

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

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

TO: All Concerned Persons

1. On July 26, 2019, the Department of Public Health and Human Services published MAR Notice No. 37-865 pertaining to the public hearing on the proposed amendment of the above-stated rules at page 1012 of the 2019 Montana Administrative Register, Issue Number 14.

2. The department has amended the following rules as proposed, but with the following changes from the original proposal, new matter underlined, deleted matter interlined:

37.86.1102 OUTPATIENT DRUGS, REQUIREMENTS (1) through (11) remain as proposed.

AUTH: 53-2-201, 53-6-113, MCA
IMP: 53-2-201, 53-6-101, 53-6-113, ~~53-6-144~~, MCA

37.86.1103 OUTPATIENT DRUGS, FRAUD, WASTE, AND ABUSE
(1) through (4) remain as proposed.
(5) "Opioid naïve member" means a member has not received a prescription for an opioid within the last 45 ~~90~~ days.
(6) through (8) remain as proposed.
(9) ~~For~~ Except as provided in (10), 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).~~

(10) The restriction imposed under (9) does not apply if the opioid is prescribed to treat:
(a) chronic pain, pain associated with cancer, or pain experienced while the patient is in palliative care; or
(b) opioid abuse or dependence, including but not limited to opioid agonists and opioid antagonists.
(10) and (11) remain the same, but are renumbered (11) and (12).

AUTH: 53-2-201, 53-6-113, MCA
IMP: 53-2-201, 53-6-101, 53-6-111, MCA

3. The department has thoroughly considered the comments and testimony received. A summary of the comments received and the department's responses are as follows:

COMMENT #1: Several commenters inquired why the opioid naïve lookback period was proposed to be 45 days, which differs from the 90-day lookback period in House Bill (HB) 86, which passed in the 2019 Legislative Session. The commenters requested the rule be changed to make it consistent with the requirements in HB 86.

RESPONSE #1: The department has determined these comments are well taken and has amended the rule to align with the statutory definition of "opioid-naïve." We concur that a 90-day lookback is appropriate for Medicaid members. The department originally drafted this rule prior to the 2019 Legislative Session and notes that there is no single and generally accepted definition of "opioid-naïve." Upon receiving the comments, the department agrees that maintaining consistency with the licensing requirements in HB 86 will help ensure compliance by providers. Therefore, the definition of "opioid-naïve" will be amended as suggested.

COMMENT #2: Commenters questioned why the exceptions in ARM 37.86.1103 differed from those in HB 86. The rule as originally proposed cited only a cancer diagnosis. The statute excludes persons receiving opioids for Medicated Assisted Treatment (MAT), cancer pain, chronic pain, or pain while in palliative care.

RESPONSE #2: The department has determined these comments are well taken and has amended the rule to align it with the statutory exceptions to the 7-day prescription supply limit. We concur that the rule should include the statutory exceptions to the 7-day supply limit and thus allow longer opioid prescription supply for Medicaid members who have cancer, chronic pain, or pain while in palliative care, or if the prescription is for the treatment of opioid abuse or dependence.

COMMENT #3: Several commenters opposed the proposed 50 morphine milligram equivalents (MME) per day limit for opioid naïve members for various reasons. Some stated the limit is arbitrary and not supported by CDC 2016 guidelines, that CDC guidelines recommend starting opioids at the "lowest effective dose." Also, persons discharged from the hospital after surgery are often on higher doses than 50 MME/day, and that the limit will impede care for members being discharged on weekends or evenings.

RESPONSE #3: The department has determined these comments are well taken and has amended the rule to eliminate the 50 MME/day limit which aligns it with the provisions of HB 86. The department's primary concern is the health and safety of Medicaid members and the community, and the 50 MME/day limit was proposed for that purpose. This rule is not intended to impede patient care or hinder providers who are prescribing according to current best practice. The department will continue discussions with providers and the Medicaid Drug Use Review Board to determine appropriate limits in the future.

COMMENT #4: The department received two comments on the 7-day supply limit on an opioid prescription. One commenter requested the limit be increased. The other commenter requested it be eliminated.

RESPONSE #4: The 7-day limit is in accordance with the licensing requirements for medical practitioners in HB 86. As noted in the department's other responses, the department believes that maintaining consistency with the licensing requirements in HB 86 will help ensure compliance by providers, including out-of-state providers who may not be subject to the requirements in HB 86.

COMMENT #5: The department received a comment noting that 53-6-141, MCA, has been repealed and should not be cited as the implementation authority for ARM 37.86.1102.

RESPONSE #5: The department has determined that the comment is well taken and has stricken the reference to the repealed statute.

/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 September 10, 2019.