

CHAPTER 201
ORGANIZED DELIVERY SYSTEMS
LICENSURE AND REGULATION

641—201.1(135,75GA,ch158) Purpose and scope. The following rules developed by the department of public health govern the organization and regulation of organized delivery systems, also referred to as accountable health plans, pursuant to the authority set forth by the Seventy-fifth General Assembly in Senate File 380, which can also be found in chapter 158 of the 1993 Iowa Acts. It is the intent of these rules to allow for flexibility in the formation of organized delivery systems while ensuring accountability for the cost, quality and access to health care for those they serve. This chapter shall apply to all organized delivery systems operating in this state or providing coverage to Iowa residents. This chapter is not intended to apply to entities that fall under the regulation of the division of insurance.

641—201.2(135,75GA,ch158) Definitions.

“*Accountable health plan (AHP)*” means a type of organized delivery system.

“*Commissioner*” means the commissioner of insurance.

“*Coverage decision*” means a final adverse decision based on medical necessity. This definition does not include a denial of coverage for a service or treatment specifically listed in plan or evidence of coverage documents as excluded from coverage.

“*Department*” means the department of public health.

“*Director*” means the director of the department of public health.

“*Emergency medical condition*” means a medical condition that manifests itself by symptoms of sufficient severity, including but not limited to severe pain, that an ordinarily prudent person, possessing average knowledge of medicine and health, could reasonably expect the absence of immediate medical attention to result in one of 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 function.
3. Serious dysfunction of a bodily organ or part.

“*Emergency services*” means covered inpatient and outpatient health care services that are furnished by a health care provider who is qualified to provide the services that are needed to evaluate or stabilize an emergency medical condition.

“*Enrollee*” means an individual, or an eligible dependent, who receives health care benefits coverage through an organized delivery system.

“*Essential community providers*” means those publicly funded health care providing organizations which the director deems to be vital to a local health care delivery system to ensure that all vulnerable populations in Iowa have assured access to health care.

“*Independent review entity*” means a reviewer or entity, certified by the commissioner pursuant to Iowa Code section 514J.6 [1999 Iowa Acts, chapter 41, section 12].

“*Organized delivery system (ODS)*” means an organization with defined governance that is responsible for delivering or arranging to deliver the full range of health care services covered under a standard benefit plan and is accountable to the public for the cost, quality and access of its services and for the effect of its services on their health. The organization operating as an ODS shall assume risk and be subject to solvency standards as found in 201.12(135,75GA,ch158).

“*Primary care*” means essential, community-based health care services that are coordinated, comprehensive, accountable and accessible on a first contact and on an ongoing basis. Primary care includes diagnosis and treatment, prevention, maintenance, management of chronic problems, and linkages for specialized care.

“*Standard benefit plan*” means, at a minimum, the same benefit plan that is required of small group insurers under Iowa Code chapter 513B.

“Utilization review” means a program or process by which an evaluation is made of the necessity, appropriateness, and efficiency of the use of health care services, procedures, or facilities given or proposed to be given to an individual within this state. Such evaluation does not apply to requests by an individual or provider for a clarification, guarantee, or statement of an individual’s health insurance coverage or benefits provided under a health insurance policy, nor to claims adjudication. Unless it is specifically stated, verification of benefits, preauthorization, or a prospective or concurrent utilization review program or process shall not be construed as a guarantee or statement of insurance coverage or benefits for any individual under a health insurance policy.

641—201.3(135,75GA,ch158) Application. An ODS shall not operate in Iowa without an approved application from the department. An application on forms provided by the department accompanied by a filing fee of \$2,000 (a portion of this fee is for the solvency review) payable to the department, shall be completed by an authorized representative of the organized delivery system. The application shall be submitted in duplicate. An application shall not be deemed to be filed until all information necessary to properly process said application has been received by the department; this includes information that addresses rules 201.4(135,75GA,ch158) through 201.15(135,75GA,ch158). The application shall set forth or be accompanied by the following:

1. A copy of the basic organizational document of the applicant such as the articles of incorporation, articles of association, partnership agreement, trust agreement, or other applicable documents and all of its amendments.
2. A copy of the bylaws, rules or similar document, if any, regulating the governance and the conduct of the internal affairs of the applicant.
3. A list of names, addresses and official position of the persons who are to be responsible for the conduct of the affairs of the applicant, including all members of the board of directors, board of trustees, executive committee, or other governing board or committee, the principal officers of a corporation and the partners or members if a partnership or association.
4. A copy of the form of evidence of coverage.
5. A copy of the form of the group contract, if any, which is to be issued to employers, unions, trustees or other organizations.
6. Financial statements showing the applicant’s current assets, liabilities and sources of financial support. If the applicant’s financial affairs are audited by an independent certified public accountant, a copy of the applicant’s most recent regular certified financial statement shall satisfy this requirement unless the department directs that additional financial information is required.
7. A description of the proposed method of marketing the plan, a financial plan which includes a three-year projection of operating results anticipated, and a statement as to the sources of funding.
8. A statement describing the geographic area to be served.
9. A description of the complaint procedures to be utilized.
10. A sample copy of the provider contract for risk-bearing providers.

641—201.4(135,75GA,ch158) Governing body. An organized delivery system shall have a basic written organizational document setting forth its scheme of organization and establishing a governing body appropriate to its form of organization. The governing body shall be responsible for matters of policy and operation.

201.4(1) The ODS shall provide for enrollee representation on the governing body. The organizational document shall describe what this representation shall be and the method the ODS proposes to use to achieve enrollee representation.

201.4(2) Advisory committee. An ODS shall have an enrollee advisory committee to the board. The majority of the members of this advisory committee shall be enrollees with no official capacity within the ODS.

641—201.5(135,75GA,ch158) Service area/geographic access.

201.5(1) An organized delivery system shall establish its own service area subject to approval by the department. The department shall approve only service areas where the county was used as the basic building block.

201.5(2) The ODS's plan of operation shall address the capability of the ODS to serve an enrollee residing anywhere in the service area.

