ARC 2348C

INSURANCE DIVISION[191]

Adopted and Filed

Pursuant to the authority of Iowa Code section 505.26 as amended by 2015 Iowa Acts, House File 632, section 9, the Insurance Division hereby adopts new Chapter 79, "Prior Authorization—Prescription Drug Benefits," Iowa Administrative Code.

The rules provide for the prior authorization for prescription drug benefits, use of a single prior authorization form and creation of a prior authorization process for approval of prescription drug benefits by health carriers and pharmacy benefits managers.

Notice of Intended Action was published in the Iowa Administrative Bulletin on October 28, 2015, as **ARC 2228C**. Written comments were accepted through November 18, 2015, and a public hearing was held on November 18, 2015, at the offices of the Iowa Insurance Division, Two Ruan Center, 601 Locust, Fourth Floor, Des Moines, Iowa. Comments were received. The following list summarizes the comments received and the changes made in response to public comment:

1. Comments suggesting further reduction of the time frames for urgent and nonurgent claims; the use of business days as opposed to calendar days; allowance of the prescribing physician to override an insurer's denial and requests to delay the effective date of the rules either conflict with the statutory provisions or are beyond the scope of this rule making, and were rejected by the Division.

2. Some commenters expressed concern that creation of a form may result in development of alternatives that would be less efficient than the NCPDP electronic prior authorization standard. The Division recognizes the importance of technology to the industry and modified the proposed rule to emphasize that the statutory language requiring a form does not preclude the use of or compliance with NCPDP SCRIPT standards. The creation of a single prior authorization form is required by Iowa Code section 505.26.

3. A comment requesting the insertion of the descriptive phrase "prescription drug" before the term "prior authorization" in the proposed rule was not accepted in order to avoid redundancy, given that the statutory language limits the subject matter to prescription drug benefits.

4. A suggestion was made during the public hearing that consideration be given to providing a cross reference or link to Iowa Code chapter 514J, External Review Standards, in the Appendix in order to avoid errors in the Appendix in the event Iowa Code chapter 514J is amended. The Division opts not to adopt the suggestion, recognizing that additional due diligence and coordination will be required on the part of the Division to ensure that the Appendix remains parallel to Iowa Code chapter 514J.

5. During the public hearing, a question arose regarding the meaning of the term "immediate" used in the Appendix. The term "immediate" or "immediately" appears several times but is not specifically defined in Iowa Code chapter 514J. The term should be construed in its ordinary and customary usage to mean without delay.

6. A comment was made regarding the applicability of the rules to Medicaid or Medicare. The Division opts not to expand applicability of the rules to Medicaid or Medicare as each program provides specific requirements regarding the prior authorization of prescription drugs, and the change is unnecessary.

7. Some comments raised concerns about the duration of an approved prior authorization request for a minimum of 12 months when such a time period may be inappropriate for certain prescription drugs with defined treatment durations according to FDA-approved package labeling or clinical practice guidelines. An example cited involved certain prescription drugs used to treat Hepatitis C, and the approved course of treatment is 12 weeks. The rule has been clarified to address those circumstances where it is clinically appropriate that a prescription drug approval may be less than 12 months.

This chapter does not provide for waivers. Persons seeking waivers must petition the Division for a waiver in the manner set forth in 191—Chapter 4.

After analysis and review of this rule making, no impact on jobs has been found.

These rules are intended to implement Iowa Code section 505.26 as amended by 2015 Iowa Acts, House File 632, section 9.

These rules will become effective February 10, 2016.

The following amendment is adopted.

Adopt the following **new** 191—Chapter 79:

CHAPTER 79
PRIOR AUTHORIZATION—PRESCRIPTION DRUG BENEFITS

191—79.1(505) Purpose. These rules implement Iowa Code section 505.26 as amended by 2015 Iowa Acts, House File 632, section 9, which requires the commissioner to adopt rules to provide for a single prior authorization form and prior authorization process for approval of prescription drug benefits by health carriers and pharmacy benefits managers.

191—79.2(505) Definitions. For purposes of this chapter, the definitions found in Iowa Code section 505.26 as amended by 2015 Iowa Acts, House File 632, section 9, shall apply. In addition, the following definitions shall apply:

"Commissioner" means the Iowa insurance commissioner.

"Division" means the Iowa insurance division.

"Exigent" means circumstances as defined under federal regulations relating to the Affordable Care Act, as provided in 45 CFR 156.122.

