner that permits verification of the health care professional's credentials. The practitioner shall be responsible for the PMP information access of the practitioner's delegates.

37.3(4) *Law enforcement officials.* A law enforcement official may register for the PMP to access information by order, subpoena, or other means of legal compulsion relating to a specific investigation and supported by a determination of probable cause.

37.3(5) *Licensing authority.* A licensing authority official may register for the PMP to access information by order, subpoena, or other means of legal compulsion relating to a specific investigation and supported by a determination of probable cause.

37.3(6) *Medical examiners and medical examiner investigators.* A medical examiner or a medical examiner investigator may register for the PMP to access information when the information relates to an investigation being conducted by the examiner or investigator.
[**ARC 4397C**, IAB 4/10/19, effective 5/15/19]

657—37.4 and **37.5** Reserved.

657—37.6(124) Security of PMP credentials. Each user registered to access PMP information shall securely maintain and use the login and password and any other secure access credentials assigned to the individual user. Except in an emergency when a patient would be placed in greater jeopardy by restricting PMP information access to the user, a registered user shall not share the user's secure access credentials.
[**ARC 4397C**, IAB 4/10/19, effective 5/15/19]

657—37.7(124) PMP reporting—exemptions.

37.7(1) *Exempted dispensing or administration.* The dispensing or administration of a controlled substance as described in this subrule shall not be considered a reportable prescription. A pharmacy engaged in the distribution of controlled substances solely pursuant to one or more of the practices identified in this subrule shall notify the PMP administrator of the exempted practice, and the pharmacy shall not be required to report to the PMP.

a. The dispensing by a licensed hospital pharmacy for the purposes of inpatient hospital care.

b. The dispensing by a licensed pharmacy for a patient residing in a health care facility or inpatient hospice facility.

c. The administration by a prescriber of a controlled substance for the purposes of outpatient procedures and treatment.

37.7(2) *Exempted practitioners.* The following entities or individuals shall not be required to report to the PMP and shall not be required to notify the PMP administrator of their exempted status:

a. A licensed pharmacy that does not have a CSA registration and does not dispense controlled substances in or into Iowa.

b. A licensed veterinarian who administers or dispenses a controlled substance in the normal course of the veterinarian's professional practice.

c. A DEA-registered narcotic treatment program which is subject to the record-keeping provisions of 21 CFR Section 1304.24.
[**ARC 4397C**, IAB 4/10/19, effective 5/15/19]

657—37.8(124) PMP reporting—dispensing prescribers. Each dispensing prescriber, unless exempt pursuant to rule 657—37.7(124), shall submit to the PMP a record of each reportable prescription dispensed during a reporting period pursuant to subrule 37.12(2). For purposes of prescriber dispensing, the prescriber shall also be identified as the dispenser or pharmacy.
[**ARC 4397C**, IAB 4/10/19, effective 5/15/19]

657—37.9(124) PMP reporting—pharmacies. Each pharmacy, unless exempt pursuant to rule 657—37.7(124), shall submit to the PMP either a record of each reportable prescription dispensed or administered during a reporting period pursuant to subrule 37.12(2) or a zero report pursuant to subrule 37.12(4), as appropriate.
[**ARC 4397C**, IAB 4/10/19, effective 5/15/19]

657—37.10 and **37.11** Reserved.

657—37.12(124) Reporting requirements.

37.12(1) *Data elements.* The information submitted to the PMP for each reportable prescription shall be accurate and shall include, at a minimum, the following data elements:

a. Dispenser DEA number.
b. Date the prescription is dispensed or administered.
c. Prescription number or unique identification number.
d. NDC number of the drug dispensed or administered.
e. Quantity of the drug dispensed or administered.
f. Number of days of drug therapy provided by the drug dispensed or administered.
g. Patient legal first and last names.
h. Patient address including street address, city, state, and ZIP code.
i. Patient phone number.
j. Patient date of birth.
k. Patient gender.
l. Prescriber name and DEA number.
m. Date the prescription was issued by the prescriber.
n. Method of payment.
o. Form of transmission of prescription origin.
p. Refill number.
q. Number of refills authorized.
r. Indication as to whether the prescription is new or a refill.

37.12(2) *Reporting periods.* A record of each reportable administration or prescription dispensed shall be submitted by each dispenser no later than the next business day following administration or dispensing.

37.12(3) *Transmission.* Prescription dispensing and administration information shall be transmitted via the PMP's current version of data upload or electronic submission.

37.12(4) *Zero reports.* If a pharmacy did not dispense or administer any reportable prescriptions during a reporting period, the dispenser shall submit a zero report no later than the next business day.

[**ARC 4397C**, IAB 4/10/19, effective 5/15/19]

657—37.13(124) Opioid antagonist administration by first responders.

37.13(1) The administration of an opioid antagonist by a first responder shall be reported to the PMP, unless such administration was reported to the Iowa department of public health bureau of emergency and trauma services.

37.13(2) The reporting of the administration of an opioid antagonist by a first responder shall include the following data elements:

a. Patient first and last names.
b. First and last names of the individual who administered the opioid antagonist.
c. Date of administration.
d. Quantity of the opioid antagonist administered.

[**ARC 4397C**, IAB 4/10/19, effective 5/15/19]

657—37.14 and **37.15** Reserved.

657—37.16(124) Access to PMP information. All information contained in the PMP is confidential and shall only be accessed as provided in this rule. All requests for PMP information must comply with the format specified by the board for the particular type of request. Once information is accessed, further dissemination or use of that information is governed by applicable federal and state laws governing the person who accessed the information. The board may charge a fee to recover the actual costs associated with responding to any request by a person other than a practitioner or a practitioner's delegate. Any fees or costs assessed by the board shall be considered repayment receipts as defined in Iowa Code section 8.2.

37.16(1) *Prescribers.* A prescriber may access a patient's prescription history report; the prescriber's activity report; proactive alerts or system user notes, such as peer-to-peer communication; and NarxCare reports.

37.16(2) *Pharmacists.* A pharmacist may access a patient's prescription history report; proactive alerts or system user notes, such as peer-to-peer communication; and NarxCare reports.

37.16(3) *Practitioner's delegates.* A practitioner's delegate may access a patient's prescription history report; proactive alerts or system user notes, such as peer-to-peer communication; and NarxCare reports.

37.16(4) *Licensing authority officials.*

a. A licensing authority with jurisdiction over a practitioner may obtain the following information, if the request is accompanied by a subpoena compelling disclosure of such information for a specific investigation into the prescribing or dispensing practices of the licensee: prescription history reports; proactive alerts or system user notes, such as peer-to-peer communication; PMP access logs and login records; and NarxCare reports.

b. A licensing authority with jurisdiction over a health care professional may obtain the following information, if the request is accompanied by a subpoena compelling disclosure of such information for a specific investigation into the licensee's misuse of controlled substances: the licensee's prescription history report.

37.16(5) *Law enforcement officials.* A law enforcement official may obtain a patient's prescription history report and the prescribing or dispensing practices of a prescriber if the request is accompanied by a subpoena or other means of legal compulsion compelling disclosure of such information for use in a specific investigation.

37.16(6) *Medical examiners and medical examiner investigators.* A medical examiner or medical examiner investigator may obtain a decedent's prescription history report for use in a specific investigation.

37.16(7) *Patients.* A patient or the patient's agent may request the patient's own prescription history report by using the board's patient request form. The request can be personally delivered to the board office where the patient will be required to present current government-issued photo identification at the time of the delivery of the request. A patient who is unable to personally deliver the request to the board office may submit a notarized request, along with a certified copy of the patient's government-issued photo identification, via mail or commercial delivery service. The following agents may submit a request on behalf of a patient: an individual with a medical power of attorney for the patient, a patient's attorney, or an executor of the patient's estate. In addition to the patient's information, the patient's agent shall be identified by name, current address, and telephone number. In lieu of the patient's signature and identification, the patient's agent shall sign the request and the government-issued photo identification shall identify the patient's agent. The patient's agent shall include a copy of the legal document that establishes the agency relationship with the patient.

[**ARC 4397C**, IAB 4/10/19, effective 5/15/19]

657—37.17(124) Integrated systems. A practitioner or a health care system may integrate its electronic health record system or a pharmacy may integrate its automated data processing system with the PMP using an application programming interface. Use of an integrated system shall comply with all of the following:

37.17(1) The integrated system shall log each user's access to PMP information. Access logs shall be retained by the practitioner, health care system, or pharmacy for a minimum of four years from the date of access and shall be provided to the board upon request.

37.17(2) If the user identified in access logs is not the practitioner, the integrated system shall clearly identify on which practitioner's behalf the user was accessing PMP information. A practitioner's delegate using an integrated system is required to maintain active PMP registration.

37.17(3) The integrated system shall maintain appropriate administrative, technical, and physical security measures to safeguard against unauthorized access, disclosure, or theft of PMP information and shall meet all HIPAA requirements for safeguarding protected health information.

37.17(4) The practitioner, health care system, or pharmacy shall notify the PMP administrator of any breach in the electronic health record system that may have included PMP information within 72 hours of making the determination that a breach occurred.

37.17(5) An integrated system shall comply with all requirements in subchapter VI of Iowa Code chapter 124 and all requirements of this chapter.
[**ARC 4397C**, IAB 4/10/19, effective 5/15/19]

657—37.18(124) PMP administrator access.

37.18(1) *PMP staff.* The board may designate PMP administrators who may access any PMP information needed to perform the functions of the job.

37.18(2) *Statistical data.* The PMP administrator or designee may provide summary, statistical, or aggregate data to public or private entities for statistical, public research, public policy, or educational purposes. The board may charge a fee to recover the actual costs associated with responding to a request for PMP data pursuant to this subrule. Any fees or costs assessed by the board shall be considered repayment receipts as defined in Iowa Code section 8.2.
[**ARC 4397C**, IAB 4/10/19, effective 5/15/19]

657—37.19(124) Prescriber activity reports. The PMP administrator shall, at least annually, electronically issue to each prescriber who prescribed a controlled substance that was reported to the program as dispensed in or into this state during the preceding reporting period an activity report which shall include, at a minimum, the following:

1. A summary of the prescriber's history of prescribing controlled substances,
2. A comparison of the prescriber's history of prescribing controlled substances with the history of other prescribers of the same profession or specialty,
3. The prescriber's history of program use,
4. General patient risk factors, and
5. Educational updates.

[**ARC 4397C**, IAB 4/10/19, effective 5/15/19]

657—37.20(124) Proactive notifications. The PMP administrator shall provide notification to a practitioner when a patient may be practitioner shopping or at risk of abusing or misusing a controlled substance based on criteria and thresholds determined by the board and the advisory council. A proactive notification pursuant to this rule will be initiated when a patient obtains prescriptions for controlled substances from a minimum number of prescribing practitioners and from a minimum number of pharmacies within a maximum number of days which exceed the thresholds established by the board and advisory council. The notification will suggest review of the patient's prescription history.
[**ARC 4397C**, IAB 4/10/19, effective 5/15/19]

657—37.21(124) Record retention. The PMP shall retain all reported prescriptions, all records of access to or query of PMP information, and all information distributed to practitioners in proactive notifications for a minimum of four years from the date of the record.
[**ARC 4397C**, IAB 4/10/19, effective 5/15/19]

657—37.22(124) Information errors. Any person who believes that PMP information is erroneous shall notify the pharmacy or dispensing practitioner. Upon notification of a potential error in PMP information, the pharmacy or dispensing practitioner shall promptly correct erroneous information in the record.
[**ARC 4397C**, IAB 4/10/19, effective 5/15/19]

657—37.23(124) Discipline. Any licensee who fails to comply with the provisions of the law or these rules is subject to disciplinary action by the board and may be subject to criminal prosecution.
[**ARC 4397C**, IAB 4/10/19, effective 5/15/19]

These rules are intended to implement Iowa Code sections 124.550 to 124.558.

[Filed ARC 7903B (Notice ARC 7676B, IAB 4/8/09), IAB 7/1/09, effective 8/5/09]
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[Filed ARC 4397C (Notice ARC 4205C, IAB 1/2/19), IAB 4/10/19, effective 5/15/19]

CHAPTER 39
EXPANDED PRACTICE STANDARDS

657—39.1(155A) Purpose and scope. The purpose of this chapter is to establish the minimum standards for the programs and activities identified in this chapter. These rules shall apply to all licensed pharmacists, other registered pharmacy personnel, and all pharmacies, including owners, engaged in the state of Iowa in the programs and activities identified in this chapter. These rules are in addition to rules of the board relating to the practice of pharmacy unless otherwise indicated by rule.
[**ARC 3858C**, IAB 6/20/18, effective 7/25/18]

657—39.2 and **39.3** Reserved.

657—39.4(155A) Pharmaceutical care. Pharmaceutical care is a comprehensive, patient-centered, outcomes-oriented pharmacy practice in which the pharmacist accepts responsibility for assisting the prescriber and the patient in optimizing the patient's drug therapy plan and works to promote health, to prevent disease, and to optimize drug therapy. Pharmaceutical care does not include the prescribing of drugs without the consent of the prescriber.

39.4(1) *Drug therapy problems.* In providing pharmaceutical care, the pharmacist shall strive to identify, resolve, and prevent drug therapy problems.

39.4(2) *Drug therapy plan.* In providing pharmaceutical care, the pharmacist shall access and evaluate patient-specific information, identify drug therapy problems, and utilize that information in a documented plan of therapy that assists the patient or the patient's caregiver in achieving optimal drug therapy. In concert with the patient, the patient's prescribing practitioner, and the patient's other health care providers, the pharmacist shall assess, monitor, and suggest modifications of the drug therapy plan as appropriate.
[**ARC 3858C**, IAB 6/20/18, effective 7/25/18]

657—39.5 Reserved.

657—39.6(155A) Statewide protocols. A pharmacist may, pursuant to statewide protocols developed by the board in consultation with the department of public health and available on the board's website at pharmacy.iowa.gov, order and dispense medications pursuant to rules 657—39.8(155A), 657—39.9(155A), and 657—39.11(155A).
[**ARC 4270C**, IAB 1/30/19, effective 3/6/19; see Delay note at end of chapter; **ARC 4387C**, IAB 4/10/19, effective 4/5/19]

657—39.7(135,147A) Opioid antagonist dispensing by pharmacist—standing order. An authorized pharmacist may dispense an opioid antagonist pursuant to a standing order established by the department, which standing order can be found via the board's website, or pursuant to a standing order authorized by an individual licensed health care professional in compliance with the requirements of this rule. An authorized pharmacist may only delegate the dispensing of an opioid antagonist to an authorized pharmacist-intern under the direct supervision of an authorized pharmacist. Nothing in this rule prohibits a prescriber or facility from establishing and implementing standing orders or protocols under the authority granted to the prescriber or facility.