201.5(3) ODSs shall cover emergency care to enrollees who are traveling outside the ODS's service area. The ODS may impose copayments or deductibles for such care to the extent permitted by the enrollee's policy and may require the enrollee to return to the service area for continuing treatment as soon as the enrollee's condition reasonably permits such travel.

201.5(4) An ODS shall provide geographic access to its enrollees within its service area as follows:

- a.* Primary care shall be available within 30 minutes' travel time.
- b.* Primary inpatient hospital care shall be available within 60 minutes' travel time. Inpatient hospital services at a secondary or tertiary level may be made available at a referral center exceeding the 60-minute limit and may be located outside the service area.
- c.* The above requirements do not require that care be provided within the state of Iowa.

201.5(5) A licensed ODS wishing to expand its service area shall seek approval from the department for the expansion. The ODS shall submit evidence that the requirements of subrules 201.5(1) through 201.5(4) can be met for the additional counties.

641—201.6(135,75GA,ch158,78GA,ch41) Provider network and contracts; treatment and services.

201.6(1) Each ODS shall have flexibility in establishing a provider network to achieve the balance of providers which best meets the needs of its enrollees. An ODS may determine its own standards and criteria by which it determines which providers will be included in its network. These standards and criteria shall be public and the ODS shall be held accountable for abiding by the standards and criteria. An ODS shall establish an internal first level provider appeal process.

201.6(2) An ODS shall not use the design of its provider network as a means for discouraging enrollment from high-risk or special needs populations.

201.6(3) Each ODS shall provide data to the department on the utilization of all providers by its enrollees, by provider type. This information shall be disseminated as part of the ODS report card.

201.6(4) A list of available ODS providers, which shall be updated at least once a year, shall be provided to enrollees on request.

201.6(5) An ODS shall be encouraged to establish working relationships with essential community providers. The department shall provide for the identification of essential community providers within the service area of each ODS. The director shall establish criteria for essential community provider designation. The criteria shall focus on:

- a.* Whether the provider has a demonstrated record of service to impoverished or medically underserved populations which face language, ethnic, or cultural barriers to health care access or which have health care needs that are not being met by other providers in the geographic area; and
- b.* Whether the provider is an entity who serves all patients regardless of ability to pay and who charges for services on an income-based sliding fee schedule.

201.6(6) Emergency services. Emergency services, as defined in rule 201.2(135,75GA,ch158), shall be provided by the ODS, either through its own facilities or through guaranteed arrangements with other providers, on a 24-hour basis.

a. A physician and sufficient other licensed and ancillary personnel shall be readily available at all times to render such services.

b. Since ODSs are not required to contract with every emergency care provider in an area, ODSs shall make every effort to inform enrollees of participating providers.

c. Reimbursement to a provider of emergency services shall not be denied by any ODS without review of the patient's medical history, presenting symptoms, and admitting or initial as well as final diagnosis, submitted by the provider, in determining whether, by definition, emergency services could reasonably have been expected to be provided.

d. Reimbursement for emergency services shall not be denied solely on the grounds that services were performed by a noncontracted provider. Coverage for emergency services is subject to the terms and conditions of the health plan or contract.

e. If reimbursement for emergency services is denied, the enrollee may file a complaint with the ODS as outlined in rule 201.7(135,75GA,ch158). Upon denial of reimbursement for emergency services, the ODS shall notify the enrollee and the provider that they may register a complaint with the department.

f. Prior authorization for emergency services shall not be required. All services necessary to evaluate and stabilize an emergency medical condition shall be considered covered emergency services.

201.6(7) All provider contracts shall contain the following provisions:

a. (Provider), or its assignee or subcontractor, hereby agrees that in no event, including, but not limited to, nonpayment by the ODS, ODS insolvency or breach of this agreement, shall (provider), or its assignee or subcontractor, bill, charge, collect a deposit from, seek compensation, remuneration or reimbursement from, or have any recourse against subscriber/enrollee or persons other than the ODS acting on their behalf for services provided pursuant to this agreement. This provision shall not prohibit collection of supplemental charges or copayments on an ODS's behalf made in accordance with the terms of (applicable agreement) between an ODS and subscriber/enrollee.

b. (Provider), or its assignee or subcontractor, further agrees that (1) this provision shall survive the termination of this agreement regardless of the cause giving rise to termination and shall be construed to be for the benefit of the ODS subscriber/enrollee and that (2) this provision supersedes any oral or written contrary agreement now existing or hereafter entered into between (provider) and subscriber/enrollee or persons acting on their behalf.

201.6(8) Prohibition of interference with medical communications.

a. An ODS shall not prohibit, penalize, or otherwise restrict a participating provider from advising an enrollee of the ODS about the health status of the enrollee or medical care or treatment of the enrollee's condition or disease, regardless of whether benefits for such care or treatment are provided under the plan, if the provider is acting within the lawful scope of practice.

b. An ODS shall not penalize a provider because the provider, in good faith, reports to state or federal authorities any act or practice by the ODS that, in the opinion of the provider, jeopardizes patient health or welfare.

c. An ODS shall not prohibit, penalize, or otherwise restrict a provider from advocating on behalf of a covered individual within a review or grievance process established by the organized delivery system.

201.6(9) Continuity of care—pregnancy.

a. An ODS that terminates its contract with a participating health care provider shall continue to provide coverage under the contract to a covered person in the second or third trimester of pregnancy for continued care from such health care provider. Such persons may continue to receive such treatment or care through postpartum care related to the child birth and delivery. Payment for covered benefits and benefit levels shall be according to the terms and conditions of the contract.

b. A covered person who makes an involuntary change in health plans may request that the new health plan cover the services of the covered person's physician specialist who is not a participating health care provider under the new health plan, if the covered person is in the second or third trimester of pregnancy. Continuation of such coverage shall continue through postpartum care related to the child birth and delivery. Payment for covered benefits and benefit level shall be according to the terms and conditions of the new health plan contract.

c. An ODS that terminates the contract of a participating health care provider for cause shall not be liable to pay for health care services provided by the health care provider to a covered person following the date of termination.

