

BEFORE THE COMMISSIONER OF SECURITIES AND INSURANCE
OFFICE OF THE MONTANA STATE AUDITOR

In the matter of the adoption of New) NOTICE OF ADOPTION
Rule I pertaining to Pharmacy Benefit)
Manager Definitions and New Rule II)
pertaining to Pharmacy Benefit)
Manager Network Adequacy)

TO: All Concerned Persons

1. On October 22, 2021, the Commissioner of Securities and Insurance, Office of the Montana State Auditor (CSI) published MAR Notice No. 6-265 pertaining to the public hearing on the proposed adoption of the above-stated rules at page 1352 of the 2021 Montana Administrative Register, Issue Number 20.

2. On November 12, 2021, a public hearing was held in-person and electronically to consider the rulemaking. Testimony was provided by five proponents and two opponents of the proposed rules; additional attendees were present but did not provide oral testimony.

3. CSI has adopted the following rules as proposed, but with the following changes from the original proposal, new matter underlined, deleted matter interlined:

NEW RULE I (ARM 6.6.7901) NETWORK ADEQUACY DEFINITIONS (1)

The following definitions apply to this subchapter:

(a) "Mail-order pharmacy" means a pharmacy that provides pharmacist services and primarily dispenses and delivers covered drugs via common carrier.

(b) "Pharmacy network" means a group of pharmacies contracted with a pharmacy benefit manager (PBM) ~~PBM~~ to provide pharmacist services at negotiated prices to an enrollee or an injured worker of a workers' compensation insurance ~~carriers~~ carrier.

(c) "Preferred pharmacy network" means a subset, group, or tier of pharmacies that is designated as preferred within a pharmacy network that ~~agree~~ agrees to charge an enrollee or an injured worker of a workers' compensation insurance ~~carriers~~ carrier a ~~reduced~~ lower copay copayment, ~~or coinsurance, or deductible~~ for pharmacist services or to accept a lower reimbursement rate than other pharmacies in the pharmacy network.

(d) "Retail pharmacy" means any pharmacy that ~~actively~~ provides pharmacist services to the walk-in general public from which an enrollee or an injured worker of a workers' compensation insurance ~~carriers~~ carrier could purchase a covered drug without being required to receive medical services from a provider or institution affiliated with that pharmacy.

AUTH: 33-1-313, 33-2-2409, 33-2-2412, MCA

IMP: 33-2-2402, 33-2-2403, 33-2-2409, MCA

4. CSI has adopted the following rules as proposed, but has moved the substance of proposed New Rule II(2)(a) and (d) to New Rule III, moved the substance of proposed New Rule II(8) to New Rule IV, and moved the substance of several paragraphs within New Rule II. The adopted rules contain the following changes from the original proposal, new matter underlined, deleted matter interlined:

NEW RULE II (ARM 6.6.7902) NETWORK ADEQUACY (1) A PBM must establish and maintain a pharmacy networks network that include ~~at least 90% of the retail pharmacies actively providing pharmacist services in this state~~ is sufficient in numbers to ensure all pharmacist services are accessible without unreasonable delay, within a reasonable proximity to the business or personal residence of an enrollee or an injured worker of a workers' compensation insurance carrier, and with sufficient choice based on the availability of retail pharmacies.

(2) ~~A PBM's pharmacy network must include a sufficient and adequate number of retail pharmacies to ensure that all pharmacist services are accessible without unreasonable delay, within a reasonable proximity, and with sufficient provider choice.~~ Each pharmacy network offered by a PBM will be considered a separate pharmacy network.