39.7(1) *Definitions.* For the purposes of this rule, the following definitions shall apply:

"Authorized pharmacist" means an Iowa-licensed pharmacist who has completed the training requirements of this rule. "Authorized pharmacist" also includes an Iowa-registered pharmacist-intern who has completed the training requirements of this rule and is working under the direct supervision of an authorized Iowa-licensed pharmacist.

"Department" means the Iowa department of public health.

"First responder" means an emergency medical care provider, a registered nurse staffing an authorized service program under Iowa Code section 147A.12, a physician assistant staffing an authorized service program under Iowa Code section 147A.13, a firefighter, or a peace officer as defined in Iowa Code section 801.4 who is trained and authorized to administer an opioid antagonist.

"Licensed health care professional" means a person licensed under Iowa Code chapter 148 to practice medicine and surgery or osteopathic medicine and surgery, an advanced registered nurse practitioner licensed under Iowa Code chapter 152 or 152E and registered with the board of nursing, or a physician assistant licensed to practice under the supervision of a physician as authorized in Iowa Code chapters 147 and 148C.

"Opioid antagonist" means the same as defined in Iowa Code section 147A.1.

"Opioid-related overdose" means the same as defined in Iowa Code section 147A.1.

"Person in a position to assist" means a family member, friend, caregiver, health care provider, employee of a substance abuse treatment facility, or other person who may be in a position to render aid to a person at risk of experiencing an opioid-related overdose.

"Recipient" means an individual at risk of an opioid-related overdose or a person in a position to assist an individual at risk of an opioid-related overdose.

"Standing order" means a preauthorized medication order with specific instructions from the licensed health care professional to dispense a medication under clearly defined circumstances.

39.7(2) *Authorized pharmacist training.* An authorized pharmacist shall document successful completion of an ACPE-approved continuing education program of at least one-hour duration related to opioid antagonist utilization prior to dispensing opioid antagonists pursuant to a standing order.

39.7(3) *Additional supply.* Notwithstanding a standing order to the contrary, an authorized pharmacist shall only dispense an opioid antagonist after completing an eligibility assessment and providing training and education to the recipient.

39.7(4) *Assessment.* An authorized pharmacist shall assess an individual for eligibility to receive an opioid antagonist pursuant to a standing order. In addition to the criteria identified in a standing order, an authorized pharmacist shall also take into consideration the following criteria to determine the eligibility of the recipient to receive and possess an opioid antagonist:

a. The person at risk of an opioid-related overdose for which the opioid antagonist is intended to be administered has no known sensitivity or allergy to naloxone, unless the person at risk is not known to the recipient, including but not limited to a first responder or member of law enforcement.

b. The recipient is oriented to person, place, and time and able to understand and learn the essential components of opioid-related overdose, appropriate response, and opioid antagonist administration.

39.7(5) *Recipient training and education.* Upon assessment and determination that an individual is eligible to receive and possess an opioid antagonist pursuant to a standing order, an authorized pharmacist shall, prior to dispensing an opioid antagonist pursuant to a standing order, provide training and education to the recipient including, but not limited to, the information identified in this subrule. An authorized pharmacist shall require the recipient to attest that, if the product will be accessible to any other individual for administration, the recipient will make available to such individual all received training and education materials. An authorized pharmacist may provide to the recipient written materials that include, but may not be limited to, the information identified in this subrule, but the written materials shall not be in lieu of direct pharmacist consultation with the recipient.

a. The signs and symptoms of opioid-related overdose as described in the standing order.

b. The importance of calling 911 as soon as possible and the potential need for rescue breathing.

c. The appropriate use and directions for administration of the opioid antagonist to be dispensed pursuant to the standing order.

d. Adverse reactions of the opioid antagonist as well as reactions resulting from opioid withdrawal following administration.

e. The proper storage conditions, including temperature excursions, of the opioid antagonist being dispensed.

f. The expiration date of the opioid antagonist being dispensed and the appropriate disposal of the opioid antagonist upon expiration.

g. The prohibition of the recipient from further distributing the opioid antagonist to another individual, unless that individual has received appropriate training and education.

h. Information about substance abuse or behavioral health treatment programs.

39.7(6) *Labeling.* Upon the determination that a recipient is eligible to receive and possess an opioid antagonist, an authorized pharmacist shall label the product pursuant to rule 657—6.10(126,155A) and 657—subrule 8.19(8). An authorized pharmacist shall ensure that the labeling does not render the expiration date of the product illegible. The medication shall be dispensed in the name of the eligible recipient.

39.7(7) *Reporting.* A copy of the assessment form shall be submitted to the department as provided on the assessment form within seven days of the dispensing of the opioid antagonist or within seven days of a denial of eligibility.

39.7(8) *Records.* An authorized pharmacist shall create and maintain an original record of each individual assessment on forms provided by the board, regardless of the eligibility determination following assessment, and dispensing of opioid antagonists pursuant to a standing order. These records shall be available for inspection and copying by the board or its authorized agent for at least two years.
[**ARC 3858C**, IAB 6/20/18, effective 7/25/18]

657—39.8(155A) Statewide protocol—naloxone. An authorized pharmacist may order and dispense naloxone to patients 18 years and older pursuant to a statewide protocol developed pursuant to rule 657—39.6(155A) and in compliance with this rule. An authorized pharmacist may only delegate the dispensing of naloxone to an authorized pharmacist-intern under the direct supervision of an authorized pharmacist.

39.8(1) *Definitions.* For the purposes of this rule, the following definitions shall apply:

"ACPE" means the Accreditation Council for Pharmacy Education.

"Authorized pharmacist" means an Iowa-licensed pharmacist who has completed the training requirements of this rule. "Authorized pharmacist" also includes an Iowa-registered pharmacist-intern who has completed the training requirements of this rule and is working under the direct supervision of an authorized pharmacist.

"Authorized pharmacist-intern" means an Iowa-registered pharmacist-intern who has completed the training requirements for an authorized pharmacist pursuant to this rule.

"Board" means the Iowa board of pharmacy.

"Patient" means an individual consulting with a pharmacist for drug therapy and may include an individual in a position to assist someone at risk of an opioid-related overdose.

39.8(2) *Authorized pharmacist training.* An authorized pharmacist shall document successful completion of an ACPE-approved continuing education program of at least one-hour duration related to naloxone utilization prior to dispensing naloxone pursuant to the statewide protocol.

39.8(3) *Assessment.* An authorized pharmacist shall assess a patient for eligibility to receive naloxone using criteria identified in the statewide protocol.

39.8(4) *Patient education.* Upon assessment and determination that a patient is eligible to receive and possess naloxone pursuant to the statewide protocol, an authorized pharmacist shall, prior to dispensing naloxone pursuant to the statewide protocol, provide training and education to the patient including, but not limited to, the information identified in this subrule. An authorized pharmacist may provide to the patient written materials that include, but may not be limited to, the information identified in this subrule, but the written materials shall not be in lieu of direct pharmacist consultation with the patient.

a. The signs and symptoms of opioid-related overdose as described in the statewide protocol.

b. The importance of calling 911 as soon as possible and the potential need for rescue breathing.

c. The appropriate use and directions for administration of the naloxone to be dispensed pursuant to the statewide protocol.

d. Adverse reactions of naloxone as well as reactions resulting from opioid withdrawal following administration.

e. The proper storage conditions, including temperature excursions, of the naloxone product being dispensed.

f. The expiration date of the naloxone product being dispensed and the appropriate disposal of the naloxone product upon expiration.

g. Information about substance abuse or behavioral health treatment programs, if applicable.

39.8(5) *Labeling.* Naloxone dispensed pursuant to this rule shall be labeled in accordance with rule 657—6.10(126,155A), and the labeling shall not render the expiration date of the product illegible.

39.8(6) *Reporting.* As soon as reasonably possible, the authorized pharmacist shall notify the patient's primary health care provider of the naloxone product provided to the patient. If the patient does not have a primary health care provider, the authorized pharmacist shall provide the patient with a written record of the naloxone product provided to the patient and shall advise the patient to consult a physician.

39.8(7) *Records.* An authorized pharmacist shall maintain records of naloxone ordered and dispensed pursuant to the statewide protocol.

[**ARC 4270C**, IAB 1/30/19, effective 3/6/19; see Delay note at end of chapter; **ARC 4387C**, IAB 4/10/19, effective 4/5/19]

657—39.9(155A) Statewide protocol—nicotine replacement tobacco cessation products. An authorized pharmacist may order and dispense nicotine replacement tobacco cessation products to patients 18 years and older pursuant to a statewide protocol developed pursuant to rule 657—39.6(155A) and in compliance with this rule. An authorized pharmacist may only delegate the dispensing of a nicotine replacement tobacco cessation product to an authorized pharmacist-intern under the direct supervision of an authorized pharmacist.

39.9(1) *Definitions.* For the purposes of this rule, the following definitions shall apply:

"ACPE" means the Accreditation Council for Pharmacy Education.

"Authorized pharmacist" means an Iowa-licensed pharmacist who has completed the training requirements of this rule. "Authorized pharmacist" also includes an Iowa-registered pharmacist-intern who has completed the training requirements of this rule and is working under the direct supervision of an authorized pharmacist.

"Authorized pharmacist-intern" means an Iowa-registered pharmacist-intern who has completed the training requirements for an authorized pharmacist pursuant to this rule.

"Board" means the Iowa board of pharmacy.

39.9(2) *Authorized pharmacist training.* An authorized pharmacist shall document successful completion of an ACPE-approved continuing education program of at least one-hour duration related to nicotine replacement tobacco cessation product utilization prior to dispensing such products under the statewide protocol.

39.9(3) *Assessment.* An authorized pharmacist shall assess a patient for appropriateness of receiving a nicotine replacement tobacco cessation product pursuant to the statewide protocol.

39.9(4) *Patient counseling and instructions.* Upon assessment and determination that provision of the nicotine replacement tobacco cessation product is appropriate pursuant to the statewide protocol, an authorized pharmacist shall, prior to dispensing such product, provide counseling and instructions to the patient pursuant to rule 657—6.14(155A).

39.9(5) *Labeling.* Nicotine replacement tobacco cessation products dispensed pursuant to this rule shall be labeled in accordance with rule 657—6.10(126,155A), and the labeling shall not render the expiration date of the product illegible.

39.9(6) *Reporting.* As soon as reasonably possible, the authorized pharmacist shall notify the patient's primary health care provider of the nicotine replacement tobacco cessation product provided to the patient. If the patient does not have a primary health care provider, the authorized pharmacist shall provide the patient with a written record of the nicotine replacement tobacco cessation product provided to the patient and shall advise the patient to consult a physician.

39.9(7) *Records.* An authorized pharmacist shall maintain records of nicotine replacement tobacco cessation products ordered and dispensed pursuant to the statewide protocol.

[**ARC 4270C**, IAB 1/30/19, effective 3/6/19; see Delay note at end of chapter; **ARC 4387C**, IAB 4/10/19, effective 4/5/19]

657—39.10(155A) Vaccine administration by pharmacists—physician-approved protocol. Through June 30, 2019, an authorized pharmacist may administer vaccines pursuant to protocols established by the CDC in compliance with the requirements of this rule. An authorized

pharmacist may only delegate the administration of a vaccine to an authorized pharmacist-intern under the direct supervision of the authorized pharmacist.

39.10(1) *Definitions.* For the purposes of this rule, the following definitions shall apply:

"ACIP" means the CDC Advisory Committee on Immunization Practices.

"ACPE" means the Accreditation Council for Pharmacy Education.

"Authorized pharmacist" means an Iowa-licensed pharmacist who has met the requirements identified in subrule 39.10(2).

"Authorized pharmacist-intern" means an Iowa-registered pharmacist-intern who has met the requirements for an authorized pharmacist identified in paragraphs 39.10(2)*"a"* and *"c."*

"CDC" means the United States Centers for Disease Control and Prevention.

"Immunization" shall have the same meaning as, and shall be interchangeable with, the term "vaccine."

"Protocol" means a standing order for a vaccine to be administered by an authorized pharmacist.

"Vaccine" means a specially prepared antigen administered to a person for the purpose of providing immunity.

39.10(2) *Authorized pharmacist training and continuing education.* An authorized pharmacist shall document successful completion of the requirements in paragraph 39.10(2)*"a"* and shall maintain competency by completing and maintaining documentation of the continuing education requirements in paragraph 39.10(2)*"b."*

a. *Initial qualification.* An authorized pharmacist shall have successfully completed an organized course of study in a college or school of pharmacy or an ACPE-accredited continuing education program on vaccine administration that:

(1) Requires documentation by the pharmacist of current certification in basic cardiac life support through a training program designated for health care providers that includes hands-on training.

(2) Is an evidence-based course that includes study material and hands-on training and techniques for administering vaccines, requires testing with a passing score, complies with current CDC guidelines, and provides instruction and experiential training in the following content areas:

1. Standards for immunization practices;
2. Basic immunology and vaccine protection;
3. Vaccine-preventable diseases;
4. Recommended immunization schedules;
5. Vaccine storage and management;
6. Informed consent;
7. Physiology and techniques for vaccine administration;
8. Pre- and post-vaccine assessment, counseling, and identification of contraindications to the vaccine;
9. Immunization record management; and
10. Management of adverse events, including identification, appropriate response, documentation, and reporting.

b. *Continuing education.* During any pharmacist license renewal period, an authorized pharmacist who engages in the administration of vaccines shall complete and document at least one hour of ACPE-approved continuing education with the ACPE topic designator "06" followed by the letter "P."

c. *Certification maintained.* During any period within which the pharmacist may engage in the administration of vaccines, the pharmacist shall maintain current certification in basic cardiac life support through a training program designated for health care providers that includes hands-on training.

