ARC 8975B

HUMAN SERVICES DEPARTMENT[441]

Notice of Intended Action

Twenty-five interested persons, a governmental subdivision, an agency or association of 25 or more persons may demand an oral presentation hereon as provided in Iowa Code section 17A.4(1)*"b."*

Notice is also given to the public that the Administrative Rules Review Committee may, on its own motion or on written request by any individual or group, review this proposed action under section 17A.8(6) at a regular or special meeting where the public or interested persons may be heard.

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 proposes to amend Chapter 78, "Amount, Duration and Scope of Medical and Remedial Services," Iowa Administrative Code.

The proposed 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 would 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 proposed 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 proposed amendment adds a requirement that the prescriber have current contact information, including 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 an approval or disapproval is not received within 48 hours.

Most prior approval requests and decisions are transmitted by fax, which allows 95 percent of requests to be handled in less than two hours. Decisions are transmitted to the prescriber and the pharmacy by mail if the Department does not have a current fax number and fax confidentiality authorization. Requiring that a response be received within 48 hours is unreasonable if the response must be mailed.

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).

Any interested person may make written comments on the proposed amendment on or before August 18, 2010. Comments should be directed to Mary Ellen Imlau, Bureau of Policy Coordination, Department of Human Services, Hoover State Office Building, 1305 East Walnut Street, Des Moines, Iowa 50319-0114. Comments may be sent by fax to (515)281-4980 or by E-mail to policyanalysis@dhs.state.ia.us.

The Department will hold a public hearing for the purposes of receiving comments on this amendment on August 18, 2010, from 9:30 to 10:30 a.m. in Conference Room 7 on Level A of the Hoover State Office Building, 1305 East Walnut Street, Des Moines. Comments may be offered at the hearing either orally or in writing. Anyone who intends to attend the hearing and has special requirements, such as those related to hearing or vision impairments, should contact the Bureau of Policy Coordination at (515)281-8440 in advance of the scheduled date to request that appropriate arrangements be made.

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

The following amendment is proposed.

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.