~~(a) A PBM must submit the following reports and information for each pharmacy network and preferred pharmacy network as part of its license or license renewal application to demonstrate to the commissioner a sufficient and adequate pharmacy network:~~

~~(i) a report in a form and in a manner prescribed by the commissioner that designates the number and location of all retail pharmacies, mail-order pharmacies, and specialty pharmacies, if any, in each PBM pharmacy network and preferred pharmacy network; and~~

~~(ii) a network accessibility report that includes:~~

~~(A) the access standard or standards the PBM establishes to determine network adequacy based on the number of miles between the enrollees or injured workers of workers' compensation insurance carriers and nearest retail pharmacy in the pharmacy network;~~

~~(B) the number of enrollees or injured workers of workers' compensation insurance carriers with access to a retail pharmacy in the pharmacy network using the access standard established by the PBM;~~

~~(C) the average number of miles between the enrollees and injured workers of workers' compensation insurance carriers identified in (B) and the nearest retail pharmacy in the pharmacy network;~~

~~(D) the number of enrollees and injured workers of workers' compensation insurance carriers without access to a retail pharmacy in the pharmacy network using the access standard established by the PBM;~~

~~(E) the average number of miles between the enrollees and injured workers of workers' compensation insurance carriers identified in (D) and the nearest retail pharmacy in the pharmacy network; and~~

~~(F) the ratios of retail pharmacies in the pharmacy network to an enrollee or an injured worker of workers' compensation insurance carriers;~~

~~(iii) the PBM's process for monitoring and ensuring on an ongoing basis a sufficient and adequate pharmacy network to meet the pharmacist services needs of enrollees and injured workers of workers' compensation insurance carriers; and~~

~~(3) The commissioner may consider reasonable criteria or standards to determine the sufficiency and adequacy of a pharmacy network, including:~~

~~(a) whether the pharmacy network includes at least 80% of retail pharmacies;~~

~~(iv)-(b) the specific, measurable criteria used by the PBM used to build its a pharmacy network, including:~~

~~(A) a description of the criteria the PBM used to build its pharmacy network, including the criteria used to select pharmacies for participation in the pharmacy network;~~

~~(B)-(c) if applicable, a description of the criteria the PBM used to build its any preferred pharmacy network, including the criteria used to place pharmacies in subsets, groups, or tiers; and~~

~~(C)-(d) if applicable, a description of the criteria used by the PBM used to select pharmacies to dispense specialty drugs in its the pharmacy network;~~

~~(e) the access standards and other information provided in the PBM's application and reports; and~~

~~(b) A PBM may identify, and must report to the commissioner, other reasonable criteria or standards it uses to establish the sufficiency and adequacy of its pharmacy networks, including (f) the willingness of retail pharmacies in the applicable geographic service area to contract with the PBM based upon the same or similar terms and conditions applicable to pharmacies of the same type participating in the pharmacy network under reasonable and relevant standard terms and conditions specific to the pharmacy's business practice and delivery model. The commissioner may require the PBM to submit credible evidence documenting a retail pharmacy's refusal to contract based upon the same or similar terms and conditions applicable to pharmacies of the same type participating in the pharmacy network reasonable and relevant standard terms and conditions specific to the pharmacy's business practice and delivery model.~~

~~(3) If a PBM does not have a sufficient and adequate pharmacy network, regardless of whether adequacy was determined by a threshold percentage of retail pharmacies in (1), the PBM must ensure that the enrollee or the injured worker of workers' compensation insurance carriers obtains pharmacist services from a retail pharmacy within reasonable proximity of the enrollee or the injured worker of workers' compensation insurance carriers at no greater level of cost sharing to the enrollees or the injured workers of workers' compensation insurance carriers than if the service were obtained from a pharmacy in the pharmacy network with the most favorable cost sharing to the enrollees the injured workers of workers' compensation insurance carriers. The cost sharing paid by the enrollees or injured workers of workers' compensation insurance carriers must accumulate toward the enrollee's plan's deductibles and maximum out-of-pocket amounts.~~

~~(4) A PBM must monitor, on an ongoing basis, the ability and capacity of its pharmacy network to furnish pharmacist services to the enrollee or the injured worker of workers' compensation insurance carriers.~~

~~(4) A PBM may decline to select a pharmacy to be in a pharmacy network if the pharmacy fails to meet legitimate and reasonable selection criteria of the PBM.~~

(5) A PBM may not use mail-order pharmacies to meet network adequacy requirements for its a pharmacy network.