39.10(3) *Protocol requirements.* A pharmacist may administer vaccines pursuant to a protocol based on CDC recommendations. A protocol shall be unique to a pharmacy. The pharmacy shall comply with the parameters of the protocol. The prescriber who signs a protocol shall identify within the protocol, by name or category, those pharmacists or other qualified health professionals that the prescriber is authorizing to administer vaccines pursuant to the protocol. A protocol:

a. Shall be signed by an Iowa-licensed prescriber practicing in Iowa.

b. Shall expire no later than one year from the effective date of the signed protocol.

c. Shall be effective for patients who wish to receive a vaccine administered by an authorized pharmacist, who meet the CDC recommended criteria, and who have no contraindications as published by the CDC.

d. Shall require the authorized pharmacist to notify the prescriber who signed the protocol within 24 hours of a serious complication, and the pharmacist shall submit a Vaccine Advisory Event Reporting System (VAERS) report.

e. Shall specifically indicate whether the authorizing prescriber agrees that the administration of vaccines may be delegated by the authorized pharmacist to an authorized pharmacist-intern under the direct supervision of the authorized pharmacist.

39.10(4) *Influenza and other emergency vaccines.* An authorized pharmacist shall only administer via protocol, to patients six years of age and older, influenza vaccines and other emergency vaccines in response to a public health emergency.

39.10(5) *Other adult vaccines.* An authorized pharmacist shall only administer via protocol, to patients 18 years of age and older, the following vaccines:

a. A vaccine on the ACIP-approved adult vaccination schedule.

b. A vaccine recommended by the CDC for international travel.

39.10(6) *Vaccines administered via prescription.* An authorized pharmacist may administer any vaccine pursuant to a prescription or medication order for an individual patient. In case of a serious complication, the authorized pharmacist shall notify the prescriber who authorized the prescription within 24 hours and shall submit a VAERS report.

39.10(7) *Verification and reporting.* The requirements of this subrule do not apply to influenza and other emergency vaccines administered via protocol pursuant to subrule 39.10(4). An authorized pharmacist shall:

a. Prior to administering a vaccine identified in subrule 39.10(5) or 39.10(6), consult the statewide immunization registry or health information network.

b. As soon as reasonably possible following administration of a vaccine identified in subrule 39.10(5) or 39.10(6), report the vaccine administration to the statewide immunization registry or health information network and to the patient's primary health care provider, if known.

[**ARC 3858C**, IAB 6/20/18, effective 7/25/18; **ARC 4270C**, IAB 1/30/19, effective 3/6/19; see Delay note at end of chapter]

657—39.11(155A) Vaccine administration by pharmacists—statewide protocol. An authorized pharmacist may order and administer vaccines and immunizations pursuant to a statewide protocol developed pursuant to rule 657—39.6(155A) and in compliance with this rule. An authorized pharmacist may only delegate the ordering and administration of a vaccine to an authorized pharmacist-intern under the direct supervision of an authorized pharmacist.

39.11(1) *Definitions.* For the purposes of this rule, the following definitions shall apply:

"ACIP" means the CDC Advisory Committee on Immunization Practices.

"ACPE" means the Accreditation Council for Pharmacy Education.

"Authorized pharmacist" means an Iowa-licensed pharmacist who has met the requirements identified in subrule 39.11(3).

"Authorized pharmacist-intern" means an Iowa-registered pharmacist-intern who has met the requirements for an authorized pharmacist identified in subrule 39.11(3).

"Board" means the Iowa board of pharmacy.

"CDC" means the United States Centers for Disease Control and Prevention.

"Immunization" shall have the same meaning as, and shall be interchangeable with, the term "vaccine."

"Vaccine" means a specially prepared antigen administered to a person for the purpose of providing immunity.

39.11(2) *Vaccines authorized by statewide protocol.* The vaccines authorized to be ordered and administered pursuant to the statewide protocol shall include:

a. To patients ages 18 years and older:

(1) An immunization or vaccination recommended by ACIP in its approved vaccination schedule for adults.

(2) An immunization or vaccination recommended by CDC for international travel.

(3) A Tdap (tetanus, diphtheria, acellular pertussis) vaccination in a booster application.

(4) Other emergency immunizations or vaccinations in response to a public health emergency.

b. To patients ages six months and older:

(1) A vaccine or immunization for influenza.

(2) Other emergency immunizations or vaccines in response to a public health emergency.

c. To patients ages 11 years and older:

(1) The final two doses in a course of vaccinations for human papillomavirus (HPV).

(2) Reserved.

39.11(3) *Authorized pharmacist training and continuing education.* An authorized pharmacist shall document successful completion of the requirements in paragraph 39.11(3)*"a"* and shall maintain competency by completing and maintaining documentation of the continuing education requirements in paragraph 39.11(3)*"b."*

a. Initial qualification. An authorized pharmacist shall have successfully completed an organized course of study in a college or school of pharmacy or an ACPE-accredited continuing education program on vaccine administration that:

(1) Requires documentation by the pharmacist of current certification in basic cardiac life support through a training program designated for health care providers that includes hands-on training.

(2) Is an evidence-based course that includes study material and hands-on training and techniques for administering vaccines, requires testing with a passing score, complies with current CDC guidelines, and provides instruction and experiential training in the following content areas:

1. Standards for immunization practices;
2. Basic immunology and vaccine protection;
3. Vaccine-preventable diseases;
4. Recommended immunization schedules;
5. Vaccine storage and management;
6. Informed consent;
7. Physiology and techniques for vaccine administration;
8. Pre- and post-vaccine assessment, counseling, and identification of contraindications to the vaccine;
9. Immunization record management; and
10. Management of adverse events, including identification, appropriate response, documentation, and reporting.

b. Continuing education. During any pharmacist license renewal period, an authorized pharmacist who engages in the administration of vaccines shall complete and document at least one hour of ACPE-approved continuing education with the ACPE topic designator "06" followed by the letter "P."

c. Certification maintained. During any period within which the pharmacist may engage in the administration of vaccines, the pharmacist shall maintain current certification in basic cardiac life support through a training program designated for health care providers that includes hands-on training.

39.11(4) *Assessment.* An authorized pharmacist shall assess a patient for appropriateness of receiving a vaccine pursuant to the statewide protocol.

39.11(5) *Verification and reporting.* Prior to the ordering and administration of an immunization pursuant to the statewide protocol, the authorized pharmacist shall consult and review the statewide immunization registry or health information network. As soon as reasonably possible following administration of a vaccine, the pharmacist shall report such administration to the patient's primary health care provider, primary physician, and a statewide immunization registry or health information network. If the patient does not have a primary health care provider, the pharmacist shall provide the

patient with a written record of the vaccine administered to the patient and shall advise the patient to consult a physician.
[**ARC 4270C**, IAB 1/30/19, effective 3/6/19; see Delay note at end of chapter; **ARC 4387C**, IAB 4/10/19, effective 4/5/19]

657—39.12 Reserved.

657—39.13(155A) Collaborative drug therapy management. An authorized pharmacist may only perform collaborative drug therapy management pursuant to protocol with an authorized provider pursuant to the requirements of this rule. The authorized provider retains the ultimate responsibility for the care of the patient. The pharmacist is responsible for all aspects of drug therapy management performed by the pharmacist.

39.13(1) *Definitions.* For the purpose of this rule, the following definitions shall apply:

"Authorized pharmacist" means an Iowa-licensed pharmacist whose license is in good standing and who meets the drug therapy management criteria defined in this subrule.

"Authorized provider" means an Iowa-licensed prescribing practitioner who is authorized by the practitioner's professional licensing authority to participate in a collaborative practice agreement with an authorized pharmacist pursuant to these rules and the rules of the practitioner's professional licensing authority. An authorized provider who executes a written protocol with an authorized pharmacist shall supervise the pharmacist's activities involved in the overall management of patients receiving medications or disease management services under the protocol. The authorized provider may delegate only drug therapies that are in areas common to the authorized provider's practice.

"Board" means the board of pharmacy.

"Collaborative drug therapy management" means participation by an authorized pharmacist and an authorized provider in the management of drug therapy pursuant to a written community practice protocol or a written hospital practice protocol.

"Collaborative practice" means that an authorized provider may delegate aspects of drug therapy management for the authorized provider's patients to an authorized pharmacist through a community practice protocol. "Collaborative practice" also means that a P&T committee may authorize hospital pharmacists to perform drug therapy management for inpatients and hospital clinic patients through a hospital practice protocol.

"Community practice protocol" means a written, executed agreement entered into voluntarily between an authorized pharmacist and an authorized provider establishing drug therapy management for one or more of the pharmacist's and authorized provider's patients residing in a community setting. A community practice protocol shall comply with the requirements of subrule 39.13(2).

"Community setting" means a location outside a hospital inpatient, acute care setting or a hospital clinic setting. A community setting may include, but is not limited to, a home, group home, assisted living facility, correctional facility, hospice, or long-term care facility.

"Drug therapy management criteria" means one or more of the following:

1. Graduation from a recognized school or college of pharmacy with a doctor of pharmacy (Pharm.D.) degree;
2. Certification by the Board of Pharmaceutical Specialties (BPS);
3. Certification by the Commission for Certification in Geriatric Pharmacy (CCGP);
4. Successful completion of a National Institute for Standards in Pharmacist Credentialing (NISPC) disease state management examination and credentialing by the NISPC;
5. Successful completion of a pharmacy residency program accredited by the American Society of Health-System Pharmacists (ASHP); or
6. Approval by the board of pharmacy.

"Hospital clinic" means an outpatient care clinic operated and affiliated with a hospital and under the direct authority of the hospital's P&T committee.

"Hospital pharmacist" means an Iowa-licensed pharmacist who meets the requirements for participating in a hospital practice protocol as determined by the hospital's P&T committee.

"Hospital practice protocol" means a written plan, policy, procedure, or agreement that authorizes drug therapy management between hospital pharmacists and authorized providers within a hospital and the hospital's clinics as developed and determined by the hospital's P&T committee. Such a protocol may apply to all pharmacists and authorized providers at a hospital or the hospital's clinics or only to those pharmacists and authorized providers who are specifically recognized. A hospital practice protocol shall comply with the requirements of subrule 39.13(3).

"P&T committee" means a committee of the hospital composed of physicians, pharmacists, and other health professionals that evaluates the clinical use of drugs within the hospital, develops policies for managing drug use and administration in the hospital, and manages the hospital drug formulary system.

"Therapeutic interchange" means an authorized exchange of therapeutic alternate drug products in accordance with a previously established and approved written protocol.

39.13(2) *Community practice protocol.*

a. An authorized pharmacist shall engage in collaborative drug therapy management with an authorized provider only under a written protocol that has been identified by topic. Protocols shall be made available upon request of the board or the licensing board of the authorized provider.

b. The community practice protocol shall include:

(1) The name, signature, date, and contact information for each authorized pharmacist who is a party to the protocol and is eligible to manage the drug therapy of a patient. If more than one authorized pharmacist is a party to the agreement, the pharmacists shall work for a single licensed pharmacy and a principal authorized pharmacist shall be designated in the protocol.

(2) The name, signature, date, and contact information for each authorized provider who may prescribe drugs and is responsible for supervising a patient's drug therapy management. The authorized provider who initiates a protocol shall be considered the main caregiver for the patient respective to that protocol and shall be noted in the protocol as the principal authorized provider.

(3) The name and contact information of the principal authorized provider and the principal authorized pharmacist who are responsible for development, training, administration, and quality assurance of the protocol.

(4) A detailed written protocol pursuant to which the authorized pharmacist will base drug therapy management decisions for patients. The protocol shall authorize one or more of the following:

1. Prescription drug orders. The protocol may authorize therapeutic interchange or modification of drug dosages based on symptoms or laboratory or physical findings defined in the protocol. The protocol shall include information specific to the dosage, frequency, duration, and route of administration of the drug authorized by the patient's authorized provider. The protocol shall not authorize the pharmacist to change a Schedule II drug or to initiate a drug not included in the established protocol.

2. Laboratory tests. The protocol may authorize the pharmacist to obtain or to conduct specific laboratory tests as long as the tests relate directly to the drug therapy management.

3. Physical findings. The protocol may authorize the pharmacist to check certain physical findings, e.g., vital signs, oximetry, or peak flows, that enable the pharmacist to assess and adjust the drug therapy, detect adverse drug reactions, or determine if the patient should be referred back to the patient's authorized provider for follow-up.

4. Patient activities. The protocol may authorize the pharmacist to monitor specific patient activities.

(5) Procedures for securing the patient's written consent. If the patient's consent is not secured by the authorized provider, the authorized pharmacist shall secure such and notify the patient's authorized provider within 24 hours.

(6) Circumstances that shall cause the authorized pharmacist to initiate communication with the authorized provider including but not limited to the need for new prescription orders and reports of the patient's therapeutic response or adverse reaction.

(7) A detailed statement identifying the specific drugs, laboratory tests, and physical findings upon which the authorized pharmacist shall base drug therapy management decisions.

(8) A provision for the collaborative drug therapy management protocol to be reviewed, updated, and reexecuted or discontinued at least every two years.

(9) A description of the method the pharmacist shall use to document the pharmacist's decisions or recommendations for the authorized provider.

(10) A description of the types of reports the authorized pharmacist is to provide to the authorized provider and the schedule by which the pharmacist is to submit these reports. The schedule shall include a time frame within which a pharmacist shall report any adverse reaction to the authorized provider.

(11) A statement of the medication categories and the type of initiation and modification of drug therapy that the provider authorizes the pharmacist to perform.

(12) A description of the procedures or plan that the pharmacist shall follow if the pharmacist modifies a drug therapy.

(13) Procedures for record keeping, record sharing, and long-term record storage.

(14) Procedures to follow in emergency situations.

(15) A statement that prohibits the authorized pharmacist from delegating drug therapy management to anyone other than another authorized pharmacist who has signed the applicable protocol.

(16) A statement that prohibits an authorized provider from delegating collaborative drug therapy management to any unlicensed or licensed person other than another authorized provider or an authorized pharmacist.

(17) A description of the mechanism for the pharmacist and the authorized provider to communicate with each other and for documentation by the pharmacist of the implementation of collaborative drug therapy.

c. Collaborative drug therapy management is valid only when initiated by a written protocol executed by at least one authorized pharmacist and at least one authorized provider.

d. The collaborative drug therapy protocol shall be kept on file in the pharmacy and be made available upon request of the board or the authorized provider's licensing board.

e. An authorized provider may terminate or amend the collaborative drug therapy management protocol with an authorized pharmacist if the authorized provider notifies the authorized pharmacist in writing. Notification shall include the name of the authorized pharmacist, the desired change, and the proposed effective date of the change. Written notification shall be maintained in the pharmacy and be made available upon request of the board or the authorized provider's licensing board.

f. The authorized provider or pharmacist who initiates a protocol with a patient is responsible for securing the patient's written consent to participate in drug therapy management and for transmitting a copy of the consent to the other party within 24 hours. The consent shall indicate which protocol is involved. Any variation in the protocol for a specific patient shall be communicated to the other party at the time of securing the patient's consent. The patient's authorized provider shall maintain the patient consent in the patient's medical record.

