

BEFORE THE DEPARTMENT OF PUBLIC  
HEALTH AND HUMAN SERVICES OF THE  
STATE OF MONTANA

In the matter of the amendment of ) NOTICE OF PUBLIC HEARING ON  
ARM 37.86.1102 and 37.86.1103 ) PROPOSED AMENDMENT  
pertaining to updating requirements )  
to limit opioid supply for members )  
without cancer diagnosis )

TO: All Concerned Persons

1. On August 15, 2019, at 1:00 p.m., the Department of Public Health and Human Services will hold a public hearing in the auditorium of the Department of Public Health and Human Services Building, 111 North Sanders, Helena, Montana, to consider the proposed amendment of the above-stated rules.

2. The Department of Public Health and Human Services will make reasonable accommodations for persons with disabilities who wish to participate in this rulemaking process or need an alternative accessible format of this notice. If you require an accommodation, contact the Department of Public Health and Human Services no later than 5:00 p.m. on August 6, 2019, to advise us of the nature of the accommodation that you need. Please contact Gwen Knight, Department of Public Health and Human Services, Office of Legal Affairs, P.O. Box 4210, Helena, Montana, 59604-4210; telephone (406) 444-4094; fax (406) 444-9744; or e-mail dphhslegal@mt.gov.

3. The rules as proposed to be amended provide as follows, new matter underlined, deleted matter interlined:

37.86.1102 OUTPATIENT DRUGS, REQUIREMENTS (1) through (4) remain the same.

(5) Each prescription must be dispensed in the quantity ordered except that:  
(a) and (b) remain the same.

(c) Prescriptions for opioids shall be dispensed in accordance with ARM 37.86.1103.

(6) through (11) remain the same.

AUTH: 53-2-201, 53-6-113, MCA

IMP: 53-2-201, 53-6-101, 53-6-113, 53-6-141, MCA

37.86.1103 OUTPATIENT DRUGS, FRAUD, WASTE, AND ABUSE

(1) through (4) remain the same.

(5) "Opioid naïve member" means a member has not received a prescription for an opioid within the last 45 days.

(5) through (7) remain the same, but are renumbered (6) through (8).

(9) For an opioid-naïve member who does not have a cancer diagnosis, the department does not authorize payment for opioid medications in quantities greater than a 7-day supply, and each day's supply must be no more than 50 morphine milligram equivalents (MME).

(8) and (9) remain the same, but are renumbered (10) and (11).

AUTH: 53-2-201, 53-6-113, MCA

IMP: 53-2-201, 53-6-101, 53-6-111, MCA

#### 4. STATEMENT OF REASONABLE NECESSITY

The Department of Public Health and Human Services (department) is proposing to amend ARM 37.86.1102 and 37.86.1103, pertaining to updating requirements to limit opioid supply for naïve members without cancer diagnosis.

The proposed amendments to these two rules will help reduce the risk of opioid-related adverse events and opioid dependence. The Centers for Disease Control (CDC) guidelines indicate by limiting the number of opioid doses in opioid naïve patients, it reduces the risk of opioid-related adverse events and overdose. Also, the CDC guidelines indicate by limiting the day supply of opioid prescriptions, it reduces the risk of developing opioid dependence. Although the CDC asserts there is no single dosage or day supply threshold which will eliminate risk, prescriptions should be limited to the lowest effective dose for the shortest possible duration, and most experts recommend a maximum dose of 50 morphine milligram equivalents (MME) and a limit of 3 to 7-day supply for opioid naïve patients. Therefore, the department is proposing to limit opioid naïve members, without a cancer diagnosis, to an initial fill of 7 days and 50 MME per day.

##### ARM 37.86.1102

The department is proposing amendments to include an exception for opioids in ARM 37.86.1102(5) that states each prescription must be dispensed in the quantity ordered. Each prescription must be dispensed in the quantity ordered except that the proposed new (c) proposes language regarding prescriptions for all opioid naïve members to be in accordance with ARM 37.86.1103.

##### ARM 37.86.1103

The department is proposing to amend ARM 37.86.1103 by providing a definition of "opioid naïve." This proposed definition provides for the number of days a member is to be without an opioid prescription in order to fall into the category that limits their day supply of the opioid drug.

##### Fiscal Impact

No fiscal impact is anticipated by these proposed rule amendments. These changes are expected to be budget neutral.

The proposed rule amendments are estimated to affect 273,904 Medicaid members. In addition, it could potentially affect 432 enrolled pharmacies.

5. The department intends to adopt these rule amendments effective October 1, 2019.

6. Concerned persons may submit their data, views, or arguments either orally or in writing at the hearing. Written data, views, or arguments may also be submitted to: Gwen Knight, Department of Public Health and Human Services, Office of Legal Affairs, P.O. Box 4210, Helena, Montana, 59604-4210; fax (406) 444-9744; or e-mail [dphhslegal@mt.gov](mailto:dphhslegal@mt.gov), and must be received no later than 5:00 p.m., August 23, 2019.

7. The Office of Legal Affairs, Department of Public Health and Human Services, has been designated to preside over and conduct this hearing.

8. The department maintains a list of interested persons who wish to receive notices of rulemaking actions proposed by this agency. Persons who wish to have their name added to the list shall make a written request that includes the name, e-mail, and mailing address of the person to receive notices and specifies for which program the person wishes to receive notices. Notices will be sent by e-mail unless a mailing preference is noted in the request. Such written request may be mailed or delivered to the contact person in 6 above or may be made by completing a request form at any rules hearing held by the department.

9. The bill sponsor contact requirements of 2-4-302, MCA, do not apply.

10. With regard to the requirements of 2-4-111, MCA, the department has determined that the amendment of the above-referenced rules will not significantly and directly impact small businesses.

11. Section 53-6-196, MCA, requires that the department, when adopting by rule proposed changes in the delivery of services funded with Medicaid monies, make a determination of whether the principal reasons and rationale for the rule can be assessed by performance-based measures and, if the requirement is applicable, the method of such measurement. The statute provides that the requirement is not applicable if the rule is for the implementation of rate increases or of federal law.

The department has determined that the proposed program changes presented in this notice are not appropriate for performance-based measurement and therefore are not subject to the performance-based measures requirement of 53-6-196, MCA.

/s/ Brenda K. Elias  
Brenda K. Elias  
Rule Reviewer

/s/ Sheila Hogan  
Sheila Hogan, Director  
Public Health and Human Services

Certified to the Secretary of State July 16, 2019.