This draft Notice, including a timeline, is being provided in advance of the regular Notice for review only. These documents are also posted at www.iowamedicaidpdl.com under the “Rules” tab.

The normal Administrative Rule process will be followed and the exact timeline for the Rules can be viewed at http://www.dhs.state.ia.us/PolicyAnalysis/RulesPages/Dockets.htm once the Notice filing occurs in July 2010. Information relative to the PDL review can be viewed at www.iowamedicaidpdl.com under the P&T Committee Info tab.

HUMAN SERVICES DEPARTMENT [441]

Notice of Intended Action

Pursuant to the authority of Iowa Code section 249A.4 , the Department of Human Services proposes to amend Chapter 78, "Amount, Duration and Scope of Medical and Remedial Service," Iowa Administrative Code.

The proposed amendments would impact mental health prescription drugs that have a significant variation in therapeutic or side effect profile from other drugs in the same therapeutic class, and the following 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 these drugs prior to January 1, 2011 are exempt from prior authorization requirements for their specific drug(s).
- Reimbursement will be made for up to a seven (7) day supply while prior authorization (PA) is being requested;
- If a prior authorization decision is not received by the prescriber within 48 hours of a request for prior approval, the prior authorization is deemed approved, contingent on the prescriber 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 Senate File 2088, sections 347-49.

Prior to SF 2088, the Preferred Drug List (PDL) legislation included the following language:

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 the above language, mental health drugs were subject to prior authorization pursuant to the PDL 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 drugs exempt from prior authorization based on the PDL because they do have a significant variation in therapeutic or side effect profile, as compared to other drugs in the same therapeutic class, as "chemically unique mental health drugs". SF 2088 now allows for PDL prior authorization requirements for "a chemically unique mental health prescription drug," subject to certain protections for patients. Based on this history, the Department understands "chemically unique mental health prescription drug" to refer to the mental health drugs formerly exempt from PDL 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 rules refer to the "chemically unique mental health drugs" referenced in SF 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, SF 2088 provides that the Department will 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 rules add 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. If deemed approval is based on receipt of approval or disapproval, the Department must have current contact information. Most prior approval requests and decisions are transmitted by fax, which allows 95% of requests to be handled in less than two hours. Some decisions are transmitted by mail, if the Department does not have a current fax number and fax confidentiality authorization. But requiring that a response must be received within 48 hours is unreasonable if the response must be mailed.

These amendments do 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 amendments on or before X, 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 these amendments on August 18, 2010, from 9:30 a.m. to 10:30 a.m. in Conference Room 07 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 hearing or vision impairments, should contact the Office of Policy Analysis at (515)281-8440 and advise of special needs.

These amendments are intended to implement Iowa Code section 249A.4.

The following amendments are proposed.

ITEM 1. Amend subrule **78.2(4)*a.***:

78.2(4) *Prescription drugs.* Drugs that may be dispensed only upon a prescription are covered subject to the following limitations.

a. Prior authorization is required as specified in the preferred drug list published by the department pursuant to Iowa Code section 249A.20A.

(1) For any drugs requiring prior authorization, reimbursement will be made for a 72-hour or 3-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 non-preferred, with prior authorization required. However, prior authorization shall not be required for such drugs in the case of a medical assistance program recipient whose regimen on such a drug was established prior to 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:

1. Reimbursement will be made for up to a 7-day supply pending prior authorization.
2. A request for prior authorization is deemed approved if:

- The prescriber has current contact information, including a current fax number, and a signed fax confidentiality form (form # 470-4914) on file with the department, and
- Approval or disapproval is not received by the prescriber within 48 hours of a request for prior authorization.