ARC 9175B

HUMAN SERVICES DEPARTMENT[441]

Adopted and Filed

Pursuant to the authority of Iowa Code section 249A.4 and 2010 Iowa Acts, Senate File 2088, sections 348 and 349, the Department of Human Services amends Chapter 78, "Amount, Duration and Scope of Medical and Remedial Services," Iowa Administrative Code.

The amendment affects Medicaid coverage of mental health prescription drugs that have a significant variation in therapeutic or side effect profile from other drugs in the same therapeutic class. The following policies will apply:

- If the manufacturer or labeler of the drug does not enter into a supplemental rebate contract, prior authorization may be required.
- Iowa Medicaid members established on one of these drugs before January 1, 2011, are exempt from prior authorization requirements for that specific drug.
- Medicaid reimbursement will be made for up to a seven-day supply while prior authorization is being requested.
- If the prescriber does not receive a prior authorization decision within 48 hours of a request for prior approval, the prior authorization is deemed approved, contingent on the prescriber's having current contact information, including a current fax number, and a signed fax confidentiality form on file with the Department.

These changes are required by 2010 Iowa Acts, Senate File 2088, sections 347 to 349. Before this legislation, Iowa Code section 249A.20A included the following language on the Medicaid Preferred Drug List (PDL):

"With the exception of drugs prescribed for the treatment of human immunodeficiency virus or acquired immune deficiency syndrome, transplantation, or cancer and drugs prescribed for mental illness with the exception of drugs and drug compounds that do not have a significant variation in a therapeutic profile or side effect profile within a therapeutic class, prescribing and dispensing of prescription drugs not included on the preferred drug list shall be subject to prior authorization."

Based on that language, mental health drugs were subject to prior authorization pursuant to the Preferred Drug List only if they did not have "a significant variation in a therapeutic profile or side effect profile within a therapeutic class." The Department has referred to the mental health drugs exempt from prior authorization based on the Preferred Drug List as "chemically unique mental health drugs" because they do have a significant variation in therapeutic or side effect profile as compared to other drugs in the same therapeutic class.

2010 Iowa Acts, Senate File 2088, now allows for Preferred Drug List prior authorization requirements for "a chemically unique mental health prescription drug," subject to certain protections for patients. Based on this history, the Department understands "a chemically unique mental health prescription drug" to refer to the mental health drugs that have been exempt from Preferred Drug List prior authorization requirements because they have a significant variation in therapeutic or side effect profile as compared to other drugs in the same therapeutic class. Therefore, the amendment refers to the chemically unique mental health drugs referenced in 2010 Iowa Acts, Senate File 2088, as mental health drugs that have "a significant variation in therapeutic or side effect profile from other drugs in the same therapeutic class."

As a protection for patients needing a "chemically unique" mental health prescription drug, 2010 Iowa Acts, Senate File 2088, requires the Department to adopt rules providing that if an approval or disapproval is not "received by the physician or other prescriber within 48 hours" of a request for prior approval, the request is deemed approved. The amendment requires that the prescriber have a current fax number and a signed fax confidentiality form on file with the Department in order for a request to be deemed approved when a decision is not received within 48 hours. Decisions are transmitted to the prescriber and the pharmacy by mail if the Department does not have current fax information. Requiring that a response be received within 48 hours is unreasonable if the response must be mailed.

Notice of Intended Action on this amendment was published in the Iowa Administrative Bulletin on July 28, 2010, as **ARC 8975B**. The Department received eight written comments on the Notice of Intended Action, and seven people attended the public hearing on the proposed amendment. Comments addressed the following concerns:

- This amendment would limit the availability of treatment options for persons with mental illness. The Iowa Medicaid program does not have a "formulary" that restricts coverage to only certain drugs. Iowa has a Preferred Drug List and requires that medications listed as "nonpreferred" be approved before service delivery. A seven-day supply is allowed pending prior approval of the nonpreferred medication.
- Coverage would be "heavily weighted" toward generic drugs. Iowa's Preferred Drug List includes both brand-name and generic drugs as preferred.
- Patients who are stabilized on "nonformulary" drugs will be forced to change medication. All established patients will be "grandfathered" to allow continued use of the same drugs.
- Providers will be overtaxed by the additional work required to obtain prior authorization. Most prior approval requests and decisions are transmitted by fax, which allows 95 percent of requests to be handled in less than two hours.
- The changes will not be cost-effective due to adverse effects on patients. All publicly funded programs must be conscious of costs, or the programs will be unsustainable. This category of medications currently represents 46 percent of all drug expenditures for Iowa Medicaid. A savings of $2.5 million per year is projected, mostly due to supplemental rebates from manufacturers of drugs that are no longer guaranteed preferred status.

This amendment does not provide for waivers in specified situations. Requests for the waiver of any rule may be submitted under the Department's general rule on exceptions at 441—1.8(17A,217).

The Council on Human Services adopted this amendment on October 13, 2010. The amendment is identical to that published under Notice of Intended Action.

This amendment is intended to implement Iowa Code section 249A.4 and 2010 Iowa Acts, Senate File 2088, sections 347 to 349.

This amendment shall become effective on January 1, 2011.

The following amendment is adopted.

Amend paragraph **78.2(4)"a"** as follows:

a. Prior authorization is required as specified in the preferred drug list published by the department pursuant to Iowa Code section 249A.20A as amended by 2010 Iowa Acts, Senate File 2088, section 347.

(1) For ~~drugs~~ any drug requiring prior authorization, reimbursement will be made for a 72-hour or three-day supply dispensed in an emergency when a prior authorization request cannot be submitted.

(2) Unless the manufacturer or labeler of a mental health prescription drug that has a significant variation in therapeutic or side effect profile from other drugs in the same therapeutic class enters into a contract to provide the state with a supplemental rebate, the drug may be placed on the preferred drug list as nonpreferred, with prior authorization required. However, prior authorization shall not be required for such a drug for a member whose regimen on the drug was established before January 1, 2011, as verified by documented pharmacy claims.

(3) For mental health prescription drugs requiring prior authorization that have a significant variation in therapeutic or side effect profile from other drugs in the same therapeutic class, reimbursement will be made for up to a seven-day supply pending prior authorization. A request for prior authorization shall be deemed approved if the prescriber:

1. Has on file with the department current contact information, including a current fax number, and a signed Form 470-4914, Fax Confidentiality Certificate, and

2. Does not receive a notice of approval or disapproval within 48 hours of a request for prior authorization.

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EDITOR'S NOTE: For replacement pages for IAC, see IAC Supplement 11/3/10.