39.13(3) *Hospital practice protocol.*

a. A hospital's P&T committee shall determine the scope and extent of collaborative drug therapy management practices that may be conducted by the hospital's pharmacists.

b. Collaborative drug therapy management within a hospital setting or the hospital's clinic setting is valid only when approved by the hospital's P&T committee.

c. The hospital practice protocol shall include:

(1) The names or groups of pharmacists and providers who are authorized by the P&T committee to participate in collaborative drug therapy management.

(2) A plan for development, training, administration, and quality assurance of the protocol.

(3) A detailed written protocol pursuant to which the hospital pharmacist shall base drug therapy management decisions for patients. The protocol shall authorize one or more of the following:

1. Medication orders and prescription drug orders. The protocol may authorize therapeutic interchange or modification of drug dosages based on symptoms or laboratory or physical findings defined in the protocol. The protocol shall include information specific to the dosage, frequency, duration, and route of administration of the drug authorized by the authorized provider. The protocol shall not authorize the hospital pharmacist to change a Schedule II drug or to initiate a drug not included in the established protocol.

2. Laboratory tests. The protocol may authorize the hospital pharmacist to obtain or to conduct specific laboratory tests as long as the tests relate directly to the drug therapy management.

3. Physical findings. The protocol may authorize the hospital pharmacist to check certain physical findings, e.g., vital signs, oximetry, or peak flows, that enable the pharmacist to assess and adjust the drug therapy, detect adverse drug reactions, or determine if the patient should be referred back to the authorized provider for follow-up.

(4) Circumstances that shall cause the hospital pharmacist to initiate communication with the patient's authorized provider including but not limited to the need for new medication orders and prescription drug orders and reports of a patient's therapeutic response or adverse reaction.

(5) A statement of the medication categories and the type of initiation and modification of drug therapy that the P&T committee authorizes the hospital pharmacist to perform.

(6) A description of the procedures or plan that the hospital pharmacist shall follow if the hospital pharmacist modifies a drug therapy.

(7) A description of the mechanism for the hospital pharmacist and the patient's authorized provider to communicate and for the hospital pharmacist to document implementation of the collaborative drug therapy.

[**ARC 3858C**, IAB 6/20/18, effective 7/25/18]

657—39.14 and **39.15** Reserved.

657—39.16(155A) Pharmacy pilot or demonstration research projects. The purpose of this rule is to specify the procedures to be followed in applying for approval of a pilot or demonstration research project for innovative applications in the practice of pharmacy as authorized by 2011 Iowa Acts, chapter 63, section 36, as amended by 2012 Iowa Acts, chapter 1113, section 31, and by 2013 Iowa Acts, chapter 138, section 128. In reviewing projects, the board will consider only projects that expand pharmaceutical care services that contribute to positive patient outcomes. The board will not consider any project intended only to provide a competitive advantage to a single applicant or group of applicants.

39.16(1) *Definitions.* For the purposes of this rule, the following definitions shall apply:

"Act" means Iowa Code chapter 155A, the Iowa pharmacy practice Act.

"Board" means the Iowa board of pharmacy.

"Practice of pharmacy" means the practice of pharmacy as defined in Iowa Code section 155A.3(34).

"Project" means a pilot or demonstration research project as described in this rule.

39.16(2) *Scope of project.* A project may not expand the definition of the practice of pharmacy. A project may include therapeutic substitution or substitution of medical devices used in patient care if such substitution is included under a collaborative drug therapy management protocol established pursuant to rule 657—39.13(155A).

39.16(3) *Board approval of a project.* Board approval of a project may include the grant of an exception to or a waiver of rules adopted under the Act or under any law relating to the authority of prescription verification and the ability of a pharmacist to provide enhanced patient care in the practice of pharmacy. Project approval, including exception to or waiver of board rules, shall initially be for a specified period of time not exceeding 18 months from commencement of the project. The board may approve the extension or renewal of a project following consideration of a petition that clearly identifies the project, that includes a report similar to the final project report described in paragraph 39.16(6)*"a,"* that describes and explains any proposed changes to the originally approved and implemented project, and that justifies the need for extending or renewing the term of the project.

39.16(4) *Applying for approval of a project.* A person who wishes the board to consider approval of a project shall submit to the board a petition for approval that contains at least the following information:

a. Responsible pharmacist. Name, address, telephone number, and pharmacist license number of each pharmacist responsible for overseeing the project.

b. Location of project. Name, address, and telephone number of each specific location and, if a location is a pharmacy, the pharmacy license number where the proposed project will be conducted.

c. Project summary. A detailed summary of the proposed project that includes at least the following information:

(1) The goals, hypothesis, and objectives of the proposed project.

(2) A full explanation of the project and how it will be conducted.

(3) The time frame for the project including the proposed start date and length of study. The time frame may not exceed 18 months from the proposed start date of the project.

(4) Background information or literature review to support the proposed project.

(5) The rule or rules to be waived in order to complete the project and a request to waive the rule or rules.

(6) Procedures to be used during the project to ensure that the public health and safety are not compromised as a result of the waiver.

39.16(5) *Review and approval or denial of a proposed project.*

a. Staff review. Upon receipt of a petition for approval of a project, board staff shall initially review the petition for completeness and appropriateness. If the petition is incomplete or inappropriate for board consideration, board staff shall return the petition to the requestor with a letter explaining the reason the petition is being returned. A petition that has been returned pursuant to this paragraph may be amended or supplemented as necessary and submitted for reconsideration.

b. Board review. Upon review by the board of a petition for approval of a project, the board shall either approve or deny the petition. If the board approves the petition, the approval:

(1) Shall be specific for the project requested;

(2) Shall approve the project for a specific time period; and

(3) May include conditions or qualifications applicable to the project.

c. Inspection. The project site and project documentation shall be available for inspection and review by the board or its representative at any time during the project review and the approval or denial processes and, if a project is approved, throughout the approved term of the project.

d. Documentation maintained. Project documentation shall be maintained and available for inspection, review, and copying by the board or its representative for at least two years following completion or termination of the project.

39.16(6) *Presentation of reports.* The pharmacist responsible for overseeing a project shall be responsible for submitting to the board any reports required as a condition of a project, including the final project report.

a. Final project report. The final project report shall include a written summary of the results of the project and the conclusions drawn from those results. The final project report shall be submitted to the board within three months after completion or termination of the project.

b. Board review. The board shall receive and review any report regarding the progress of a project and the final project report at a regularly scheduled meeting of the board. The report shall be an item on the open session agenda for the meeting.

[**ARC 3858C**, IAB 6/20/18, effective 7/25/18]

These rules are intended to implement Iowa Code sections 135.190, 147.76, 147A.18, 155A.2, 155A.3, 155A.13, 155A.33, and 155A.44; 2018 Iowa Acts, Senate File 2322; and 2011 Iowa Acts, chapter 63, section 36, as amended by 2012 Iowa Acts, chapter 1113, section 31, and by 2013 Iowa Acts, chapter 138, section 128.

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[Filed Emergency ARC 4387C, IAB 4/10/19, effective 4/5/19]

[1] March 6, 2019, effective date of ARC 4270C [amendments to ch 39] delayed 70 days by the Administrative Rules Review Committee at its meeting held February 8, 2019; delay lifted at the meeting held April 5, 2019.

CHAPTER 181
STATEWIDE STANDARD FOR PERMITTING CERTAIN IMPLEMENTS OF HUSBANDRY

761—181.1(321) Statewide standard.

181.1(1) A local authority may issue a special permit, based on this rule, allowing the operation over a bridge within its jurisdiction of a fence-line feeder, grain cart, tank wagon or tracked implement of husbandry with a weight in excess of the weights allowed under Iowa Code chapter 321.

181.1(2) A local authority shall evaluate a bridge according to section 6 of the American Association of State Highway and Transportation Officials (AASHTO) Manual for Bridge Evaluation (MBE), Third Edition (2018). The operating level shall be used for the evaluation of the bridge with only one fence-line feeder, grain cart, tank wagon or tracked implement of husbandry on the bridge at a time. The live load to be used in the analysis for permit decisions should be the actual vehicle crossing the bridge, together with a dynamic load allowance in accordance with section 6A.4.4.3 or 6A.4.5.5 of the AASHTO MBE, Third Edition (2018).

181.1(3) A local authority is not liable for damage to any vehicle operating within the terms of a permit the local authority issues under this rule, or to the vehicle's cargo, if the local authority imposes weight limits on a bridge specified in the permit subsequent to the issuance of the permit. The weight limits are effective when signs giving notice of the limits are erected.

181.1(4) The AASHTO publications may be ordered from the website www.transportation.org. They may be inspected at the department's office of bridges and structures.

This rule is intended to implement Iowa Code sections 321.1, 321.463(4) and 321.471.

[**ARC 1451C**, IAB 4/30/14, effective 6/4/14; **ARC 4400C**, IAB 4/10/19, effective 5/15/19]

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CHAPTER 520
REGULATIONS APPLICABLE TO CARRIERS

[Prior to 6/3/87, Transportation Department[820]—(07,F) Ch 8]

761—520.1(321) Safety and hazardous materials regulations.

520.1(1) *Regulations.*

a. *Motor carrier safety regulations.* The Iowa department of transportation adopts the Federal Motor Carrier Safety Regulations, 49 CFR Parts 385 and 390-399 (October 1, 2018).

b. *Hazardous materials regulations.* The Iowa department of transportation adopts the Federal Hazardous Materials Regulations, 49 CFR Parts 107, 171-173, 177, 178, and 180 (October 1, 2018).

c. *Copies of regulations.* Copies of the federal regulations may be reviewed at the state law library or through the Internet at www.fmcsa.dot.gov.

520.1(2) *Carriers subject to regulations.*

a. Operators of commercial vehicles, as defined in Iowa Code section 321.1, are subject to the Federal Motor Carrier Safety Regulations adopted in this rule unless exempted under Iowa Code section 321.449.

b. Operators of vehicles transporting hazardous materials in commerce are subject to the Federal Hazardous Materials Regulations adopted in this rule unless exempted under Iowa Code section 321.450.

c. Operators of vehicles for hire, designed to transport 7 or more persons, but fewer than 16, including the driver, must comply with 49 CFR Part 395 of the Federal Motor Carrier Safety Regulations. In addition, operators of vehicles for hire designed to transport 7 or more persons, but fewer than 16, including the driver, are not exempt from logbook requirements afforded the 100-air-mile radius driver under 49 CFR 395.1(e). However, the provisions of 49 CFR Part 395 shall not apply to vehicles offered to the public for hire that are used principally in intracity operation and are regulated by local authorities.

520.1(3) *Declaration of knowledge of regulations.* Operators of commercial vehicles who are subject to the regulations adopted in this rule shall at the time of application for authority to operate in Iowa or upon receipt of their Iowa registration declare knowledge of the Federal Motor Carrier Safety Regulations and Federal Hazardous Materials Regulations adopted in this rule.

This rule is intended to implement Iowa Code sections 321.1, 321.449 and 321.450.

[**ARC 7750B**, IAB 5/6/09, effective 6/10/09; **ARC 8720B**, IAB 5/5/10, effective 6/9/10; **ARC 9493B**, IAB 5/4/11, effective 6/8/11; **ARC 0034C**, IAB 3/7/12, effective 4/11/12; **ARC 0660C**, IAB 4/3/13, effective 5/8/13; **ARC 2019C**, IAB 6/10/15, effective 7/15/15; **ARC 2525C**, IAB 5/11/16, effective 6/15/16; **ARC 2986C**, IAB 3/15/17, effective 4/19/17; **ARC 3840C**, IAB 6/6/18, effective 7/11/18; **ARC 4401C**, IAB 4/10/19, effective 5/15/19]

761—520.2(321) Definitions. The following definitions apply to the regulations adopted in rule 761—520.1(321):

"Any requirements which impose any restrictions upon a person" as used in Iowa Code section 321.449(6) means the requirements in 49 CFR Parts 391 and 395.

"Driver age qualifications" as used in Iowa Code section 321.449(3) means the age qualifications in 49 CFR 391.11(b)(1).

"Driver qualifications" as used in Iowa Code section 321.449(2) means the driver qualifications in 49 CFR Part 391.

"Farm customer" as used in Iowa Code section 321.450(3) means a retail consumer residing on a farm or in a rural area or city with a population of 3000 or less.

"Hours of service" as used in Iowa Code section 321.449(2) means the hours of service requirements in 49 CFR Part 395.

"Record-keeping requirements" as used in Iowa Code section 321.449(2) means the record-keeping requirements in 49 CFR Part 395.

"Rules adopted under this section concerning physical and medical qualifications" as used in Iowa Code sections 321.449(5) and 321.450(2) means the regulations in 49 CFR 391.11(b)(4) and 49 CFR Part 391, Subpart E.

"Rules adopted under this section for a driver of a commercial vehicle" as used in Iowa Code section 321.449(4) means the regulations in 49 CFR Parts 391 and 395.

This rule is intended to implement Iowa Code sections 321.449 and 321.450.

[**ARC 2019C**, IAB 6/10/15, effective 7/15/15]

761—520.3(321) Motor carrier safety regulations exemptions.

520.3(1) The following intrastate vehicle operations are exempt from the motor carrier safety regulations concerning inspection in 49 CFR Part 396.17 as adopted in rule 761—520.1(321):

a. Implements of husbandry including nurse tanks as defined in Iowa Code section 321.1.

b. Special mobile equipment (SME) as defined in Iowa Code section 321.1.

c. Unregistered farm trailers as defined in rule 761—400.1(321), pursuant to Iowa Code section 321.123.

d. Motor vehicles registered for a gross weight of five tons or less when used by retail dealers or their employees to deliver hazardous materials, fertilizers, petroleum products and pesticides to farm customers.

520.3(2) Reserved.

This rule is intended to implement Iowa Code sections 321.1, 321.123, 321.449 and 321.450.