201.6(10) Continuity of care—terminal illness.

a. If an ODS terminates its contract with a participating health care provider, a covered individual who is undergoing a specified course of treatment for a terminal illness or a related condition, with the recommendation of the covered individual's treating physician licensed under Iowa Code chapter 148, 150, or 150A, may continue to receive coverage for treatment received from the covered individual's physician for the terminal illness or a related condition, for a period of up to 90 days. Payment for covered benefits and benefit level shall be according to the terms and conditions of the contract.

b. A covered person who makes a change in health plans involuntarily may request that the new health plan cover services of the covered person's treating physician licensed under Iowa Code chapter 148, 150, or 150A, who is not a participating health care provider under the new health plan, if the covered person is undergoing a specified course of treatment for a terminal illness or a related condition. Continuation of such coverage shall continue for up to 90 days. Payment for covered benefits and benefit levels shall be according to the terms and conditions of the contract.

c. Notwithstanding paragraphs "*a*" and "*b*" above, an ODS that terminates the contract of a participating health care provider for cause shall not be required to cover health care services provided by the health care provider to a covered person following the date of termination.

201.6(11) Experimental treatment review. An ODS that limits coverage for experimental medical treatment, drugs, or devices, shall develop and implement a procedure to evaluate experimental medical treatments.

a. A description of the procedure must be submitted to the division of insurance in writing and include, at a minimum:

(1) The process used to determine whether the ODS will provide coverage for new medical technologies and new uses of existing technologies;

(2) A requirement for review of information from appropriate government regulatory agencies and published scientific literature concerning new medical technologies, new uses of existing technologies, and the use of external experts in making decisions; and

(3) A process for a person covered under a plan or contract to request an appeal of a denial of coverage because the proposed treatment is experimental.

b. An evaluation of a particular treatment shall not be required more than once a year.

c. An ODS shall include appropriately licensed or qualified professionals in the evaluation process.

d. An ODS that limits coverage for experimental treatment, drugs, or devices shall clearly disclose such limitations in a contract, policy, or certificate of coverage.

201.6(12) Utilization review requirements. An organized delivery system that provides health benefits to a covered individual residing in this state shall not conduct utilization review, either directly or indirectly, under a contract with a third party who does not meet the requirements established for accreditation by the Utilization Review Accreditation Commission, National Committee on Quality Assurance, or another national accreditation entity recognized and approved by the commissioner. This subrule does not apply to any utilization review performed solely under contract with the federal government for review of patients eligible for services under any of the following:

1. Title XVIII of the federal Social Security Act.

2. The civilian health and medical program of the uniformed services.

3. Any other federal employee health benefit plan.

641—201.7(135,75GA,ch158) Complaints. Each ODS shall provide in its bylaws for a system to resolve and record complaints.

201.7(1) The complaint system shall provide for the resolution of the following kinds of complaints:

a. Complaints about the quality of health care services provided by the ODS.

b. Complaints about the availability of health care services.

c. Complaints relating to enrollee participation in the operation of the ODS.

d. Complaints relating to reimbursement.

201.7(2) An ODS shall submit to the department an annual report in a form prescribed by the department which shall include:

- a. A description of the procedures of the complaint system.
- b. The total number of complaints handled through the complaint system and a compilation of reasons underlying the complaints filed in accord with 201.7(1).
- c. The number, amount and disposition of malpractice claims settled during the year by the ODS and any of its providers.

641—201.8(135,75GA,ch158) Accountability. Accountability measures shall be in place to ensure access and quality of care. Each ODS shall provide information to the department on measures of quality, access, member satisfaction, membership and utilization, finance, and management. The department shall publish annually, by November 1 of each year, the indicators that will be required for the reporting year in a document that shall be shared with all licensed ODSs as well as all applicants. Indicators shall be based upon nationally recognized, documented standards.

201.8(1) Quality. The department shall establish indicators to measure the quality of care provided by an ODS.

201.8(2) Access. The department shall establish indicators of access to care within an ODS. At least one of the indicators shall be the ratio of primary care providers to enrollees by category of provider.

201.8(3) Member satisfaction. The following shall be reported by the ODS to demonstrate member satisfaction.

- a. Percent of members indicating overall satisfaction with plan from a member survey.
- b. Submission of a copy of the member satisfaction survey used by the ODS.

201.8(4) Membership and utilization. Indicators of utilization shall be established by the department for costs, frequency of procedures, inpatient and outpatient services. Indicators of membership shall include the following:

- a. Member months stratified by age, gender, residence, and purchaser.
- b. Disenrollments by month stratified by age, gender, residence, and purchaser.

201.8(5) Finance. Indicators of financial stability and solvency shall be reported according to the standard established in rules 201.12(135,75GA,ch158) and 201.13(135,75GA,ch158).

201.8(6) Management practices. Management practices shall be described for the following areas:

- a. Credentialing. The ODS shall describe its credentialing process as provided for in 201.6(1).
- b. Points of service. The ODS shall provide information on the location of providers, including primary care providers, specialty providers, and hospitals, as provided for in 201.5(4).
- c. Quality assessment and improvement activities.
- d. Case management.
- e. Risk management.
- f. Community needs assessments.
- g. Relationships with essential community providers.
- h. Efforts to address the needs of underserved populations and geographic areas.

641—201.9(135,75GA,ch158) Reporting.

201.9(1) An ODS shall, as part of the application for licensure, submit documentation of ability to comply or plans to achieve compliance with the reporting of the accountability requirements.

201.9(2) Narrative information shall be submitted in report format as specified by the department. Until such time that the data for the calculation of the indicators is available from the Community Health Management Information System (CHMIS), the ODS shall submit the calculated indicator, including documentation of the numerator and denominator used, to the department.

201.9(3) Reports shall be based upon calendar year information. Narrative information shall be submitted within 90 days of the close of the reporting period. Indicator reports shall be submitted within 45 days of the end of each quarter.