(6) A PBM may not require an enrollee or an injured worker of a workers' compensation insurance ~~carriers~~ carrier to use any pharmacy, including a mail-order pharmacy, in which the PBM has an ownership interest, either directly or indirectly through an affiliate, holding company, or subsidiary, for prescriptions, refills, or specialty drugs regardless of day supply.

~~(7) A PBM may decline to select a pharmacy to be in the pharmacy network if the pharmacy fails to meet legitimate and reasonable selection criteria of the PBM.~~

~~(8) A PBM must post electronically a current, accurate, and searchable directory of pharmacies for each of its pharmacy networks.~~

~~(a) In making the directory available electronically, the PBM must ensure that the general public is able to view all pharmacies included in its pharmacy network and preferred pharmacy network through a clearly identifiable link or tab, without creating an account or entering a policy or contract number.~~

~~(b) A PBM must clearly identify in its electronic directories the pharmacies that are in each of its pharmacy networks.~~

~~(c) A PBM must include in its electronic directory a customer service email address and telephone number or electronic link that enrollees, injured workers of workers' compensation insurance carriers, or the general public may use to notify the PBM of inaccurate directory information.~~

~~(9) (7) A PBM may use a restricted pharmacy network as long as the PBM otherwise meets the network adequacy requirements set forth in these rules. A PBM may place legitimate and reasonable requirements on pharmacies with whom which it contracts.~~

(8) A PBM must monitor, on an ongoing basis, the ability and capacity of the pharmacy network to furnish pharmacist services to an enrollee or an injured worker of a workers' compensation insurance carrier.

AUTH: 33-1-313, 33-2-2409, 33-2-2412, MCA
IMP: 33-2-2402, 33-2-2403, 33-2-2409, MCA

5. CSI has adopted the following rules comprised of wording from proposed New Rule II and structured as separate, new rules. CSI has moved the substance of proposed New Rule II(2)(a) and (d) to New Rule III and moved the substance of proposed New Rule II(8) to New Rule IV. The adopted rules contain the following changes from the original proposal, new matter underlined, deleted matter interlined:

NEW RULE III (ARM 6.6.7903) NETWORK ADEQUACY REPORTING (1)
~~(2)(a)~~ A PBM must submit the following reports and information for each pharmacy network ~~and preferred pharmacy network~~ as part of its license or license renewal application to demonstrate to the commissioner a sufficient and adequate pharmacy network:

~~(+)~~ (a) a report in a form and in a manner prescribed by the commissioner that designates the number and location of all retail pharmacies, mail-order pharmacies, and specialty pharmacies, if any, in each pharmacy network ~~and preferred pharmacy network~~; ~~and~~

(ii) ~~(b)~~ a network accessibility report that includes:

~~(A)~~ ~~(i)~~ the access standard or standards the PBM establishes to determine network adequacy based on the number of miles between ~~the an enrollees enrollee~~ or ~~an injured workers worker~~ of ~~a workers' compensation insurance carriers carrier~~ and nearest retail pharmacy in the pharmacy network;

~~(B)~~ ~~(ii)~~ the number of enrollees or injured workers of ~~a workers' compensation insurance carriers carrier~~ with access to a retail pharmacy in the pharmacy network using the access standard established by the PBM;

~~(C)~~ ~~(iii)~~ the average number of miles between the enrollees and injured workers of ~~a workers' compensation insurance carriers carrier~~ identified in ~~(B)~~ ~~(ii)~~ and the nearest retail pharmacy in the pharmacy network;

~~(D)~~ ~~(iv)~~ the number of enrollees and injured workers of ~~a workers' compensation insurance carriers carrier~~ without access to a retail pharmacy in the pharmacy network using the access standard established by the PBM;