"Prescription drug prior authorization" means requests for preapproval from a payor for specified medications or quantities of medications.

"Qualified health plan" or *"QHP"* means a health insurance plan under the Affordable Care Act, which is certified by the health insurance marketplace.

"Urgent" means any claim for medical care or treatment to which the application of time periods that either could seriously jeopardize the life or health of the patient or the ability of the patient to regain maximum function or, in the opinion of the physician or health care professional, as defined in Iowa Code chapter 514J, with knowledge of the patient's medical condition, would subject the patient to severe pain that cannot be adequately managed without the care or treatment that is the subject of the claim.

191—79.3(505) Prior authorization protocols. All health carriers, health benefit plans and pharmacy benefits managers must accept the approved prior authorization form from health care providers.

79.3(1) *Duration of approved prior authorization request.* Health carriers, health benefit plans, and pharmacy benefits managers shall provide that approval of a prior authorization request shall be valid for a minimum of 12 months or for a duration that is clinically appropriate for the condition being treated, in accordance with the rules adopted pursuant to Iowa Code section 505.26 as amended by 2015 Iowa Acts, House File 632, section 9. Updates on disease progression must be provided with each renewal request.

79.3(2) *Posting of prior authorization form.* The approved prior authorization form shall be made available electronically on the Web site of the division and on the Web site of each health carrier, health benefit plan or pharmacy benefits manager that uses the form. Health carriers, health benefit plans and pharmacy benefits managers shall allow health care providers to submit a prior authorization request electronically.

79.3(3) *Assignment of identification number.* The health carrier, health benefit plan or pharmacy benefits manager shall assign to each prior authorization request a unique electronic identification number that a provider may use during the prior authorization process to track the request electronically, through a call center, or by fax. This unique identifier may include a format that consists of a patient's first name, last name and date of birth.

79.3(4) *Posting of required information.* Health carriers, health benefit plans, and pharmacy benefits managers shall make the following available and accessible on their Internet sites:

a. Prior authorization requirements and restrictions, including a list of drugs that require prior authorization.

b. Clinical criteria that are easily understandable to health care providers, including clinical criteria for reauthorization of a previously approved drug after the prior authorization period has expired.

c. Standards for submitting and considering requests, including evidence-based guidelines, when possible, for making prior authorization determinations.

d. Health carriers shall provide a process for health care providers to appeal a prior authorization determination as provided in Iowa Code chapter 514J. Pharmacy benefits managers shall provide a process for health care providers to appeal a prior authorization determination that is consistent with the process provided in Iowa Code chapter 514J. Appeal standards as provided in Iowa Code chapter 514J are set out in Appendix A herein.

79.3(5) *Urgent claims.* Prior authorization requests for urgent claims shall be approved or denied as soon as possible, but in no case later than 72 hours after receipt of the request.

79.3(6) *Nonurgent claims.* Prior authorization requests for nonurgent claims shall be approved or denied as soon as possible, but in no case later than five calendar days after receipt of the request.

79.3(7) *Incomplete or additional information.* If a request for a prescription drug prior authorization is incomplete or additional information is required, the health carrier, health benefit plan, or pharmacy benefits manager may request additional information within the applicable time periods provided in this rule. Once the additional information is submitted, the applicable time period for approval or denial shall begin again.

79.3(8) *Prescription drug benefits provided by a qualified health plan.* A QHP shall have procedures in place that comply with the health insurance issuer standards related to expedited review based on exigent circumstances and coverage determinations no later than 24 hours after receipt of requests as provided for in 45 CFR 156.122(c).

79.3(9) *Prior authorization granted.* If a health carrier, health benefit plan or pharmacy benefits manager does not approve or deny a completed prior authorization request or request additional information from a health care provider within the time limits set forth in this rule, the prior authorization request shall be deemed to have been granted.

79.3(10) *Denial of prior authorization request.* In the case of a denial of a prior authorization request, the health carrier, health benefit plan or pharmacy benefits manager shall provide the reason for the denial, information regarding the denial and, if formulary alternatives are available, direction on how to contact the health carrier or health benefit plan.

191—79.4(505) Filing with the division.

79.4(1) A prior authorization form approved by the commissioner shall meet all of the following requirements:

a. Not exceed two pages in length, except that a prior authorization form may exceed that length as determined to be appropriate by the commissioner. Exceptions to the two-page limit shall consider clinical differences and complexity of the requested prescription drugs.

b. Be available in electronic format.

c. Be transmissible in an electronic format or a fax transmission.