201.9(4) The department or its subcontractor shall have the right to validate reports, including record review and site visits. Reasonable costs related to this review shall be the responsibility of the ODS.

641—201.10(135,75GA,ch158) Evaluation. The department shall adopt nationally recognized benchmarks for indicators of quality and access. The department shall seek input and advice from the provider community on the indicators and benchmarks. These benchmarks will include minimum performance standards for identifying ODSs with deficit performance. The department shall establish criteria for issuing provisional licenses and corrective plans of action. Evaluation criteria shall be published annually with the indicators and shall be based upon established criteria. Utilization, member satisfaction, and management information shall be reported as submitted without established benchmarks.

641—201.11(135,75GA,ch158) Annual report. The department shall publish annually a report comparing all ODSs licensed in the state on all information contained in 201.8(135,75GA,ch158). The report shall also include comparisons by geographic area.

641—201.12(135,75GA,ch158) Finance and solvency. Solvency oversight shall be conducted by the division of insurance under an agreement with the department with examination fees paid as provided for in 201.3(135,75GA,ch158). For purposes of finance and solvency, including investments as detailed in 201.13(135,75GA,ch158), the ODS submits to the jurisdiction of the insurance division.

201.12(1) Accounting system. Statutory accounting principles shall apply to ODSs to ensure the accurate and complete reporting of financial information. Any premium or assessment amount that is not paid within three months of the due date shall be assumed uncollectible for financial statement purposes and in considering the amount of assessments and dividends.

201.12(2) Unencumbered funds. ODSs shall maintain at all times unencumbered funds that are the greater of:

a. \$1 million; or

b. Three times its average monthly claims for third-party providers. Average monthly expenditure is defined as liabilities incurred, including those which are outstanding. In addition to the requirements set forth above, the required unencumbered funds may be increased when, in the insurance commissioner's judgment, it is necessary to do so to protect the enrollees of the ODS.

201.12(3) Bond requirement. ODSs shall obtain a surety bond designating the commissioner of insurance as beneficiary in the event of the insolvency of the ODS in the amount and form acceptable to the commissioner of insurance.

201.12(4) Financially impaired or insolvent ODSs. The provisions of Iowa Code chapter 507C shall apply to ODSs, which shall be considered insurers for the purposes of chapter 507C. All HMOs and ODSs in the state operating within the service area of the ODS will provide a 30-day open enrollment in the event of insolvency of the ODS with no underwriting or preexisting conditions imposed. The open enrollment plan shall be actuarially equivalent to the standard benefit plan adopted by the small group reinsurance board.

201.12(5) Examination. The commissioner of insurance shall make an examination of the affairs of any ODS and its providers as often as the commissioner deems necessary for the protection of the interests of the residents of Iowa, but not less frequently than once every five years. Iowa Code chapter 507 shall be applicable to the examination of ODSs. The expense of such examination shall be assessed against the ODS in the same manner that insurers are assessed for examinations pursuant to chapter 507. ODS providers shall agree to fully cooperate with the insurance commissioner in providing access to books and records necessary for the commissioner to perform the examination process.

201.12(6) *Annual financial statement.* An ODS shall annually, on or before March 1 of each year, file with the commissioner of insurance an annual financial statement, covering the preceding calendar year, in a form prescribed by the commissioner. Such statement shall be verified by at least two of the ODS's principal officers. The ODS shall also file at this time an independent actuarial opinion certifying the adequacy of the ODS unencumbered funds. The commissioner may also request quarterly filings.

641—201.13(135,75GA,ch158) Investment.

201.13(1) All ODS assets, including unencumbered funds referenced in subrule 201.12(2), shall be invested only in securities or other investments as follows:

a. All investments made pursuant to this subrule shall have investment qualities and characteristics such that the speculative elements are not predominant.

b. Financial terms relating to an ODS have the meanings assigned to them under statutory accounting methods.

c. Investments shall be valued in accordance with the valuation procedures established by the National Association of Insurance Commissioners, unless the commissioner requires or finds another method of valuation reasonable under the circumstances.

d. If an investment qualifies under more than one subrule, the ODS may elect to hold the investment under the subrule of its choice.

201.13(2) An ODS's investments shall be held in its own name or the name of its nominee, except as follows:

a. Investments may be held in the name of a clearing corporation or of a custodian bank or in the name of the nominee of either on the following conditions:

(1) The clearing corporation, custodian bank, or nominee must be legally authorized to hold the particular investment for the account of others.

(2) When the investment is evidenced by a certificate and held in the name of a custodian bank or the nominee of a custodian bank, a written agreement shall provide that certificates so deposited shall at all times be kept separate and apart from other deposits with the depository, so that at all times they may be identified as belonging solely to the ODS making the deposit.

(3) If a clearing corporation is to act as depository, the investment may be merged or held in bulk in the name of the clearing corporation or its nominee with other investments deposited with the clearing corporation by any other person, if a written agreement between the clearing corporation and the ODS provides that adequate evidence of the deposit is to be obtained and retained by the ODS or a custodian bank.

b. An ODS may loan stocks or obligations held by it under this rule to a broker-dealer registered under the federal Securities Exchange Act of 1934 or to a member bank. The loan must be evidenced by a written agreement which provides all of the following:

(1) That the loan shall be fully collateralized by cash or obligations issued or guaranteed by the United States or any agency or an instrumentality of the United States and that the collateral shall be adjusted as necessary each business day during the term of the loan to maintain the required collateralization in the event of market value changes in the loaned securities or collateral.

(2) That the loan may be terminated by the ODS at any time and that the borrower shall return the loaned stocks or obligations within five business days after termination.