~~(E)~~ ~~(v)~~ the average number of miles between the enrollees and injured workers of ~~a workers' compensation insurance carriers carrier~~ identified in ~~(D)~~ ~~(iv)~~ and the nearest retail pharmacy in the pharmacy network; and

~~(F)~~ ~~(vi)~~ the ratios of retail pharmacies in the pharmacy network to an enrollee or an injured worker of ~~a workers' compensation insurance carriers carrier~~;

~~(iii)~~ ~~(c)~~ the PBM's process for monitoring and ensuring on an ongoing basis a sufficient and adequate pharmacy network to meet the pharmacist services needs of enrollees and injured workers of ~~a workers' compensation insurance carriers carrier~~; and

~~(d)~~ ~~(2)~~ A PBM must file and update the report required in ~~(a)(i)~~ ~~(a)~~ with the commissioner if the number of pharmacies in the pharmacy network decreases by more than 5% during the year.

AUTH: 33-1-313, 33-2-2409, 33-2-2412, MCA

IMP: 33-2-2402, 33-2-2403, 33-2-2409, MCA

NEW RULE IV (ARM 6.6.7904) NETWORK ADEQUACY DIRECTORIES (1)

~~(8)~~ A PBM must post electronically a current, accurate, and searchable directory of pharmacies for each of its pharmacy ~~networks~~ network.

(a) In making the directory available electronically, the PBM must ensure that the general public is able to view all pharmacies included in its each pharmacy network ~~and preferred pharmacy network~~ through a clearly identifiable link or tab, without creating an account or entering a policy or contract number.

(b) A PBM must clearly identify in its electronic directories the pharmacies that are in each of its pharmacy ~~networks~~ network.

(c) A PBM must include in its electronic directory a customer service email address and telephone number or electronic link that enrollees, injured workers of a workers' compensation insurance ~~carriers~~ carrier, or the general public may use to notify the PBM of inaccurate directory information.

AUTH: 33-1-313, 33-2-2409, 33-2-2412, MCA

IMP: 33-2-2402, 33-2-2403, 33-2-2409, MCA

6. CSI has thoroughly considered the comments and testimony received. A summary of the comments and testimony received and CSI's responses are as follows:

COMMENT 1: Multiple commentors requested that the rules apply to plan and policy years on or after January 1, 2023. One of the commentor suggested that PBMs need time to build provider networks and to develop processes to compile required reports. Another commentor stated that network filings were submitted and approved by CSI earlier this year for 2022.

RESPONSE 1: The Legislature made the Montana Pharmacy Benefit Manager Oversight Act ("the Act"), including the licensing requirement, effective January 1, 2022.

COMMENT 2: Multiple commentors stated that the proposed New Rules, or parts thereof, were complex or needed additional clarification.

RESPONSE 2: Proposed New Rule II has been separated for clarity into specific rules focusing on network adequacy (New Rule II), network adequacy reporting (New Rule III), and network adequacy directories (New Rule IV). Changes to the substance of New Rules III and IV from the proposed rules in response to public comment are reflected in the underlining and interlining within those rules. Restructuring within New Rule II is reflected in the underlining and interlining within that rule.

COMMENT 3: Multiple commentors stated that the definition of "mail-order pharmacy" in proposed New Rule I was not consistent with the definition of "out-of-state mail service pharmacy" in § 37-7-702, MCA. These commentors further stated that the definition of "mail-order pharmacy" either should be made consistent or should be stricken. One of the commentors also stated that an "out-of-state mail service pharmacy" meets the definition of "pharmacy" in § 33-2-2402, MCA.