[**ARC 2019C**, IAB 6/10/15, effective 7/15/15]

761—520.4(321) Hazardous materials exemptions. These exemptions apply to the regulations adopted in rule 761—520.1(321):

520.4(1) Pursuant to Iowa Code section 321.450(3), "retail dealers of fertilizers, petroleum products, and pesticides and their employees while delivering fertilizers, petroleum products, and pesticides to farm customers within a one-hundred-mile radius of their retail place of business" are exempt from 49 CFR 177.804; and, pursuant to Iowa Code section 321.449(4), they are exempt from 49 CFR Parts 391 and 395. However, pursuant to Iowa Code section 321.449, the retail dealers and their employees under the specified conditions are subject to the regulations in 49 CFR Parts 390, 392, 393, 396 and 397.

520.4(2) Rescinded IAB 3/10/99, effective 4/14/99.

This rule is intended to implement Iowa Code section 321.450.

[**ARC 2019C**, IAB 6/10/15, effective 7/15/15]

761—520.5(321) Safety fitness.

520.5(1) *New motor carrier safety audits.* Peace officers in the office of motor vehicle enforcement of the Iowa department of transportation shall perform safety audits of new motor carriers and shall have the authority to enter a motor carrier's place of business for the purpose of performing these audits. These audits shall be performed in compliance with 49 CFR Part 385 and shall be completed within 18 months from the day the motor carrier commences business.

520.5(2) *Motor carrier compliance reviews.* Peace officers in the office of motor vehicle enforcement of the Iowa department of transportation shall perform compliance reviews of motor carriers and shall have the authority to enter a motor carrier's place of business for the purpose of performing these compliance reviews. These compliance reviews shall be performed in compliance with 49 CFR Part 385.

This rule is intended to implement Iowa Code sections 321.449 and 321.450.

761—520.6(321) Out-of-service order. A person shall not operate a commercial vehicle or transport hazardous material in violation of an out-of-service order issued by an Iowa peace officer. An out-of-service order for noncompliance shall be issued when either the vehicle operator is not qualified to operate the vehicle or the vehicle is unsafe to be operated until required repairs are made. The out-of-service order shall be consistent with the North American Uniform Out-of-Service Criteria.

This rule is intended to implement Iowa Code sections 321.3, 321.208A, 321.449, and 321.450.

761—520.7(321) Driver's statement. A "driver" as used in Iowa Code sections 321.449(5) and 321.450(2) shall carry at all times a notarized statement of employment. The statement shall include the following:

1. The driver's name, address and social security number;
2. The name, address and telephone number of the driver's pre-July 29, 1996, employer;
3. A statement, signed by the pre-July 29, 1996, employer or the employer's authorized representative, that the driver was employed to operate a commercial vehicle only in Iowa; and
4. A statement showing the driver's physical or medical condition existed prior to July 29, 1996.

This rule is intended to implement Iowa Code sections 321.449 and 321.450.

[**ARC 2019C**, IAB 6/10/15, effective 7/15/15]

761—520.8(321) Planting and harvesting period. In accordance with the provisions of 49 CFR 395.1(k), the planting and harvesting period pertaining to agricultural operations is January 1 through December 31.

This rule is intended to implement Iowa Code sections 321.449 and 321.450.

[**ARC 2019C**, IAB 6/10/15, effective 7/15/15; **ARC 3483C**, IAB 12/6/17, effective 12/18/17; **ARC 3609C**, IAB 1/31/18, effective 3/7/18]

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[1] Effective date of 520.1(1)*"a"* and *"b";* rescission of 520.1(2)*"b";* and 520.3 delayed until adjournment of the 1993 Regular Session of the General Assembly by the Administrative Rules Review Committee at its meeting held October 14, 1992; delay lifted by the Committee November 10, 1992.

CHAPTER 529
FOR-HIRE INTERSTATE MOTOR CARRIER AUTHORITY

[Prior to 6/3/87, Transportation Department[820]—(07,F)Ch 5]

761—529.1(327B) Motor carrier regulations. The Iowa department of transportation adopts the Code of Federal Regulations, 49 CFR Parts 365-368 and 370-379, dated October 1, 2018, for regulating interstate for-hire carriers.

Copies of this publication are available from the state law library or through the Internet at www.fmcsa.dot.gov.

[**ARC 7901B**, IAB 7/1/09, effective 8/5/09; **ARC 8837B**, IAB 6/16/10, effective 7/21/10; **ARC 0136C**, IAB 5/30/12, effective 7/4/12; **ARC 2986C**, IAB 3/15/17, effective 4/19/17; **ARC 3840C**, IAB 6/6/18, effective 7/11/18; **ARC 4401C**, IAB 4/10/19, effective 5/15/19]

761—529.2(327B) Registering interstate authority in Iowa. Registration for interstate exempt and nonexempt authority shall be either mailed to the Office of Vehicle and Motor Carrier Services, Iowa Department of Transportation, P.O. Box 10382, Des Moines, Iowa 50306-0382; delivered in person to 6310 SE Convenience Blvd., Ankeny, Iowa; or sent by facsimile to (515)237-3257.

[**ARC 3840C**, IAB 6/6/18, effective 7/11/18]

761—529.3(327B) Waiver of rules. In accordance with 761—Chapter 11, the director of transportation may, in response to a petition, waive provisions of this chapter. A waiver shall not be granted unless the director finds that special or emergency circumstances exist.

"Special or emergency circumstances" means one or more of the following:

1. Circumstances where the movement is necessary to cooperate with cities, counties, other state agencies or other states in response to a national or other disaster.
2. Circumstances where the movement is necessary to cooperate with national defense officials.
3. Circumstances where the movement is necessary to cooperate with public or private utilities in order to maintain their public services.
4. Circumstances where the movement is essential to ensure safety and protection of any person or property due to events such as, but not limited to, pollution of natural resources, a potential fire or explosion.
5. Circumstances where weather or transportation problems create an undue hardship for citizens of the state of Iowa.
6. Circumstances where movement involves emergency-type vehicles.
7. Uncommon or extraordinary circumstances where the movement is essential to the existence of an Iowa business and the move may be accomplished without causing undue hazard to the safety of the traveling public or undue damage to private or public property.

These rules are intended to implement Iowa Code chapter 327B.

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CHAPTER 607
COMMERCIAL DRIVER LICENSING

761—607.1(321) Scope. This chapter applies to licensing persons for the operation of commercial motor vehicles. Unless otherwise stated, the provisions of this chapter are in addition to other motor vehicle licensing rules.

This rule is intended to implement Iowa Code chapter 321.

761—607.2(17A) Information.

607.2(1) *Information and location.* Applications, forms and information about the commercial driver's license (CDL) are available at any driver's license examination station. Assistance is also available by mail from Driver and Identification Services, Iowa Department of Transportation, P.O. Box 9204, Des Moines, Iowa 50306-9204; in person at 6310 SE Convenience Blvd., Ankeny, Iowa; by telephone at (515)244-8725; by facsimile at (515)239-1837; or on the department's website at www.iowadot.gov.

607.2(2) *Manual.* A copy of a study manual for the commercial driver's license tests is available upon request at any driver's license examination station and on the department's Web site.

This rule is intended to implement Iowa Code section 17A.3.

[**ARC 2530C**, IAB 5/11/16, effective 6/15/16; **ARC 3689C**, IAB 3/14/18, effective 4/18/18]

761—607.3(321) Definitions. The definitions in Iowa Code section 321.1 apply to this chapter of rules. In addition, the following definitions are adopted:

"Air brake system" means a system that uses air as a medium for transmitting pressure or force from the driver's control to the service brake. "Air brake system" shall include any braking system operating fully or partially on the air brake principle.

"Air over hydraulic brakes" means any braking system operating partially on the air brake and partially on the hydraulic brake principle.

"Automatic transmission" means any transmission other than a manual transmission.

"CDLIS" means "commercial driver's license information system" as defined in Iowa Code section 321.1.

"Commercial driver's license downgrade" or *"CDL downgrade"* means either:

1. The driver changes the driver's self-certification of type of driving from non-excepted interstate to excepted interstate, non-excepted intrastate, or excepted intrastate driving, or
2. The department removed the CDL privilege from the driver's license.

"Commercial motor vehicle" or *"CMV"* as defined in Iowa Code section 321.1 does not include a motor vehicle designed as off-road equipment rather than as a motor truck, such as a forklift, motor grader, scraper, tractor, trencher or similar industrial-type equipment. "Commercial motor vehicle" also does not include self-propelled implements of husbandry described in Iowa Code subsection 321.1(32).

"Controlled substance" as used in Iowa Code section 321.208 means a substance defined in Iowa Code section 124.101.

"Hazardous materials" means any material that has been designated as hazardous under 49 U.S.C. Section 5103 and is required to be placarded under 49 CFR Part 172, Subpart F, or any quantity of a material listed as a select agent or toxin in 42 CFR Part 73.

"Manual transmission" means a transmission utilizing a driver-operated clutch that is activated by a pedal or lever and a gear-shift mechanism operated either by hand or by foot. All other transmissions, whether semi-automatic or automatic, will be considered automatic.

"Medical examiner" means a person who is licensed, certified or registered, in accordance with applicable state laws and regulations, to perform physical examinations. The term includes but is not limited to doctors of medicine, doctors of osteopathy, physician assistants, advanced registered nurse practitioners, and doctors of chiropractic.

"Medical examiner's certificate" means a certificate completed and signed by a medical examiner under the provisions of 49 CFR Section 391.43.

"Medical variance" means a driver has received one of the following from the Federal Motor Carrier Safety Administration that allows the driver to be issued a medical certificate:

1. An exemption letter permitting operation of a commercial motor vehicle pursuant to 49 CFR Part 381, Subpart C, or 49 CFR Section 391.62, or 49 CFR Section 391.64.

2. A skill performance evaluation certificate permitting operation of a commercial motor vehicle pursuant to 49 CFR Section 391.49.

"Passenger vehicle" means either of the following:

1. A motor vehicle designed to transport 16 or more persons including the operator.

2. A motor vehicle of a size and design to transport 16 or more persons including the operator which is redesigned or modified to transport fewer than 16 persons with disabilities. The size of a redesigned or modified vehicle shall be any such vehicle with a gross vehicle weight rating of 10,001 or more pounds.

"School bus" means a commercial motor vehicle used to transport pre-primary, primary, or secondary school students from home to school, from school to home, or to and from school-sponsored events. "School bus" does not include a bus used as a common carrier.

"Self-certification" means a written certification of which category of type of driving an applicant for a commercial driver's license engages in or intends to engage in, from the following categories:

1. Non-excepted interstate. The person certifies that the person operates or expects to operate in interstate commerce, is both subject to and meets the qualification requirements under 49 CFR Part 391, and is required to obtain a medical examiner's certificate by 49 CFR Section 391.45.

2. Excepted interstate. The person certifies that the person operates or expects to operate in interstate commerce, but engages exclusively in transportation or operations excepted under 49 CFR Section 390.3(f), 391.2, 391.68 or 398.3 from all or parts of the qualification requirements of 49 CFR Part 391, and is therefore not required to obtain a medical examiner's certificate by 49 CFR Section 391.45.

3. Non-excepted intrastate. The person certifies that the person operates only in intrastate commerce and is subject to state driver qualification requirements.

4. Excepted intrastate. The person certifies that the person operates only in intrastate commerce, but engages exclusively in transportation or operations excepted from all or parts of the state driver qualification requirements as set forth in Iowa Code section 321.449.

"State," as used in this chapter and in "another state" in Iowa Code subsection 321.174(2), "former state of residence" in Iowa Code subsection 321.188(5), or "any state" in Iowa Code subsection 321.208(1), means one of the United States or the District of Columbia unless the context means the state of Iowa.

This rule is intended to implement Iowa Code sections 321.1, 321.174, 321.188, 321.191, 321.193, 321.207 and 321.208.

[**ARC 7902B**, IAB 7/1/09, effective 8/5/09; **ARC 9954B**, IAB 1/11/12, effective 1/30/12; **ARC 0031C**, IAB 3/7/12, effective 4/11/12; **ARC 2071C**, IAB 8/5/15, effective 7/14/15; **ARC 2337C**, IAB 1/6/16, effective 2/10/16; **ARC 2530C**, IAB 5/11/16, effective 6/15/16]

761—607.4 and **607.5** Reserved.

761—607.6(321) Exemptions.

607.6(1) *Persons exempt.* A person listed in Iowa Code section 321.176A is exempt from commercial driver licensing requirements.

607.6(2) *Exempt until April 1, 1992.* Rescinded IAB 6/23/93, effective 7/28/93.

This rule is intended to implement Iowa Code sections 321.1 and 321.176A.

761—607.7(321) Records. The operating record of a person who has been issued a commercial driver's license or a commercial learner's permit or a person who has been disqualified from operating a commercial motor vehicle shall be maintained as provided in the department's "Record Management Manual" adopted in 761—Chapter 4.

This rule is intended to implement Iowa Code sections 22.11, 321.12 and 321.199.

[**ARC 2071C**, IAB 8/5/15, effective 7/14/15; **ARC 2337C**, IAB 1/6/16, effective 2/10/16; **ARC 2530C**, IAB 5/11/16, effective 6/15/16]

761—607.8 and **607.9** Reserved.

761—607.10(321) Adoption of federal regulations.

607.10(1) *Code of Federal Regulations.* The department's administration of commercial driver's licenses shall be in compliance with the state procedures set forth in 49 CFR Section 383.73, and this chapter shall be construed to that effect. The department adopts the following portions of the Code of Federal Regulations which are referenced throughout this chapter of rules:

a. 49 CFR Section 391.11 as adopted in 761—Chapter 520.

b. 49 CFR Section 392.5 as adopted in 761—Chapter 520.

c. The following portions of 49 CFR Part 383 (October 1, 2018):

(1) Section 383.51, Disqualification of drivers.

(2) Subpart E—Testing and Licensing Procedures.

(3) Subpart G—Required Knowledge and Skills.

(4) Subpart H—Tests.

607.10(2) *Copies of regulations.* Copies of the federal regulations may be reviewed at the state law library or through the Internet at www.fmcsa.dot.gov.

This rule is intended to implement Iowa Code sections 321.187, 321.188, 321.207, 321.208 and 321.208A.

[**ARC 7902B**, IAB 7/1/09, effective 8/5/09; **ARC 9954B**, IAB 1/11/12, effective 1/30/12; **ARC 0031C**, IAB 3/7/12, effective 4/11/12; **ARC 2071C**, IAB 8/5/15, effective 7/14/15; **ARC 2337C**, IAB 1/6/16, effective 2/10/16; **ARC 2530C**, IAB 5/11/16, effective 6/15/16; **ARC 2986C**, IAB 3/15/17, effective 4/19/17; **ARC 3840C**, IAB 6/6/18, effective 7/11/18; **ARC 4401C**, IAB 4/10/19, effective 5/15/19]

761—607.11 to **607.14** Reserved.