(3) That the ODS shall have the right to retain the collateral or use the collateral to purchase investments equivalent to the loaned securities if the borrower defaults under the terms of the agreement and that the borrower shall remain liable for any losses and expenses incurred by the association due to default that are not covered by the collateral.

c. An ODS may participate through a member bank in the United States federal reserve book entry system, and the records of the member bank shall at all times show that the investments are held for the ODS or for specific accounts of the ODS.

d. An investment may consist of an individual interest in a pool of obligations or a fractional interest in a single obligation if the certificate of participation or interest or the confirmation of participation or interest in the investment is issued in the name of the ODS, the name of the custodian bank, or the nominee of either, and, if the interest as evidenced by the certificate or confirmation is, if held by a custodian bank, kept separate and apart from the investments of others so that at all times the participation may be identified as belonging solely to the ODS making the investment.

e. Transfers of ownership of investments held as described in subparagraph 201.13(2)“a”(3) and paragraphs 201.13(2)“c” and “d” may be evidenced by bookkeeping entry on the books of the issuer of the investment, its transfer or recording agent, or the clearing corporation without physical delivery of a certificate evidencing the ODS’s investment.

201.13(3) Except as provided in paragraph 201.13(2)“e,” if an investment is not evidenced by a certificate, adequate evidence of the ODS’s investment shall be obtained from the issuer or its transfer or recording agent and retained by the ODS, a custodian bank, or clearing corporation. Adequate evidence, for purposes of this subrule, means a written receipt or other verification issued by the depository or issuer or a custodian bank which shows that the investment is held for the ODS.

201.13(4) Except as otherwise permitted by this rule, an ODS licensed under this chapter shall only invest in the following:

a. *United States government obligations.* Obligations issued or guaranteed by the United States or an agency or instrumentality of the United States.

b. *Certain development bank obligations.* Obligations issued or guaranteed by the international bank for reconstruction and development, the Asian development bank, the inter-American development bank, the export-import bank, the world bank, or any United States government-sponsored organization of which the United States is a member, if the principal and interest is payable in United States dollars. An ODS shall not invest more than 5 percent of its total admitted assets in the obligations of any one of these banks or organizations and shall not invest more than a total of 10 percent of its total admitted assets in the obligations authorized by this subrule.

c. *State obligations.* Obligations issued or guaranteed by a state, a political subdivision of a state, or an instrumentality of a state.

d. *Canadian government obligations.* Obligations issued or guaranteed by Canada, by an agency or province of Canada, by a political subdivision of such province, or by an instrumentality of any of those provinces or political subdivisions.

e. *Corporate and business trust obligations.* Obligations issued, assumed, or guaranteed by a corporation or business trust organized under the laws of the United States or a state, or the laws of Canada or a province of Canada, provided that a company shall not invest more than 5 percent of its admitted assets in the obligations of any one corporation or business trust. Investments shall be made only in investment grade bonds.

f. Stocks. Common stocks, common stock equivalents, mutual fund shares securities convertible into common stocks or common stock equivalents, or preferred stocks issued or guaranteed by a corporation incorporated under the laws of the United States or a state, or the laws of Canada or a province of Canada. Aggregate investments in non-dividend-paying stocks shall not exceed 5 percent of unencumbered funds.

(1) Stocks purchased under this lettered paragraph shall not exceed 50 percent of unencumbered funds. With the approval of the commissioner of insurance, an ODS may invest any amount in common stocks, preferred stocks, or other securities of one or more subsidiaries provided that after such investments the insurer's surplus as regards policyholders will be reasonable in relation to the insurer's outstanding liabilities and adequate to its financial needs.

(2) An ODS shall not invest more than 10 percent of its unencumbered funds in the stocks of any one corporation.

g. Home office real estate. Funds may be invested in a home office building, at the direction of the board of directors and with the prior approval of the commissioner of insurance. An ODS shall not invest more than 25 percent of its total admitted assets in such real estate. With the prior approval of the commissioner, an ODS may exceed the real estate investment limitation to effectuate a merger with, or the acquisition of, another ODS.

641—201.14(135,75GA,ch158) Rating practices. An ODS shall use the rate restrictions and regulations applicable to each market segment. All form filings shall include an actuarial certification by a fellow in the society of actuaries (FSA) attesting to the adequacy and fairness of the rates.

641—201.15(135,75GA,ch158) Name. No name other than that certified by the department may be used. The name of an ODS or AHP must clearly identify the entity as an ODS or AHP and all literature published by the ODS or AHP must identify its status as an ODS or AHP.

641—201.16(135,75GA,ch158) Change in organizational documents or control.

201.16(1) Changes to bylaws, articles of incorporation and any other document that would affect the operation and governance of the ODS shall be filed with the department at least 30 days prior to their proposed implementation date.

201.16(2) An ODS which desires to transfer ownership or control of more than 10 percent of ownership interest in the ODS shall not do so without first submitting a proposed plan to the department for review.

641—201.17(135,75GA,ch158) Appeal. A decision by the department to deny an application for licensure as an ODS may be appealed following the procedures in 641—Chapter 173.

641—201.18(135,78GA,ch41) External review. This rule is intended to implement the provisions of 1999 Iowa Acts, chapter 41, to provide a uniform process for enrollees of organized delivery systems to appeal a final adverse coverage decision based on medical necessity. This rule applies to any ODS that issues health plans or policies delivered in the state of Iowa. At the time of a coverage decision, an organized delivery system shall notify the enrollee in writing of the right to have the coverage decision reviewed under the external review process established pursuant to 1999 Iowa Acts, chapter 41, by the division of insurance. The request for an external review shall meet the requirements of the commissioner contained at 191—Chapter 76.

641—201.19 Reserved.

ANTITRUST

641—201.20(135,75GA,ch158) Purpose. The Iowa legislature has determined that the goals of controlling health care costs and improving the quality of and access to health care services will be significantly enhanced by cooperative arrangements involving providers wishing to become an ODS that might be prohibited by state and federal antitrust law if undertaken without governmental involvement. The purpose of the following rules is to institute new public policy by creating an opportunity for the state to review proposed arrangements and to substitute regulation for competition when an arrangement is likely to result in lower costs, or greater access or quality, than would otherwise occur in the marketplace. It is the intent that approval of arrangements be accompanied by appropriate conditions, supervision, and regulation to protect against private abuses of economic power, and that an arrangement approved by the department and accompanied by such appropriate conditions, supervision, and regulation shall not be subject to state and federal antitrust liability. It is the further intent that any immunity from scrutiny under federal or state antitrust statutes offered under these exceptions shall be limited to such specific agreements as are approved by the department, and shall not be extended or applied to unforeseen circumstances, parties, acts, or other agreements which were not part of or contemplated by the approved agreement.