79.4(2) The prior authorization form utilized by health carriers, health benefit plans, and pharmacy benefits managers shall first be examined and approved by the commissioner. Health carriers shall submit the form electronically using the National Association of Insurance Commissioners' System for Electronic Rate and Form Filing (SERFF). Pharmacy benefits managers shall submit the form in writing to the commissioner by regular mail, fax or electronic means. Nothing in this rule shall preclude the use of standards by health carriers and pharmacy benefits managers in accordance with NCPDP SCRIPT.

79.4(3) The form submitted for approval shall consider any prior authorization forms developed by the federal Centers for Medicare and Medicaid Services or the U.S. Department of Health and Human Services and any national standards pertaining to electronic prior authorization for prescription drugs, including ASC X12 278 standard transactions and NCPDP SCRIPT Standard ePA transactions.

191—79.5(505) Violations. A health carrier, health benefit plan or pharmacy benefits manager found after hearing to have violated a provision of this chapter shall be subject to the penalties set forth in Iowa Code chapter 505.

191—79.6(505) Applicability. This chapter shall not apply to Medicare or Medicaid.

These rules are intended to implement Iowa Code section 505.26 as amended by 2015 Iowa Acts, House File 632, section 9.

APPENDIX A
Standards Related to Appeals
(as provided in Iowa Code chapter 514J)

514J.107 External review — standard.

1. A covered person or the covered person's authorized representative may file a written request for an external review with the commissioner within four months after any of the following events:

a. The date of receipt of a final adverse determination.

b. The failure of a health carrier to issue a written decision within thirty days following the date the covered person or the covered person's authorized representative filed a grievance involving an adverse determination as provided in section 514J.106, subsection 2.

c. The agreement of the health carrier to waive the requirement that the covered person or the covered person's authorized representative exhaust the health carrier's internal grievance procedures before filing a request for external review of an adverse determination as provided in section 514J.106, subsection 4.

2. Within one business day after the date of receipt of a request for external review, the commissioner shall send a copy of the request to the health carrier.

3. Within five business days following the date of receipt of the external review request from the commissioner, the health carrier shall complete a preliminary review of the request to determine whether:

a. The individual is or was a covered person under the health benefit plan at the time the health care service was recommended or requested.

b. The health care service that is the subject of the adverse determination or of the final adverse determination, is a covered service under the covered person's health benefit plan, but for a determination by the health carrier that the health care service is not covered because it does not meet the health carrier's requirements for medical necessity, appropriateness, health care setting, level of care, or effectiveness.

c. The covered person or the covered person's authorized representative has exhausted the health carrier's internal grievance process, unless the covered person or the covered person's authorized representative is not required to exhaust the health carrier's internal grievance process pursuant to section 514J.106 or this section.

d. The covered person or the covered person's authorized representative has provided all the information and forms required to process an external review request.

4. Within one business day after completion of a preliminary review pursuant to subsection 3, the health carrier shall notify the commissioner and the covered person or the covered person's authorized representative in writing whether the request is complete and whether the request is eligible for external review.

a. If the health carrier determines that the request is not complete, the health carrier shall notify the covered person or the covered person's authorized representative and the commissioner in writing that the request is not complete and what information or materials are needed to make the request complete.

b. If the health carrier determines that the request is not eligible for external review, the health carrier shall issue a notice of initial determination in writing informing the covered person or the covered person's authorized representative and the commissioner of that determination and the reasons the request is not eligible for review. The health carrier shall also include a statement in the notice informing the covered person or the covered person's authorized representative that the health carrier's initial determination of ineligibility may be appealed to the commissioner.

5. The commissioner may specify by rule the form required for the health carrier's notice of initial determination and any supporting information to be included in the notice.

6. The commissioner may determine that a request is eligible for external review, notwithstanding a health carrier's initial determination that the request is not eligible, and refer the request for external review. In making this determination, the commissioner's decision shall be made in accordance with the terms of the covered person's health benefit plan and shall be subject to all applicable provisions of this chapter.