RESPONSE 3: The definition in § 37-7-702, MCA, applies to out-of-state mail service pharmacies. The proposed definition of "mail-order pharmacy" in New Rule I includes both in-state and out-of-state pharmacy services providers. Using the definition of "out-of-state mail service pharmacy" in § 37-7-702, MCA, and the definition of "retail pharmacy" in proposed New Rule I would exclude application of the proposed rules to in-state, mail-order pharmacies. CSI intends for these new rules to apply to in-state, mail-order pharmacies.

COMMENT 4: A commentor expressed concern that the definition of "pharmacy network" in proposed New Rule I(1)(b) could be interpreted to mean the entirety of all pharmacies contracted with a PBM, even if the PBM has several limited or restricted networks within this larger umbrella, which could prevent meaningful assessment of PBM network adequacy.

RESPONSE 4: Network adequacy will be determined at the pharmacy network level, which includes any preferred pharmacy network. Redundant references in the proposed rules to “preferred pharmacy network” are removed in the adopted rule because the definition of pharmacy network includes any preferred pharmacy network.

COMMENT 5: A commentor requested clarification about what constitutes “actively providing pharmacy services in this state” in the definition of “retail pharmacy”.

RESPONSE 5: The word “actively” has been removed from the adopted version of New Rule I.

COMMENT 6: A commentor expressed concern that the definition of “preferred pharmacy network” in proposed New Rule I(1)(c) may incorrectly categorize pharmacies that are lower paid but still non-preferred where the definition includes pharmacies that agree “to accept a lower reimbursement rate than other pharmacies in the pharmacy network.” The commentor suggested regarding proposed New Rule I(1)(c) that wording be added to clarify that no matter how a PBM defines, configures, or labels its networks, each subset that is offered to plans or patients must be considered individually. The commentor also stated that a pharmacy’s preferred status may have no relation to its reimbursement rates.

RESPONSE 6: CSI has modified the definition of “preferred pharmacy network” to clarify that accepting a lower reimbursement rate does not automatically include a pharmacy in the definition of a “preferred pharmacy network.”

COMMENT 7: A commentor suggested specific wording for the definition of “preferred pharmacy network” in proposed New Rule I(1)(c) to include lower deductibles, in addition to lower copayments or coinsurance, to more fully capture the various ways in which cost sharing might be reduced in preferred networks.

RESPONSE 7: CSI has modified the definition of “preferred pharmacy network” to reference lower deductibles.

COMMENT 8: Multiple commentors expressed concern about the requirement in proposed New Rule II(1) that a pharmacy network include at least 90% of retail pharmacies in the state. The commentors stated that requiring a fixed percentage in a pharmacy network is inconsistent with the statutory requirement for an adequate network and accessible pharmacy network that ensures reasonable proximity of pharmacies to the businesses or personal residences of enrollees and injured workers. Commentors also asserted that the 90% threshold percentage is contrary to § 33-22-1706, MCA, which applies to network adequacy of a health benefit plan. Multiple commentors suggested that the 90% requirement should be removed or included as one criterion for establish network adequacy.

RESPONSE 8: CSI does not agree that it is constrained from adopting a fixed percentage or that such a standard is inconsistent with the statutory requirement for

an adequate and accessible pharmacy network. Using a percentage of retail pharmacies as a criterion for determining network adequacy is consistent with the approach for determining network adequacy for health insurers in § 33-22-1706, MCA. CSI has, however, modified the wording from proposed New Rule II to include an 80% threshold percentage as one criterion for the commissioner to consider regarding pharmacy network sufficiency and adequacy.

COMMENT 9: A commentor expressed concern about proposed New Rule II(1) and the 90% threshold percentage, stating that it would undermine competition among pharmacies and would eliminate incentives to offer discounts to consumers. Another commentor expressed concern that the 90% rule will adversely impact health insurers that have a geographically limited service area. The commentor also expressed uncertainty about how a health insurer offering a Health Maintenance Organization (HMO) or a narrow Preferred Provider Organization (PPO) would comply with the 90% rule. The commentor also stated that the 90% rule is inflexible and an arbitrary percentage that excludes consideration of location and number of members in each geographic area.