641—201.21(135,75GA,ch158) Definitions.

“Access” means the financial, temporal, and geographic availability of health care to individuals who need it.

“Applicant” means the party or parties to an agreement or business arrangement for which the department’s approval is sought under this provision.

“Certificate of public advantage” means the sanction by and protection of the department of public health of an operating arrangement which otherwise might be excepted under certain antitrust regulations.

“Cost” or “cost of health care” means the amount paid by consumers or third-party payers for health care services or products.

“Criteria” means the cost, access, and quality of health care.

“Department” means the department of public health.

“Person” means an individual or legal entity.

641—201.22(135,75GA,ch158) Scope.

201.22(1) Certificate of public advantage. Providers or purchasers wishing to engage in contracts, business or financial arrangement, or other activities, practices, or arrangements that might be construed to be violations of state or federal antitrust laws but which are in the best interests of the state and further the policies and goals of this provision may apply to the department for a certificate of public advantage.

201.22(2) *Immunity regarding negotiation.* Directors, trustees, or other representatives of a health care provider or third-party payer who participate in discussion or negotiation culminating in any arrangement as described in subrule 201.22(1) are immune from civil actions or criminal prosecution for a violation of state or federal antitrust laws, unless the discussion or negotiation exceeds the scope authorized in this subrule.

201.22(3) *Disputes among the parties.* Any dispute among the parties to an arrangement as described in subrule 201.22(1) concerning the meaning or terms of their agreement is governed by normal principles of contract law.

201.22(4) *Department approval.* Approval by the department is an absolute defense against any action under state and federal antitrust laws, except as provided under subrule 201.30(5).

201.22(5) *Application cannot be used to impose liability.* The department shall ask the attorney general to comment on an application. The application and any information obtained by the department under rules 201.23(135,75GA,ch158) through 201.25(135,75GA,ch158) that is not otherwise available is not admissible in any civil or criminal proceeding brought by the attorney general or any other person based on an antitrust claim, except (a) a proceeding brought under subrule 201.30(5), based on an applicant's failure to substantially comply with the terms of the application; or (b) a proceeding based on actions taken by the applicant prior to submitting the application, where such actions are admitted to in the application.

201.22(6) *Out-of-state applicant.* Providers or purchasers not physically located in Iowa are eligible to seek a certificate of public advantage for an arrangement in which they transact business in Iowa.

641—201.23(135,75GA,ch158) Application.

201.23(1) *Disclosure.* An application for approval must include, to the extent applicable, disclosure of the following:

- a. A descriptive title;
- b. A table of contents;
- c. Exact names of each party to the application and the address of the principal business office of each party;
- d. The name, address, and telephone number of the persons authorized to receive notices and communications with respect to the application;
- e. A verified statement by a responsible officer of each party to the application attesting to the accuracy and completeness of the enclosed information;
- f. Background information relating to the proposed arrangement, including:
 - (1) A description of the proposed arrangement, including a list of any services or products that are the subject of the proposed arrangement;
 - (2) An identification of any tangential services or products associated with the services or products that are the subject of the proposed arrangement;
 - (3) A description of the geographic territory involved in the proposed arrangement;

(4) If the geographic territory described in subparagraph 201.23(1)“f”(3) is different from the territory in which the applicants have engaged in the type of business at issue over the last five years, a description of how and why the geographic territory differs;

(5) Identification of all products or services that a substantial share of consumers would consider substitutes for any service or product that is the subject of the proposed arrangement;

(6) Identification of whether any services or products of the proposed arrangement are currently being offered, capable of being offered, utilized, or capable of being utilized by other providers or purchasers in the geographic territory described in subparagraph 201.23(1)“f”(3);

(7) Identification of the steps necessary, under current market and regulatory conditions, for other parties to enter the territory described in subparagraph 201.23(1)“f”(3) and compete with the applicant;

(8) A description of the previous history of dealings between the parties to the application;

(9) A detailed explanation of the projected effects, including expected volume, change in price, and increased revenue, of the arrangement on each party’s current businesses, both generally as well as the aspects of the business directly involved in the proposed arrangement;

(10) The present market share of the parties to the application and of others affected by the proposed arrangement, and projected market shares after implementation of the proposed arrangement; and

(11) A statement of why the projected levels of cost, access, or quality could not be achieved in the existing market without the proposed arrangement.

g. A detailed explanation of how the transaction will affect cost, access, and quality. The explanation must address the factors in paragraphs 201.26(2)“b” to “d” to the extent applicable.

201.23(2) Administrative bulletin notice. In addition to the disclosures required in subrule 201.23(1), the application must contain a written description of the proposed arrangement for purposes of publication in the Iowa Administrative Bulletin. The notice must include sufficient information to advise the public of the nature of the proposed arrangement and to enable the public to provide meaningful comments concerning the expected results of the arrangement. The notice must also state that any person may provide written comments to the department, with a copy to the applicant, within 20 days of the notice’s publication. The department shall approve the notice before publication. If the department determines that the submitted notice does not provide sufficient information, the department may amend the notice before publication and may consult with the applicant in preparing the amended notice. The department shall not publish an amended notice without the applicant’s approval.

201.23(3) Multiple parties to proposed arrangement. For a proposed arrangement involving multiple parties, one joint application shall be submitted on behalf of all parties to the arrangement.