7. Within one business day after receipt of notice from a health carrier that a request for external review is eligible for external review or upon a determination by the commissioner that a request is eligible for external review, the commissioner shall do all of the following:

a. Assign an independent review organization from the list of approved independent review organizations maintained by the commissioner and notify the health carrier of the name of the assigned independent review organization. The assignment of an independent review organization shall be done on a random basis among those approved independent review organizations qualified to conduct the particular external review based on the nature of the health care service that is the subject of the adverse determination or final adverse determination and other circumstances, including conflict of interest concerns.

b. Notify the covered person or the covered person's authorized representative in writing that the request is eligible and has been accepted for external review including the name of the assigned independent review organization and that the covered person or the covered person's authorized representative may submit in writing to the independent review organization within five business days following receipt of such notice from the commissioner, additional information that the independent review organization shall consider when conducting the external review. The independent review organization may, in the organization's discretion, accept and consider additional information submitted by the covered person or the covered person's authorized representative after five business days.

8. Within five business days after receipt of notice from the commissioner pursuant to subsection 7, the health carrier shall provide to the independent review organization the documents and any information considered in making the adverse determination or final adverse determination. Failure by the health carrier to provide the documents and information within the time specified shall not delay the conduct of the external review.

9. If the health carrier fails to provide the documents and information within the time specified, the independent review organization may terminate the external review and make a decision to reverse the adverse determination or final adverse determination. Within one business day after making such a decision, the independent review organization shall notify the covered person or the covered person's authorized representative, the health carrier, and the commissioner of its decision.

10. The independent review organization shall review all of the information and documents received pursuant to subsection 8 and any other information submitted in writing to the independent review organization by the covered person or the covered person's authorized representative pursuant to subsection 7, paragraph *"b"*. Upon receipt of any information submitted by the covered person or the covered person's authorized representative, the independent review organization shall, within one business day, forward the information to the health carrier. In reaching a decision the independent review organization is not bound by any decisions or conclusions reached during the health carrier's internal grievance process.

11. Upon receipt of information forwarded pursuant to subsection 10, a health carrier may reconsider its adverse determination or final adverse determination that is the subject of the external review.

a. Reconsideration by the health carrier of its determination shall not delay or terminate the external review. The external review shall only be terminated if the health carrier decides, upon completion of its reconsideration, to reverse its determination and provide coverage or payment for the health care service that is the subject of the adverse determination or final adverse determination.

b. Within one business day after making a decision to reverse its adverse determination or final adverse determination, the health carrier shall notify the covered person or the covered person's authorized representative, the independent review organization, and the commissioner in writing of

its decision. The independent review organization shall terminate the external review upon receipt of notice of the health carrier's decision to reverse its adverse determination or final adverse determination.

12. In addition to the documents and information provided to the independent review organization pursuant to this section, the independent review organization shall, to the extent the information or documents are available and the independent review organization considers them appropriate, consider the following in reaching a decision:

a. The covered person's pertinent medical records.

b. The treating health care professional's recommendation.

c. Consulting reports from appropriate health care professionals and other documents submitted by the health carrier, covered person, or the covered person's treating physician or other health care professional.

d. The terms of coverage under the covered person's health benefit plan with the health carrier, to ensure that the independent review organization's decision is not contrary to the terms of coverage under the covered person's health benefit plan with the health carrier.

e. The most appropriate practice guidelines, which shall include applicable evidence-based standards and may include any other practice guidelines developed by the federal government, national or professional medical societies, boards, and associations.

f. Any applicable clinical review criteria developed and used by the health carrier.

g. The opinion of the independent review organization's clinical reviewer after considering the information or documents described in paragraphs *"a"* through *"f"* to the extent the information or documents are available and the clinical reviewer considers them relevant.

13. *a.* Within forty-five days after the date of receipt of a request for an external review, the independent review organization shall provide written notice of its decision to uphold or reverse the adverse determination or final adverse determination of the health carrier to the covered person or the covered person's authorized representative, the health carrier, and the commissioner.

b. The independent review organization shall include in its decision all of the following:

(1) A general description of the reason for the request for external review.

(2) The date the independent review organization received the assignment from the commissioner to conduct the external review.

(3) The date the external review was conducted.

(4) The date of the decision.

(5) The principal reason or reasons for its decision, including what applicable evidence-based standards, if any, were a basis for its decision.

(6) The rationale for its decision.

(7) References to evidence or documentation, including evidence-based standards, considered in reaching its decision.

14. Upon receipt of notice of a decision reversing the adverse determination or final adverse determination of the health carrier, the health carrier shall immediately approve the coverage that was the subject of the determination.

514J.108 External review — expedited.