RESPONSE 9: Please see Response to Comment 8. The adopted version of New Rule II lists various criteria, including an 80% threshold percentage criterion, that may be considered by the commissioner to assess network sufficiency and adequacy. In addition, CSI may consider the access standards and other information included in a PBM's reports to assess network sufficiency and adequacy, which includes consideration of location and number of enrollees or injured workers of workers' compensation insurance carriers.

COMMENT 10: A commentor stated that network adequacy should be determined for each pharmacy network, including any preferred pharmacy network within the pharmacy network. Multiple commentors stated that network adequacy should be determined for a PBM based on the overall network, which includes every pharmacy in the PBM's network.

RESPONSE 10: Network adequacy will be determined at the pharmacy network level, which includes any preferred pharmacy network. Redundant references in the proposed rules to "preferred pharmacy network" are removed in the adopted rule because the definition of pharmacy network includes any preferred pharmacy network.

COMMENT 11: A commentor asserted that proposed New Rule II(2) is inconsistent with the requirements of § 33-22-1704, MCA, including the requirement for a health insurer to develop network criteria and to conduct competitive bids or offers.

RESPONSE 11: The adopted version of New Rule II includes an 80% threshold percentage as one criterion for the commissioner's consideration regarding pharmacy network sufficiency and adequacy. CSI retains the discretion to review restricted or narrow networks based on reasonable criteria, including the criteria

listed in New Rule II, recognizing that those networks, in light of their purposes and objectives, may not meet the threshold percentage.

COMMENT 12: A commentor asserted that proposed New Rule II(2)(b) exceeds the scope and intent of the Act by requiring consideration of, and a report to the Commissioner about, a pharmacy's individual business practices and delivery model. The commentor stated that the requirement is vague and there is no way to objectively determine if contract terms are reasonable when applied to the subjective business practices of a specific pharmacy.

RESPONSE 12: While CSI does not agree that the rule exceeds the scope of its authorizing statute, it has removed the reference to "reasonable and relevant terms and conditions specific to the pharmacy's business practice and delivery model." CSI has updated the adopted rule to clarify CSI will review any "refusal to contract" claim by a PBM on whether a retail pharmacy was offered "the same or similar terms and conditions as other pharmacies of the same type participating in the network."

COMMENT 13: A commentor suggested specific wording changes for proposed New Rule II(2)(d) to address potential, mid-year network inadequacy due to changes like the addition of new individuals onto plans, the movement of individuals from one pharmacy network to another, or the addition of new pharmacy networks.

RESPONSE 13: Under New Rule III(1)(c), a PBM must monitor network sufficiency and adequacy on an ongoing basis. If a PBM adds a new pharmacy network, the PBM would need to submit the new network on the form required by the commissioner for review and approval.

COMMENT 14: A commentor requested clarification about the phrase "reasonable proximity" and suggested that the phrase mean reasonable proximity to the enrollee's home residence.

RESPONSE 14: The adopted version of New Rule II clarifies that reasonable proximity means proximity of pharmacies to the businesses or personal residences of enrollees and injured workers.

COMMENT 15: A commentor stated that the proposed rules are very extensive and have subjective standards for approval of network adequacy. The commentor requested clarification of the phrase "using the access standard established by the PBM" that is used in proposed New Rule II(2)(a)(ii)(B), (D).

RESPONSE 15: The proposed New Rule II has been separated for clarity into separate rules focusing on network adequacy (New Rule II), network adequacy reporting (New Rule III) and network adequacy directories (New Rule IV). Network adequacy should not be a new concept for PBMs. As commentors have pointed out, pharmacy networks used by health insurers have long been required to meet network adequacy standards. In this instance, CSI has requested each PBM

seeking licensure to provide the access standards it has established for network sufficiency and adequacy.

COMMENT 16: A commentor requested clarification regarding the purpose and calculation of the ratios in proposed New Rule II(2)(a)(ii)(F).