761—607.15(321) Application. An applicant for a commercial driver's license shall comply with the requirements of Iowa Code sections 321.180(2)*"e,"*321.182 and 321.188, and 761—Chapter 601, and must provide the proofs of citizenship or lawful permanent residence and state of domicile required by 49 CFR Section 383.71. If the applicant is domiciled in a foreign jurisdiction and applying for a nondomiciled commercial driver's license, the applicant must provide a document required by 49 CFR Section 383.71(f).

This rule is intended to implement Iowa Code sections 321.180, 321.182 and 321.188.

[**ARC 2071C**, IAB 8/5/15, effective 7/14/15; **ARC 2337C**, IAB 1/6/16, effective 2/10/16; **ARC 2530C**, IAB 5/11/16, effective 6/15/16]

761—607.16(321) Commercial driver's license (CDL).

607.16(1) *Classes.* The department may issue a commercial driver's license only as a Class A, B or C driver's license. The license class identifies the types of vehicles that may be operated. A commercial driver's license may have endorsements which authorize additional vehicle operations or restrictions which limit vehicle operations.

607.16(2) *Validity.*

a. A Class A commercial driver's license allows a person to operate a combination of commercial motor vehicles as specified in Iowa Code paragraph 321.189(1)*"a."* With the required endorsements and subject to the applicable restrictions, a Class A commercial driver's license is valid to operate any vehicle.

b. A Class B commercial driver's license allows a person to operate a commercial motor vehicle as specified in Iowa Code paragraph 321.189(1)*"b."* With the required endorsements and subject to the applicable restrictions, a Class B commercial driver's license is valid to operate any vehicle except a truck-tractor semitrailer combination as a chauffeur (Class D) or a vehicle requiring a Class A commercial driver's license.

c. A Class C commercial driver's license allows a person to operate a commercial motor vehicle as specified in Iowa Code paragraph 321.189(1)*"c."* With the required endorsements and subject to the applicable restrictions, a Class C commercial driver's license is valid to operate any vehicle except a truck-tractor semitrailer combination as a chauffeur (Class D) or a vehicle requiring a Class A or Class B commercial driver's license.

d. A commercial driver's license is valid for operating a motorcycle as a commercial motor vehicle only if the license has a motorcycle endorsement and a hazardous material endorsement. A commercial driver's license is valid for operating a motorcycle as a noncommercial motor vehicle only if the license has a motorcycle endorsement.

e. A commercial driver's license valid for eight years shall be issued to a qualified applicant who is at least 18 years of age but not yet 72 years of age. However, the expiration date of the license issued shall not exceed the licensee's 74th birthday.

f. A commercial driver's license valid for two years shall be issued to a qualified applicant 72 years of age or older. A two-year license may also be issued, at the discretion of the department, to an applicant whose license is restricted due to vision or other physical disabilities.

g. A commercial driver's license is valid for 60 days after the expiration date.

h. A person with a commercial driver's license valid for the vehicle operated is not required to obtain a Class D driver's license to operate the vehicle as a chauffeur.

607.16(3) *Requirements.*

a. The minimum age to obtain a commercial driver's license is 18 years.

b. The applicant shall meet the requirements set forth in rule 761—607.15(321).

607.16(4) *Transition from five-year to eight-year licenses.* During the period January 1, 2014, to December 31, 2018, the department shall issue qualified applicants otherwise eligible for an eight-year license a five-year, six-year, seven-year, or eight-year license, subject to all applicable limitations for age and ability. The applicable period shall be randomly assigned to the applicant by the department's computerized issuance system based on a distribution formula intended to spread renewal volumes as equally as practical over the eight-year period beginning January 1, 2019, and ending December 31, 2026.

This rule is intended to implement Iowa Code sections 321.177, 321.182, 321.188, 321.189, and 321.196 and 2013 Iowa Acts, chapter 104, section 2.

[**ARC 1714C**, IAB 11/12/14, effective 12/17/14; **ARC 2071C**, IAB 8/5/15, effective 7/14/15; **ARC 2337C**, IAB 1/6/16, effective 2/10/16]

761—607.17(321) Endorsements. All endorsements except the hazardous material endorsement continue to be valid without retesting or additional fees when renewing or upgrading a license. The endorsements that authorize additional commercial motor vehicle operations with a commercial driver's license are:

607.17(1) *Hazardous material.* A hazardous material endorsement (H) is required to transport hazardous materials. Upon license renewal, retesting and fee payment are required. Retesting and fee payment are also required when an applicant upgrades an Iowa license or transfers a commercial driver's license from another state unless the applicant provides evidence of passing the endorsement test within the preceding 24 months. A farmer or a person working for a farmer is not subject to the hazardous material endorsement while operating either a pickup or a special truck within 150 air miles of the farmer's farm to transport supplies to or from the farm.

607.17(2) *Passenger vehicle.* A passenger vehicle endorsement (P) is required to operate a passenger vehicle as defined in rule 761—607.3(321).

607.17(3) *Tank vehicle.* A tank vehicle endorsement (N) is required to operate a tank vehicle as defined in Iowa Code section 321.1. A vehicle transporting a tank, regardless of the tank's capacity, which does not otherwise meet the definition of a commercial motor vehicle in Iowa Code section 321.1 is not a tank vehicle.

607.17(4) *Double/triple trailer.* A double/triple trailer endorsement (T) is required to operate a commercial motor vehicle with two or more towed trailers when the combination of vehicles meets the criteria for a Class A commercial motor vehicle. Operation of a triple trailer combination vehicle is not permitted in Iowa.

607.17(5) *Hazardous material and tank.* A combined endorsement (X) authorizes both hazardous material and tank vehicle operations.

607.17(6) *School bus.* After September 30, 2005, a school bus endorsement (S) is required to operate a school bus as defined in rule 761—607.3(321). An applicant for a school bus endorsement must also qualify for a passenger vehicle endorsement.

607.17(7) *Exceptions for towing operations.*

a. A driver who tows a vehicle in an emergency "first move" from the site of a vehicle malfunction or accident on a highway to the nearest appropriate repair facility is not required to have the endorsement(s) applicable to the towed vehicle. In any subsequent move, a driver who tows a vehicle from one repair or disposal facility to another is required to have the endorsement(s) applicable to the towed vehicle with one exception: A tow truck driver is not required to have a passenger endorsement to tow a passenger vehicle.

b. The double/triple trailer endorsement is not required to operate a commercial motor vehicle with two or more towed vehicles that are not trailers.

This rule is intended to implement Iowa Code sections 321.1, 321.176A and 321.189.

[**ARC 2071C**, IAB 8/5/15, effective 7/14/15; **ARC 2337C**, IAB 1/6/16, effective 2/10/16; **ARC 2530C**, IAB 5/11/16, effective 6/15/16]

761—607.18(321) Restrictions. The restrictions that may limit commercial motor vehicle operation with a commercial driver's license are listed in 761—subrule 605.5(3) and are explained below:

607.18(1) *Air brake.* The air brake restriction (L, no air brake equipped CMV) applies to a licensee who either fails the air brake component of the knowledge test or performs the skills test in a vehicle not equipped with air brakes and prohibits the operation of a commercial motor vehicle equipped with an air brake system until the licensee passes the required air brake tests and pays the fee for upgrading the license. Retesting and fee payment are not required when the license is renewed.

607.18(2) *Full air brake.* The full air brake restriction (Z, no full air brake equipped CMV) applies to a licensee who performs the skills test in a vehicle equipped with air over hydraulic brakes and prohibits the operation of a commercial motor vehicle equipped with any braking system operating fully on the air brake principle until the licensee passes the required air brake tests and pays the fee for upgrading the license. Retesting and fee payment are not required when the license is renewed.

607.18(3) *Manual transmission.* The manual transmission restriction (E, no manual transmission equipped CMV) applies to a licensee who performs the skills test in a vehicle equipped with automatic transmission and prohibits the operation of a commercial motor vehicle equipped with a manual transmission until the licensee passes the required tests and pays the fee for upgrading the license. Retesting and fee payment are not required when the license is renewed.

607.18(4) *Tractor-trailer.* The tractor-trailer restriction (O, no tractor trailer CMV) applies to a licensee who performs the skills test in a combination vehicle for a Class A commercial driver's license with the power unit and towed unit connected with a pintle hook or other non-fifth wheel connection and prohibits operation of a tractor-trailer combination connected by a fifth wheel that requires a Class A commercial driver's license until the licensee passes the required tests and pays the fee for upgrading the license. Retesting and fee payment are not required when the license is renewed.

607.18(5) *Class A passenger vehicle.* The Class A passenger vehicle restriction (M, no Class A passenger vehicle) applies to a licensee who applies for a passenger endorsement and performs the skills test in a passenger vehicle that requires a Class B commercial driver's license and prohibits operation of a passenger vehicle that requires a Class A commercial driver's license.

607.18(6) *Class A and B passenger vehicle.* The Class A and B passenger vehicle restriction (N, no Class A and B passenger vehicle) applies to a licensee who applies for a passenger endorsement and performs the skills test in a passenger vehicle that requires a Class C commercial driver's license and prohibits operation of a passenger vehicle that requires a Class A or Class B commercial driver's license.

607.18(7) *Intrastate only.* The intrastate only restriction (K, intrastate only) applies to a licensee who self-certifies to non-excepted intrastate or excepted intrastate driving and prohibits the operation of a commercial motor vehicle in interstate commerce.

607.18(8) *Medical variance.* The medical variance restriction (V, medical variance) applies to a licensee when the department is notified pursuant to 49 CFR Section 383.73(o)(3) that the driver has

been issued a medical variance and indicates there is information about a medical variance on the CDLIS driver record.

This rule is intended to implement Iowa Code sections 321.189 and 321.191.

[**ARC 2071C**, IAB 8/5/15, effective 7/14/15; **ARC 2337C**, IAB 1/6/16, effective 2/10/16; **ARC 2530C**, IAB 5/11/16, effective 6/15/16]

761—607.19 Reserved.

761—607.20(321) Commercial learner's permit.

607.20(1) *Validity.*

a. A commercial learner's permit allows the permit holder to operate a commercial motor vehicle when accompanied as required by Iowa Code section 321.180(2)*"d."*

b. A commercial learner's permit is valid for one year without retaking the general and endorsement knowledge tests required by Iowa Code section 321.188.

c. A commercial learner's permit is invalid after the expiration date of the underlying commercial or noncommercial driver's license issued to the permit holder or the expiration date of the permit whichever occurs first.

d. The issuance of a commercial learner's permit is a precondition to the initial issuance of a commercial driver's license. The issuance of a commercial learner's permit is also a precondition to the upgrade of a commercial driver's license if the upgrade requires a skills test. The holder of a commercial learner's permit is not eligible to take a required driving skills test for the first 14 days after the permit holder is issued the permit. The 14-day period includes the day the commercial learner's permit was issued.

EXAMPLE: The commercial learner's permit is issued on September 1. The earliest date the permit holder would be eligible to take the skills test is September 15.

e. A commercial learner's permit is not valid for the operation of a vehicle transporting hazardous materials.

607.20(2) *Requirements.*

a. An applicant for a commercial learner's permit must hold a valid Class A, B, C, or D driver's license issued in this state that is not an instruction permit, a special instruction permit, a motorized bicycle license or a temporary restricted license; must be at least 18 years of age; and must meet the requirements to obtain a valid commercial driver's license, including the requirements set forth in Iowa Code section 321.188. However, the applicant does not have to complete the driving skills tests required for a commercial driver's license to obtain a commercial learner's permit.

b. The applicant must successfully pass a general knowledge test that meets the federal standards contained in 49 CFR Part 383, Subparts F, G and H, for the commercial motor vehicle the applicant operates or expects to operate, including any endorsement for which the applicant applies.

607.20(3) *Endorsements.* A commercial learner's permit may include the following endorsements. All other endorsements are prohibited on a commercial learner's permit.

a. An applicant for a passenger endorsement (P) must take and pass the passenger endorsement knowledge test. A commercial learner's permit holder with a passenger endorsement is prohibited from operating a commercial motor vehicle carrying passengers, other than federal/state auditors and inspectors, test examiners, other trainees, and the commercial driver's license holder accompanying the permit holder required by Iowa Code section 321.180(2)*"d."*

b. An applicant for a school bus endorsement (S) must take and pass the school bus endorsement knowledge test. A commercial learner's permit holder with a school bus endorsement is prohibited from operating a commercial motor vehicle carrying passengers, other than federal/state auditors and inspectors, test examiners, other trainees, and the commercial driver's license holder accompanying the permit holder required by Iowa Code section 321.180(2)*"d."*

c. An applicant for a tank vehicle endorsement (N) must take and pass the tank vehicle endorsement knowledge test. A commercial learner's permit holder with a tank vehicle endorsement may only operate an empty tank vehicle and is prohibited from operating any tank vehicle that previously contained hazardous materials that has not been purged of any residue.

607.20(4) *Restrictions.* A commercial learner's permit may include the air brake (L), medical variance (V), Class A passenger vehicle (M), Class A and B passenger vehicle (N) and intrastate only (K) restrictions described in rule 761—607.18(321). In addition, a commercial learner's permit may include the following restrictions that are specific to the commercial learner's permit:

a. *Passenger.* The passenger restriction (P, no passengers in CMV bus) applies to a permit holder who has a commercial learner's permit with a passenger or school bus endorsement and prohibits the operation of a commercial motor vehicle carrying passengers, other than federal/state auditors and inspectors, test examiners, other trainees, and the commercial driver's license holder accompanying the permit holder required by Iowa Code section 321.180(2)*"d."*

b. *Cargo.* The cargo restriction (X, no cargo in CMV tank vehicle) applies to a permit holder who has a commercial learner's permit with a tank vehicle endorsement and prohibits the operation of any tank vehicle containing cargo or any tank vehicle that previously contained hazardous materials that has not been purged of any residue.

This rule is intended to implement Iowa Code sections 321.180, 321.186 and 321.188.

[**ARC 2071C**, IAB 8/5/15, effective 7/14/15; **ARC 2337C**, IAB 1/6/16, effective 2/10/16; **ARC 2530C**, IAB 5/11/16, effective 6/15/16; **ARC 3689C**, IAB 3/14/18, effective 4/18/18]

761—607.21 to **607.24** Reserved.