1. Notwithstanding section 514J.107, a covered person or the covered person's authorized representative may make an oral or written request to the commissioner for an expedited external review at the time the covered person or the covered person's authorized representative receives any of the following:

a. An adverse determination that involves a medical condition of the covered person for which the time frame for completion of an internal review of a grievance involving an adverse determination would seriously jeopardize the life or health of the covered person or would jeopardize the covered person's ability to regain maximum function.

b. A final adverse determination that involves a medical condition where the time frame for completion of a standard external review would seriously jeopardize the life or health of the covered person or would jeopardize the covered person's ability to regain maximum function.

c. A final adverse determination that concerns an admission, availability of care, continued stay, or health care service for which the covered person received emergency services, and the covered person has not been discharged from a facility.

2. *a.* Upon receipt of a request for an expedited external review, the commissioner shall immediately send written notice of the request to the health carrier.

b. Immediately upon receipt of notice of a request for expedited external review, the health carrier shall complete a preliminary review of the request to determine whether the request meets the eligibility requirements for external review set forth in section 514J.107, subsection 3, and this section.

c. The health carrier shall then immediately issue a notice of initial determination informing the commissioner and the covered person or the covered person's authorized representative of its eligibility determination including a statement informing the covered person or the covered person's authorized representative of the right to appeal that determination to the commissioner.

d. The commissioner may specify by rule the form required for the health carrier's notice of initial determination and any supporting information to be included in the notice.

3. The commissioner may determine that a request is eligible for expedited external review, notwithstanding a health carrier's initial determination that the request is not eligible. In making a determination, the commissioner's decision shall be made in accordance with the terms of the covered person's health benefit plan and shall be subject to all applicable provisions of this chapter. The commissioner shall make a determination pursuant to this subsection as expeditiously as possible.

4. *a.* Upon receipt of notice from a health carrier that a request is eligible for expedited external review or upon a determination by the commissioner that a request is eligible for expedited external review, the commissioner shall immediately assign an independent review organization from the list of approved independent review organizations maintained by the commissioner to conduct the expedited external review. The commissioner shall then immediately notify the health carrier and the covered person or the covered person's authorized representative of the name of the assigned independent review organization.

b. The assignment of an independent review organization shall be done on a random basis among those approved independent review organizations qualified to conduct the particular external review based on the nature of the health care service that is the subject of the adverse determination or final adverse determination and other circumstances, including conflict of interest concerns.

5. Upon receiving notice of the independent review organization assigned to conduct the expedited external review, the health carrier shall provide or transmit all necessary documents and information considered in making the adverse determination or final adverse determination to the independent review organization electronically or by telephone or facsimile or any other available expeditious method.

6. The independent review organization is not bound by any decisions or conclusions reached during the health carrier's internal grievance process. The independent review organization shall consider the documents and information provided by the health carrier, and to the extent the information or documents are available and the independent review organization considers them appropriate, shall consider the following in reaching a decision:

a. The covered person's pertinent medical records.

b. The treating health care professional's recommendation.

c. Consulting reports from appropriate health care professionals and other documents submitted by the health carrier, covered person or the covered person's authorized representative, or the covered person's treating physician or other health care professional.

d. The terms of coverage under the covered person's health benefit plan with the health carrier, to ensure that the independent review organization's decision is not contrary to the terms of coverage under the covered person's health benefit plan with the health carrier.

e. The most appropriate practice guidelines, which shall include applicable evidence-based standards and may include any other practice guidelines developed by the federal government, national or professional medical societies, boards, and associations.

f. Any applicable clinical review criteria developed and used by the health carrier.

g. The opinion of the independent review organization's clinical reviewer after considering the information or documents described in paragraphs *"a"* through *"f"* to the extent the information or documents are available and the clinical reviewer considers them relevant.

7. *a.* As expeditiously as the covered person's medical condition or circumstances require, but in no event more than seventy-two hours after the date of receipt of an eligible request for expedited external review, the assigned independent review organization shall do all of the following:

(1) Make a decision to uphold or reverse the adverse determination or final adverse determination of the health carrier.

(2) Notify the covered person or the covered person's authorized representative, the health carrier, and the commissioner of its decision.

b. If the notice given by the independent review organization pursuant to paragraph *"a"* was not in writing, within forty-eight hours after providing that notice, the independent review organization shall provide written confirmation of the decision to the covered person or the covered person's authorized representative, the health carrier, and the commissioner that includes the information set forth in section 514J.107, subsection 13, paragraph *"b"*.

c. Upon receipt of the notice of decision by an independent review organization pursuant to paragraph *"a"* reversing the adverse determination or final adverse determination, the health carrier shall immediately approve the coverage that was the subject of the adverse determination or final adverse determination.

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