201.23(4) Department’s authority to refuse to review.

a. If the department determines that an application is unclear, incomplete, or provides an insufficient basis on which to base a decision, the department may return the application. The applicant may complete or revise the application and resubmit it.

b. If, upon review of the application and upon advice from the attorney general, the department concludes that the proposed arrangement does not present any potential for liability under the state or federal antitrust laws, the department may decline to review the application, and so notify the applicant.

c. The department may decline to review any application relating to arrangements already in effect before the submission of the application. However, the department shall review any application if the review is expressly provided for in a settlement agreement entered into by the applicant and the attorney general before the enactment of these rules.

201.23(5) *Department's authority to extend time limit.* Upon the showing of good cause, the department may extend any of the time limits stated in rules 201.23(135,75GA,ch158) and 201.24(135,75GA,ch158) at the request of the applicant or another person.

641—201.24(135,75GA,ch158) Notice and comment.

201.24(1) *Notice.* The department shall cause the notice described in subrule 201.23(2) to be published in the Iowa Administrative Bulletin and sent to any person who has requested to be placed on a list to receive notice of applications. The department may maintain separate notice lists for different regions of the state. The department may also send a copy of the notice to any person together with a request that the person comment as provided under subrule 201.24(2). Copies of the request must be provided to the applicant.

201.24(2) *Comments.* Within 20 days after the notice is published, any person may mail to the department written comments with respect to the application. Persons submitting comments shall provide a copy of the comments to the applicant. The applicant may mail to the department written responses to any comments within 10 days after the deadline for mailing such comments. The applicant shall send a copy of the response to the person submitting the comment.

641—201.25(135,75GA,ch158) Procedure for review of applications.

201.25(1) *Choice of procedures.* After the conclusion of the period provided in subrule 201.24(2) for the applicant to respond to comments, the department shall select one of the two procedures provided in subrule 201.25(2). In determining which procedure to use, the department shall consider the following criteria:

- a. The size of the proposed arrangement, in terms of number of parties and amount of money involved;
- b. The complexity of the proposed arrangement;
- c. The novelty of the proposed arrangement;
- d. The substance and quantity of the comments received; and
- e. The presence or absence of any significant gaps in the factual record.

If the applicant demands a contested case hearing no later than the conclusion of the period provided in subrule 201.24(2) for the applicant to respond to comments, the department shall not select a procedure. Instead, the applicant shall be given a contested case proceeding as a matter of right.

201.25(2) *Procedures available.*

a. Decision on the written record. The department may issue a decision based on the application, the comments and the applicant's responses to the comments, to the extent each is relevant. In making the decision, the department may consult with the attorney general or the staff of the department and may rely on department data.

b. Contested case hearing. The department may order a contested case hearing. A contested case hearing shall be heard before an administrative law judge who shall issue a written recommendation to the department and shall follow the procedures in 641—Chapter 173. All factual issues relevant to a decision must be presented in the contested case. The attorney general may appear as a party. The record in the contested case shall include the application, the comments, the applicant's response to the comments, and any other evidence that is part of the record under 641—Chapter 173.

641—201.26(135,75GA,ch158) Criteria for decision.

201.26(1) The department shall not approve an application unless the department determines that the arrangement is more likely to result in lower costs, increased access, or increased quality of health care, than would otherwise occur under existing market condition or conditions likely to develop without an exemption from state and federal antitrust law. In the event that a proposed arrangement appears likely to improve one or two of the criteria at the expense of another one or two of the criteria, the department shall not approve the application unless the department determines that the proposed arrangement, taken as a whole, is likely to substantially further the purpose of this chapter. In making such a determination, the department may employ a cost/benefit analysis.

201.26(2) *Factors.*

a. Generally applicable factors. In making a determination about cost, access, and quality, the department may consider the following factors, to the extent relevant:

- (1) Market structure: actual and potential sellers and buyers, or providers and purchasers; actual and potential consumers; geographic market area; and entry conditions;
- (2) Current market condition;
- (3) The historical behavior of the market;
- (4) Performance of other similar arrangements;
- (5) Whether the proposal unnecessarily restrains competition, or restrains competition in ways not reasonably related to the purposes of this chapter; and
- (6) The financial condition of the applicant.

b. Cost. The department's analysis of cost must focus on the individual consumer of health care. Cost savings to be realized by providers, health carriers, group purchasers, or other participants in the health care system are relevant only to the extent that the savings are likely to be passed on to the consumer. However, where an application is submitted by providers or purchasers who are paid primarily by third-party payers unaffiliated with the applicant, it is sufficient for the applicant to show that cost savings are likely to be passed on to the unaffiliated third-party payers; the applicants do not have the burden of proving that third-party payers with whom the applicants are not affiliated will pass on cost savings to individuals receiving coverage through the third-party payers. In making determinations as to costs, the department may consider:

- (1) The cost savings likely to result to the applicant;
- (2) The extent to which the cost savings are likely to be passed on to the consumer and in what form;
- (3) The extent to which the proposed arrangement is likely to result in cost-shifting by the applicant onto other payers or purchasers of other products or services;
- (4) The extent to which the cost-shifting by the applicant is likely to be followed by other persons in the market;
- (5) The current and anticipated supply and demand for any products or services at issue;
- (6) The representations and guarantees of the applicant, and their enforceability;
- (7) Likely effectiveness of regulation by the department;
- (8) Inferences to be drawn from market structure;
- (9) The cost of regulation, both for the state and for the applicant; and
- (10) Any other factors tending to show that the proposed arrangement is or is not likely to reduce cost.

c. Access. In making determinations as to access, the department may consider:

- (1) The extent to which the utilization of needed health care services or products by the intended targeted population is likely to increase or decrease. When a proposed arrangement is likely to increase access in one geographic area, by lowering prices or otherwise expanding supply, but limits access in another geographic area by removing service capabilities from that second area, the department shall articulate the criteria employed to balance these effects;
- (2) The extent to which the proposed arrangement is likely to make available a new and needed service or product to a certain geographic area; and
- (3) The extent to which the proposed arrangement is likely to otherwise make health care services or products more financially or geographically available to persons who need them.