761—607.25(321) Examination for a commercial driver's license. In addition to the requirements of 761—Chapter 604, an applicant for a commercial driver's license shall pass the knowledge and skills tests as required in 49 CFR Part 383, Subparts G and H.

This rule is intended to implement Iowa Code section 321.186.

761—607.26(321) Vision screening. An applicant for a commercial driver's license or commercial learner's permit must pass a vision screening test administered by the department. The vision standards are given in 761—604.11(321).

This rule is intended to implement Iowa Code sections 321.186 and 321.186A.

[**ARC 2071C**, IAB 8/5/15, effective 7/14/15; **ARC 2337C**, IAB 1/6/16, effective 2/10/16]

761—607.27(321) Knowledge tests.

607.27(1) *General knowledge test.* The general knowledge test for a commercial driver's license is a written test of topics such as vehicle inspection, operation, safety and control in accordance with 49 CFR Section 383.111.

607.27(2) *Additional tests.* In addition to the general knowledge test for a commercial driver's license, an additional knowledge test is required for each of the following:

a. Class A license for combination vehicle operation as required in 49 CFR Section 383.111.

b. Hazardous material endorsement as required in 49 CFR Section 383.121. The knowledge test for a hazardous material endorsement shall not be administered orally or in a language other than English.

c. Passenger vehicle endorsement as required in 49 CFR Section 383.117.

d. Tank vehicle endorsement as required in 49 CFR Section 383.119.

e. Double/triple trailer endorsement as required in 49 CFR Section 383.115.

f. School bus endorsement as required in 49 CFR Section 383.123. The applicant must also qualify for a passenger vehicle endorsement.

g. Removal of the air brake restriction as required in 49 CFR Section 383.111.

607.27(3) *Test methods.* All knowledge tests shall be administered in compliance with 49 CFR Section 383.133(b). All tests other than the hazardous material endorsement test may be administered in written form, verbally, or in automated format and can be administered in a foreign language, provided no interpreter is used in administering the test. A verbal test shall be offered only at specified locations. Information about the locations is available at any driver's license examination station.

607.27(4) *Waiver.* A waiver of any knowledge test is permitted only as provided in Iowa Code subsection 321.188(5). The burden of proof of having passed the hazardous material endorsement test within the preceding 24 months rests with the applicant.

607.27(5) *Requirement.* An applicant must pass the applicable knowledge test(s) before taking the skills test. Passing scores for a knowledge test shall meet the standards contained in 49 CFR Section 383.135(a).

This rule is intended to implement Iowa Code sections 321.186 and 321.188.

[**ARC 2071C**, IAB 8/5/15, effective 7/14/15; **ARC 2337C**, IAB 1/6/16, effective 2/10/16; **ARC 2530C**, IAB 5/11/16, effective 6/15/16]

761—607.28(321) Skills test.

607.28(1) *Content.* The skills test for a commercial driver's license is a three-part test as required in 49 CFR Part 383, Subparts E, G and H.

607.28(2) *Test methods.* All skills tests shall be administered in compliance with 49 CFR Section 383.133(c). Interpreters are prohibited during the administration of skills tests. Applicants must be able to understand and respond to verbal commands and instructions in English by a skills test examiner. Neither the applicant nor the examiner may communicate in a language other than English during the skills test.

607.28(3) *Order.* The skills test must be administered and successfully completed in the following order: pre-trip inspection, basic vehicle control skills, on-road skills. If an applicant fails one segment of the skills test, the applicant cannot continue to the next segment of the test, and scores for the passed segments of the test are only valid during initial issuance of the commercial learner's permit.

607.28(4) *Vehicle.* The applicant shall provide a representative vehicle for the skills test. "Representative vehicle" means a commercial motor vehicle that meets the statutory description for the class of license applied for.

a. To obtain a passenger vehicle endorsement applicable to a specific vehicle class, the applicant must take the skills test in a passenger vehicle, as defined in rule 761—607.3(321), satisfying the requirements of that class, as required in 49 CFR Section 383.117.

b. To obtain a school bus endorsement, the applicant must qualify for a passenger vehicle endorsement and take the skills test in a school bus, as defined in rule 761—607.3(321), in the same vehicle class as the applicant will drive, as required in 49 CFR Section 383.123. Up to and including September 30, 2005, the skills test for a school bus endorsement is waived for an applicant meeting the requirements of 49 CFR Section 383.123(b).

c. To remove an air brake or full air brake restriction, the applicant must take the skills test in a vehicle equipped with an air brake system, as defined in rule 761—607.3(321) and as required in 49 CFR Section 383.113.

d. To remove a manual transmission restriction, the applicant must take the skills test in a vehicle equipped with a manual transmission, as defined in rule 761—607.3(321).

607.28(5) *Skills test scoring.* Passing scores for a skills test shall meet the standards contained in 49 CFR Section 383.135(b).

607.28(6) *Military waiver.* The department may waive the requirement that an applicant pass a required skills test for an applicant who is on active duty in the military service or who has separated from such service in the past year, provided the applicant meets the requirements of Iowa Code subsection 321.188(6).

607.28(7) *Locations.* The skills test for a commercial driver's license shall be given only at specified locations where adequate testing facilities are available. An applicant may contact any driver's license examination station for the location of the nearest skills testing station. A skills test by appointment shall be offered only at specified regional test sites.

This rule is intended to implement Iowa Code sections 321.186 and 321.188.

[**ARC 2071C**, IAB 8/5/15, effective 7/14/15; **ARC 2337C**, IAB 1/6/16, effective 2/10/16; **ARC 2530C**, IAB 5/11/16, effective 6/15/16; **ARC 3689C**, IAB 3/14/18, effective 4/18/18]

761—607.29(321) Waiver of skills test. Rescinded IAB 6/23/93, effective 7/28/93.

761—607.30(321) Third-party testing.

607.30(1) *Purpose and definitions.* The skills test required by rule 761—607.28(321) may be administered by third-party testers and third-party skills test examiners approved and certified by the

department. For the purpose of administering third-party skills testing and this rule, the following definitions shall apply:

"Community college" means an Iowa community college established under Iowa Code chapter 260C.

"Iowa-based motor carrier" means a motor carrier or its subsidiary that has its principal place of business in the state of Iowa and operates a permanent commercial driver training facility in the state of Iowa.

"Motor carrier" means the same as defined in 49 CFR Section 390.5.

"Permanent commercial driver training facility" means a facility dedicated to a program of commercial driving instruction that is offered to employees or potential employees of the motor carrier as incident to the motor carrier's commercial operations, that requires at least 40 hours of instruction, and that includes fixed and permanent structures and facilities for the off-road portions of commercial driving instruction, including classroom, pretrip inspection, and basic vehicle control skills. A permanent commercial driver training facility must include a fixed and paved or otherwise hard-surfaced area for basic vehicle control skills testing that is permanently marked and capable of inspection and measurement by the department.

"Skills test" means the skills test required by rule 761—607.28(321).

"Subsidiary" means a company that is partly or wholly owned by a motor carrier that holds a controlling interest in the subsidiary company.

"Third-party skills test examiner" means the same as defined in 49 CFR Section 383.5.

"Third-party tester" means the same as defined in 49 CFR Section 383.5.

607.30(2) *Certification of third-party testers.*

a. The department may certify as a third-party tester a community college or Iowa-based motor carrier to administer skills tests. A community college or Iowa-based motor carrier that seeks certification as a third-party tester shall contact the department's office of driver services and schedule a review of the proposed testing program, which shall include the proposed testing courses and facilities, information sufficient to identify all proposed third-party skills test examiners, and any other information necessary to demonstrate compliance with 49 CFR Section 383.75.

b. No community college or Iowa-based motor carrier shall be certified to conduct third-party testing unless and until the community college or Iowa-based motor carrier enters an agreement with the department that meets the requirements of 49 CFR Section 383.75 and demonstrates sufficient ability to conduct skills tests in a manner that consistently meets the requirements of 49 CFR Section 383.75.

c. The department shall issue a certified third-party tester a certificate of authority that identifies the classes and types of vehicles for which skills tests may be administered. The certificate shall be valid for the duration of the agreement executed pursuant to paragraph 607.30(2)*"b,"* unless revoked by the department for engaging in fraudulent activities related to conducting skills tests or failing to comply with the requirements, qualifications, and standards of this chapter, the agreement, or 49 CFR Section 383.75.

607.30(3) *Certification of third-party skills test examiners.*

a. A certified third-party tester shall not employ or otherwise use as a third-party skills test examiner a person who has not been approved and certified by the department to administer skills tests. Each certified third-party tester shall submit for approval the names of all proposed third-party skills test examiners on a form provided by the department. The department shall not approve as a third-party skills test examiner a person who does not meet the requirements, qualifications and standards of 49 CFR Sections 383.75 and 384.228, including but not limited to all required training and examination and a nationwide criminal background check. The criteria for passing the nationwide criminal background check shall include no felony convictions within the last ten years and no convictions involving fraudulent activities.

b. The department shall issue a certificate of authority for each person certified as a third-party skills test examiner that identifies the certified third-party tester for which the person will administer skills tests and the classes and types of vehicles for which the person may administer skills tests. The certificate shall be valid for a period of four years from the date of issuance of the certificate.

c. The department shall revoke the certificate if the person holding the certificate does not administer skills tests to at least ten different applicants per calendar year; does not successfully complete the refresher training required by 49 CFR Section 384.228 every four years; is involved in fraudulent activities related to conducting skills tests; or otherwise fails to comply with and meet the requirements, qualifications and standards of this chapter or 49 CFR Sections 383.75 and 384.228.

d. A third-party skills test examiner who is also a skills instructor shall not administer a skills test to an applicant who received skills training from that third-party skills test examiner.

607.30(4) *Bond.* As a condition of certification, an Iowa-based motor carrier must maintain a bond in the amount of $50,000 to pay for the retesting of drivers in the event that the third-party tester or one or more of its third-party skills test examiners are involved in fraudulent activities related to conducting skills tests of applicants for a commercial driver's license.

607.30(5) *Limitation applicable to Iowa-based motor carriers.* An Iowa-based motor carrier certified as a third-party tester may only administer the skills test to persons who are enrolled in the Iowa-based motor carrier's commercial driving instruction program and shall not administer skills tests to persons who are not enrolled in that program.

607.30(6) *Training and refresher training for third-party skills test examiners.* All training and refresher training required under this rule shall be provided by the department, in form and content that meet the recommendations of the American Association of Motor Vehicle Administrators' International Third-Party Examiner/Tester Certification Program.

This rule is intended to implement Iowa Code section 321.187.

[**ARC 2530C**, IAB 5/11/16, effective 6/15/16]

761—607.31(321) Test results.

607.31(1) *Period of validity.* Passing knowledge and skills test results shall remain valid for a period of one year.

607.31(2) *Retesting.* Subject to rule 761—607.28(321), an applicant shall be required to repeat only the knowledge test(s) or part(s) of the skills test that the applicant failed. An applicant who fails a test shall not be permitted to repeat that test the same day.

607.31(3) *Skills test results from other states.* As required by 49 CFR Section 383.79, the department shall accept the valid results of a skills test administered to an applicant who is domiciled in the state of Iowa and that was administered by another state, in accordance with 49 CFR Part 383, Subparts F, G and H, in fulfillment of the applicant's testing requirements under 49 CFR Section 383.71 and the state's test administration requirements under 49 CFR Section 383.73. The results must be transmitted directly from the testing state to the department as required by 49 CFR Section 383.79.

607.31(4) *Skills test results from certified third-party testers.* A third-party skills tester certified under rule 761—607.30(321) shall transmit the skills test results of tests administered by the third-party tester through secure electronic means determined by the department. The department may retest any person who has passed a skills test administered by a certified third-party tester if it appears to the department that the skills test administered by the third-party tester was administered fraudulently or improperly, and as needed to meet the third-party skills test examiner oversight requirements of 49 CFR Section 383.75(a)(5).

This rule is intended to implement Iowa Code sections 321.180, 321.186, 321.187 and 321.188.

[**ARC 2071C**, IAB 8/5/15, effective 7/14/15; **ARC 2337C**, IAB 1/6/16, effective 2/10/16; **ARC 2530C**, IAB 5/11/16, effective 6/15/16; **ARC 3689C**, IAB 3/14/18, effective 4/18/18]

761—607.32 to **607.34** Reserved.

761—607.35(321) Issuance of commercial driver's license and commercial learner's permit. A commercial driver's license or commercial learner's permit issued by the department shall include the information and markings required by Iowa Code section 321.189(2)*"b."*

This rule is intended to implement Iowa Code section 321.189.

[**ARC 2071C**, IAB 8/5/15, effective 7/14/15; **ARC 2337C**, IAB 1/6/16, effective 2/10/16; **ARC 2530C**, IAB 5/11/16, effective 6/15/16]

761—607.36(321) Conversion to commercial driver's license. Rescinded IAB 6/23/93, effective 7/28/93.

761—607.37(321) Commercial driver's license renewal. The department shall administer commercial driver's license renewals as required by 49 CFR Section 383.73.

607.37(1) *Licensee requirements.* To renew a commercial driver's license, the licensee shall apply at a driver's license examination station and complete the following requirements:

a. The licensee shall make a written self-certification of type of driving as required by rule 761—607.50(321) and provide a current medical examiner's certificate if required.

b. If the licensee has and wishes to retain a hazardous material endorsement, the licensee shall pass the test required in 49 CFR Section 383.121 and comply with the Transportation Security Administration security threat assessment standards specified in 49 CFR Sections 383.71(b)(8) and 383.141 for such endorsement. A lawful permanent resident of the United States must also provide the licensee's U.S. Citizenship and Immigration Services alien registration number.

c. The licensee shall provide proof of citizenship or lawful permanent residency and state of domicile as required by rule 761—607.15(321) and 49 CFR 383.73(d)(7). Proof of citizenship or lawful permanent residency is not required if the licensee provided such proof at initial issuance or a previous renewal or upgrade of the license and the department has a notation on the licensee's record confirming that the required proof of legal citizenship or legal presence check was made and the date on which it was made.

d. If the licensee is domiciled in a foreign jurisdiction and renewing a non-domiciled commercial driver's license, the licensee must provide a document required by 49 CFR 383.71(f) at each renewal.