If the department determines that the proposed arrangement is likely to increase access and bases that determination on a projected increase in utilization, the department shall also determine and make a specific finding that the increased utilization does not reflect overutilization.

d. Quality. In making determinations as to quality, the department may consider the extent to which the proposed arrangement is likely to:

- (1) Decrease morbidity and mortality;
- (2) Result in faster convalescence;
- (3) Result in fewer hospital days;
- (4) Permit providers to attain needed experience or frequency of treatment likely to lead to better outcomes;
- (5) Increase patient satisfaction; and
- (6) Have any other features likely to improve or reduce the quality of health care.

641—201.27(135,75GA,ch158) Decision.

201.27(1) Approval or disapproval. The department shall issue a written decision approving or disapproving the application within 45 days after receipt of the application or, in the case of a contested hearing, within 10 days of receipt of the administrative law judge's recommendation. The department may condition approval on a modification of all or part of the proposed arrangement to eliminate any restriction on competition that is not reasonably related to the goals of reducing cost or improving access or quality. The department may also establish conditions for approval that are reasonably necessary to protect against abuses of private economic power and to ensure that the arrangement is appropriately supervised and regulated by the state.

201.27(2) Findings of fact. The department's decision shall make specific findings of fact concerning the cost, access, and quality criteria, and identify one or more of those criteria as the basis for the decision.

201.27(3) Data for supervision. A decision approving an application shall require the periodic submission of specific data relating to cost, access, and quality, and to the extent feasible, identify objective standards of cost, access, and quality by which the success of the arrangement will be measured. However, if the department determines that the scope of a particular proposed arrangement is such that the arrangement is certain to have neither a positive nor negative impact on one or two of the criteria, the department's decision need not require the submission of data or establish an objective standard relating to those criteria.

641—201.28(135,75GA,ch158) Appeal. After the department has rendered a decision, the applicant or any other person aggrieved may appeal the decision to the district court within 30 days after receipt of the department's decision. The appeal is governed by Iowa Code chapter 17A. The department's determination, under subrule 201.25(1), of which procedure to use may not be raised as an issue on appeal.

641—201.29(135,75GA,ch158) Supervision after approval.

201.29(1) Active supervision. The department shall actively supervise, monitor, and regulate approved arrangements, as described below.

201.29(2) Procedures. The department shall review data submitted periodically by the applicant. The department's order shall set forth the time schedule for the submission of data, which shall be at least once a year. The department's order must identify the data that must be submitted, although the department may subsequently require the submission of additional data or alter the time schedule. Upon review of the data submitted, the department shall notify the applicant of whether the arrangement is in compliance with the department's order. If the arrangement is not in compliance with the department's order, the department shall identify those respects in which the arrangement does not conform to the department's order.

An applicant receiving notification that an arrangement is not in compliance has 30 days in which to respond with additional data. The response may include a proposal and a time schedule by which the applicant shall bring the arrangement into compliance with the department's order. If the arrangement is not in compliance and the department and the applicant cannot agree to the terms of bringing the arrangement into compliance, the matter shall be set for a contested case hearing.

The department shall publish notice in the Iowa Administrative Bulletin two years after the date of an order approving an application, and at two-year intervals thereafter, soliciting comments from the public concerning the impact that the arrangement has had on cost, access, and quality. The department may request additional oral and written information from the applicant or from any other source.

641—201.30(135,75GA,ch158) Revocation.

201.30(1) Conditions. The department may revoke a certificate of public advantage only if:

- a. The arrangement is not in substantial compliance with the terms of the application;
- b. The arrangement is not in substantial compliance with the conditions of approval;
- c. The arrangement is not in substantial compliance with 641—Chapter 201;
- d. The arrangement has not and is not likely to substantially achieve the improvements in cost, access, or quality identified in the approval order as the basis for the department's approval of the arrangement; or
- e. The conditions in the marketplace have changed to such an extent that competition would promote reductions in cost and improvements in access and quality better than does the arrangement at issue. In order to revoke on the basis that conditions in the marketplace have changed, the department's order shall identify specific changes in the marketplace and articulate why those changes warrant revocation.

201.30(2) Notice. The department shall begin a proceeding to revoke approval by providing written notice to the applicant describing in detail the basis for the proposed revocation. Notice of the proceeding shall be published in the Iowa Administrative Bulletin. The notice shall invite the submission of written comments to the department, with a copy to the applicant. Comments must be received by the department within 20 days of the publication of the notice.

201.30(3) Procedure. A proceeding to revoke an approval shall be conducted as a contested case proceeding upon the written request of the applicant. Contested cases regarding revocations shall be heard by an administrative law judge who shall issue a written recommendation to the department and shall follow the procedures in 641—Chapter 5. Decisions of the department in a proceeding to revoke approval are subject to judicial review under Iowa Code chapter 17A.

201.30(4) Alternatives to revocation preferred. In deciding whether to revoke an approval, the department shall take into account the hardship that the revocation may impose on the applicant and any potential disruption of the market as a whole. The department shall not revoke an approval if the arrangement can be modified, restructured, or regulated so as to remedy the problem upon which the revocation proceeding is based. The applicant may submit proposals for alternatives to revocation. Before approving an alternative to revocation that involves modifying or restructuring an arrangement, the department shall publish notice in the Iowa Administrative Bulletin that any person may comment on the proposed modification or restructuring within 20 days after publication of the notice. The department shall not approve the modification or restructuring until the comment period has concluded. An approved, modified, or restructured arrangement shall be subject to appropriate supervision under rule 201.29(135,75GA,ch158).

201.30(5) Impact of revocation. An applicant that has had its approval revoked is not required to terminate the arrangement. The applicant cannot be held liable under state or federal antitrust law for acts that occurred while the approval was in effect, except to the extent that the applicant failed to substantially comply with the terms of the approval. The applicant is fully subject to state and federal antitrust law after the revocation becomes effective and may be held liable for acts that occur after the revocation.

These rules are intended to implement 1993 Iowa Acts, chapter 158, section 3.

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