607.37(2) *Early renewal.* A valid commercial driver's license may be renewed 90 days before the expiration date. If this is impractical, the department for good cause may renew a license earlier, not to exceed 364 days prior to the expiration date. The department may allow renewal earlier than 364 days prior to the expiration date for active military personnel being deployed due to actual or potential military conflict.

This rule is intended to implement Iowa Code sections 321.186, 321.188 and 321.196.

[**ARC 2337C**, IAB 1/6/16, effective 2/10/16; **ARC 2337C**, IAB 1/6/16, effective 2/10/16; **ARC 2530C**, IAB 5/11/16, effective 6/15/16]

761—607.38(321) Transfers from another state. Upon initial application for an Iowa license, an Iowa resident who has a valid commercial driver's license from a former state of residence is not required to retest except as specified in Iowa Code subsection 321.188(5) but is required to pay the applicable endorsement and restriction removal fees.

This rule is intended to implement Iowa Code sections 321.188 and 321.191.

761—607.39(321) Disqualification.

607.39(1) *Date.* A disqualifying act, action or offense under Iowa Code section 321.208, that occurred before July 1, 1990, shall not be grounds for disqualification from operating a commercial motor vehicle.

607.39(2) *Notice.* A 30-day advance notice of disqualification shall be served by the department in accordance with rule 761—615.37(321). Pursuant to Iowa Code subsection 321.208(12), a peace officer on behalf of the department may serve the notice of disqualification immediately.

607.39(3) *Hearing and appeal process.* A person who has received a notice of disqualification may contest the disqualification in accordance with 761—615.38(17A,321).

607.39(4) *Reduction of lifetime disqualification.* Reserved.

This rule is intended to implement Iowa Code chapter 17A and section 321.208.

[**ARC 2530C**, IAB 5/11/16, effective 6/15/16]

761—607.40(321) Sanctions. When a person's motor vehicle license is denied, canceled, suspended, revoked or barred, the person is also disqualified from operating a commercial motor vehicle.

This rule is intended to implement Iowa Code section 321.208.

761—607.41 to **607.44** Reserved.

761—607.45(321) Reinstatement. To reinstate a commercial driver's license after completion of a period of disqualification, a person shall appear at a driver's license examination station. The person must also meet the vision standards for licensing, pass the applicable knowledge test(s) and the skills test, and pay the required reinstatement fee and the fees for a new license.

This rule is intended to implement Iowa Code sections 321.191 and 321.208.

761—607.46 to **607.48** Reserved.

761—607.49(321) Restricted commercial driver's license.

607.49(1) *Scope.* This rule pertains to the issuance of restricted commercial driver's licenses to suppliers or employees of suppliers of agricultural inputs. Issuance is permitted by 49 CFR 383.3(f). A restricted commercial driver's license shall meet all requirements of a regular commercial driver's license, as set out in Iowa Code chapter 321 and this chapter of rules, except as specified in this rule.

607.49(2) *Agricultural inputs.* The term "agricultural inputs" means suppliers or applicators of agricultural chemicals, fertilizer, seed or animal feeds.

607.49(3) *Validity.*

a. A restricted commercial driver's license allows the licensee to drive a commercial motor vehicle for agricultural input purposes. The license is valid to:

(1) Operate Group B and Group C commercial motor vehicles including tank vehicles and vehicles equipped with air brakes, except passenger vehicles.

(2) Transport the hazardous materials listed in paragraph 607.49(3)*"b."*

(3) Operate only during the current, validated seasonal period.

(4) Operate between the employer's place of business and the farm currently being served, not to exceed 150 miles.

b. A restricted commercial driver's license is not valid for transporting hazardous materials requiring placarding, except as follows:

(1) Liquid fertilizers such as anhydrous ammonia may be transported in vehicles or implements of husbandry with total capacities of 3,000 gallons or less.

(2) Solid fertilizers such as ammonium nitrate may be transported provided they are not mixed with any organic substance.

(3) A hazardous material endorsement is not needed to transport the products listed in the preceding subparagraphs.

c. When not driving for agricultural input purposes, the license is valid for operating a noncommercial motor vehicle that may be legally operated under the noncommercial license held by the licensee.

607.49(4) *Requirements.*

a. The applicant must have two years of previous driving experience. This means that the applicant must have held a license that permits unaccompanied driving for at least two years. This does not include a motorized bicycle license, a minor's school license or a minor's restricted license.

b. The applicant must have a good driving record for the most recent two-year period, as defined in subrule 607.49(5).

c. An applicant who currently holds a commercial driver's license or a commercial learner's permit is not eligible for issuance of a restricted commercial driver's license.

607.49(5) *Good driving record.* A "good driving record" means a driving record showing:

a. No multiple licenses.

b. No driver's license suspensions, revocations, disqualifications, denials, bars, or cancellations of any kind.

c. No convictions in any type of motor vehicle for:

(1) Driving under the influence of alcohol or drugs.

(2) Leaving the scene of an accident.

(3) Committing any felony involving a motor vehicle.
(4) Speeding 15 miles per hour or more over the posted speed limit.
(5) Reckless driving, drag racing, or eluding or attempting to elude a law enforcement officer.
(6) Improper or erratic lane changes.
(7) Following too closely.
(8) A moving violation that contributed to a motor vehicle accident.
(9) A violation deemed serious under rule 761—615.17(321).

d. No record of contributive accidents, as defined in rule 761—615.1(321).

607.49(6) *Issuance.*

a. The knowledge and skills tests described in rules 761—607.27(321) and 761—607.28(321) are waived.

b. A restricted commercial driver's license shall be coded with restriction "W" on the face of the driver's license, with the restriction explained in text on the back of the driver's license. In addition, the license shall be issued with a restriction stating the license's period of validity.

c. The expiration date for a restricted commercial driver's license that is converted to this license from another Iowa license shall carry the same expiration date as the previous license.

d. A restricted commercial driver's license may be renewed for the period of time specified in Iowa Code section 321.196. The licensee's good driving record shall be confirmed at the time of renewal.

e. The fee for a restricted commercial driver's license shall be as specified in Iowa Code section 321.191.

f. On or before December 31, 2016, there are two periods of validity for commercial motor vehicle operation: March 15 through June 30, and October 4 through December 14. Validity shall not exceed 180 days in any 12-month period. Any period of validity authorized previously by another state's license shall be considered a part of the 180-day maximum period of validity.

g. On or after January 1, 2017, a licensee may have up to three individual periods of validity for a restricted commercial driver's license, provided the cumulative period of validity for all individual periods does not exceed 180 days in any calendar year. An individual period of validity may be 60, 90, or 180 consecutive days, at the election of the licensee. A licensee may add 30 days to an individual period of validity by applying for an extension, subject to the 180-day cumulative maximum period of validity. A request for extension must be made no later than the date of expiration of the individual period of validity for which an extension is requested; a request for extension made after that date shall be treated as a request for a new individual period of validity. An extension shall be calculated from the date of expiration of the individual period of validity for which an extension is requested. Any period of validity authorized previously by another state's license shall be considered a part of the 180-day cumulative maximum period of validity.

h. A restricted commercial driver's license must be validated for commercial motor vehicle operation for each individual period of validity. This means that the applicant/licensee must have the person's good driving record confirmed at each application for an individual period of validity. Upon confirmation, the department shall issue a replacement license with a restriction validating the license for that individual period of validity, provided the person is otherwise eligible for the license. The fee for a replacement license shall be as specified in Iowa Code section 321.195.

i. The same process must be repeated for each individual period of validity within a calendar year.

This rule is intended to implement Iowa Code section 321.176B.

[**ARC 2071C**, IAB 8/5/15, effective 7/14/15; **ARC 2337C**, IAB 1/6/16, effective 2/10/16; **ARC 2530C**, IAB 5/11/16, effective 6/15/16]

761—607.50(321) Self-certification of type of driving and submission of medical examiner's certificate.

607.50(1) *Applicants for commercial learner's permit or new, transferred, renewed or upgraded CDL.*

a. A person shall provide to the department a self-certification of type of driving if the person is applying for:

(1) A commercial learner's permit,

(2) An initial commercial driver's license,

(3) A transfer of a commercial driver's license from a prior state of domicile to the state of Iowa,

(4) Renewal of a commercial driver's license, or

(5) A license upgrade for a commercial driver's license or an endorsement authorizing the operation of a commercial motor vehicle not covered by the current commercial driver's license.

b. The self-certification shall be on a form or in a format, which may be electronic, as provided by the department.

607.50(2) *Submission of medical examiner's certificate by persons certifying to non-excepted interstate driving.* Every person who self-certifies to non-excepted interstate driving must give the department a copy of the person's current medical examiner's certificate. A person who fails to provide a required medical examiner's certificate shall not be allowed to proceed with an initial issuance, transfer, renewal, or upgrade of a license until the person gives the department a medical examiner's certificate that complies with the requirements of this subrule, or changes the person's self-certification of type of driving to a type other than non-excepted interstate driving. For persons submitting a current medical examiner's certificate, the department shall post a medical certification status of "certified" on the person's CDLIS driver's record. A person who self-certifies to a type of driving other than non-excepted interstate shall have no medical certification status on the CDLIS driver's record.

607.50(3) *Maintaining certified status.* To maintain a medical certification status of "certified," a person who self-certifies to non-excepted interstate driving must give the department a copy of each subsequently issued medical examiner's certificate valid for the person. The copy must be given to the department at least ten days before the previous medical examiner's certificate expires.

607.50(4) *CDL downgrade.* If the medical examiner's certificate or medical variance for a person self-certifying to non-excepted interstate driving expires or if the Federal Motor Carrier Safety Administration notifies the department that the person's medical variance was removed or rescinded, the department shall post a medical certification status of "not certified" to the person's CDLIS driver's record and shall initiate a downgrade of the person's commercial driver's license or commercial learner's permit. The medical examiner's certificate of a person who fails to maintain a medical certification status of "certified" as required by subrule 607.50(3) shall be deemed to be expired on the date of expiration of the last medical examiner's certificate filed for the person as shown by the person's CDLIS driver's record. The downgrade will be initiated and completed as follows:

a. The department shall give the person written notice that the person's medical certification status is "not certified" and that the commercial motor vehicle privileges will be removed from the person's commercial driver's license or commercial learner's permit 60 days after the date the medical examiner's certificate or medical variance expired or the medical variance was removed or rescinded unless the person submits to the department a current medical certificate or medical variance or self-certifies to a type of driving other than non-excepted interstate.

b. If the person submits a current medical examiner's certificate or medical variance before the end of the 60-day period, the department shall post a medical certification status of "certified" on the person's CDLIS driver's record and shall terminate the downgrade of the person's commercial driver's license or commercial learner's permit.

c. If the person self-certifies to a type of driving other than non-excepted interstate before the end of the 60-day period, the department shall not remove the commercial motor vehicle privileges from the person's commercial driver's license or commercial learner's permit, and the person will have no medical certification status on the person's CDLIS driver's record.

d. If the person fails to take the action in either paragraph 607.50(4)*"b"* or *"c"* before the end of the 60-day period, the department shall remove the commercial motor vehicle privileges from the person's commercial driver's license or commercial learner's permit and shall leave the person's medical certification status as "not certified" on the person's CDLIS driver's record.

607.50(5) *Establishment or reestablishment of "certified" status.* A person who has no medical certification status or whose medical certification status has been posted as "not certified" on the person's CDLIS driver's record may establish or reestablish the status as "certified" by submitting a current medical examiner's certificate or medical variance to the department. A person who has failed

to self-certify to a type of driving or has self-certified to a type of driving other than non-excepted interstate must also make a self-certification of type of driving to non-excepted interstate driving. The department shall then post a medical certification status of "certified" on the person's CDLIS driver's record.

607.50(6) *Reestablishment of the CDL privilege.* A person whose commercial motor vehicle privileges have been removed from the person's commercial driver's license or commercial learner's permit under the provisions of paragraph 607.50(4)*"d"* may reestablish the commercial motor vehicle privileges by either of the following methods:

a. Submitting a current medical examiner's certificate or medical variance to the department. A person who has failed to self-certify to a type of driving must also make an initial self-certification of type of driving to non-excepted interstate driving. The department shall then post a medical certification status of "certified" on the person's CDLIS driver's record and reestablish the commercial motor vehicle privileges, provided that the person otherwise remains eligible for a commercial driver's license or commercial learner's permit.

b. Self-certifying to a type of driving other than non-excepted interstate. The department shall then reestablish the commercial motor vehicle privileges, provided that the person otherwise remains eligible for a commercial driver's license or commercial learner's permit; the person will have no medical certification status on the driver's CDLIS driver's record.

607.50(7) *Change of type of driving.* A person may change the person's self-certification of type of driving at any time. As required by subrule 607.50(2), a person certifying to non-excepted interstate driving must give the department a copy of the person's current medical examiner's certificate prepared by a medical examiner.

607.50(8) *Record keeping.* The department shall comply with the medical record-keeping requirements set forth in 49 CFR Section 383.73.

This rule is intended to implement Iowa Code sections 321.182, 321.188 and 321.207.

[**ARC 9954B**, IAB 1/11/12, effective 1/30/12; **ARC 0031C**, IAB 3/7/12, effective 4/11/12; **ARC 2071C**, IAB 8/5/15, effective 7/14/15; **ARC 2337C**, IAB 1/6/16, effective 2/10/16; **ARC 2530C**, IAB 5/11/16, effective 6/15/16]

761—607.51(321) Determination of gross vehicle weight rating.

607.51(1) *Actual weight prohibited.* In determining whether the vehicle is a representative vehicle for the skills test and the group of commercial driver's license for which the applicant is applying, the vehicle's gross weight rating or gross combination weight rating must be used, not the vehicle's actual gross weight or gross combination weight. For purposes of this rule, "gross weight rating" and "gross combination weight rating" mean as defined in 49 CFR Section 383.5.

607.51(2) *Vehicle without legible manufacturer's certification label.* To complete a skills test using a vehicle that has no legible manufacturer's certification label, whether a power unit or towed vehicle, the applicant must provide documentation of the vehicle's gross vehicle weight rating, such as a manufacturer's certificate of origin, a title, or the vehicle identification number information for the vehicle. In the absence of such documentation, the vehicle may not be used, either alone or in combination.

This rule is intended to implement Iowa Code section 321.1.

[**ARC 2071C**, IAB 8/5/15, effective 7/14/15; **ARC 2337C**, IAB 1/6/16, effective 2/10/16; **ARC 2530C**, IAB 5/11/16, effective 6/15/16]

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