RESPONSE 16: The purpose is to identify the number of pharmacies in relation to enrollees and injured workers of workers' compensation insurance carriers to ensure reasonable and timely access to pharmacist services.

COMMENT 17: A commentor stated that proposed New Rule II uses the singular "network" and the plural "networks" inconsistently.

RESPONSE 17: The use of singulars and plurals has been revised in the adopted rules to be consistent, depending on context.

COMMENT 18: A commentor stated that network adequacy should be limited to retail pharmacy networks. The commentor asserted that applying network adequacy to non-retail pharmacy networks would establish an arbitrary standard based on the existence of physical pharmacies rather than the availability of services.

RESPONSE 18: CSI considers criteria to determine sufficiency and adequacy that includes the number and location of retail pharmacies included in a pharmacy network.

COMMENT 19: Multiple commentors asserted that proposed New Rule II(3) exceeded the scope and intent of the Act. The commentors stated that proposed New Rule II(3) regulated the conduct of health benefit plans and not PBMs; the commentors asserted that proposed New Rule II(3) may be a benefit mandate of a health benefit plan

RESPONSE 19: CSI recognizes that health insurers generally establish a plan's benefit design, including cost-sharing levels. On that basis, proposed New Rule II(3), which imposed certain requirements related to cost-sharing on PBMs, was not adopted as a final rule. However, CSI retains the authority to take licensure action against a PBM for an insufficient or inadequate pharmacy network.

COMMENT 20: A commentor suggested specific wording changes for proposed New Rule II(3) to disallow a deductible differential, along with prohibition of a copayment or coinsurance differential, for inadequate networks.

RESPONSE 20: Proposed New Rule II(3), which included cost-sharing requirements, was not adopted as a final rule.

COMMENT 21: A commentor suggested that proposed New Rule II(4)-8(b) apply to each pharmacy network and each preferred pharmacy network.

RESPONSE 21: Network adequacy will be determined at the pharmacy network level, which includes any preferred pharmacy network. Redundant references in the proposed rules to “preferred pharmacy network” are removed in the adopted rule because the definition of pharmacy network includes any preferred pharmacy network.

COMMENT 22: Multiple commentors asserted that proposed New Rule II(5), a requirement that a PBM may not use a mail-order pharmacy to meet the network adequacy, contradicted the Act. The commentors stated that the definition of “pharmacy” in § 33-2-2402(10), MCA included both physical and electronic pharmacies. Commentors asserted that the Legislature intended physical and electronic pharmacies to be considered for network adequacy purposes.

RESPONSE 22: The use of the term “electronic pharmacy” is not equivalent to the pharmacy being a mail-order pharmacy. The Legislature’s use of “physical pharmacy” in § 33-2-2409(2), MCA, demonstrates its intent for physical pharmacies to be considered for network adequacy purposes.

COMMENT 23: A commentor asserted that the use of “relative availability of physical pharmacies” in § 33-2-2409(2), MCA, indicates the Legislature’s intent that mail-order pharmacies be included in the determination of an adequate network particularly in those instances when physical pharmacies are not available in a geographic area. Another commentor stated that, based on proposed New Rule II(5), every enrollee would have access to a retail pharmacy.

RESPONSE 23: When determining the sufficiency and adequacy of a pharmacy network, consideration is given to the availability of retail pharmacies. CSI recognizes that the availability of retail pharmacies may vary by geographic service area.

COMMENT 24: Multiple commentors asserted that proposed New Rule II(6) exceeds the scope of the Act because the Legislature did not limit a PBM’s use of pharmacies in which it has an ownership interest.

RESPONSE 24: Proposed New Rule II(6) did not prohibit the use of a pharmacy in which the PBM has an ownership interest. However, a PBM cannot require the use of a pharmacy in which a PBM has an ownership interest.

COMMENT 25: A commentor asserted that proposed New Rule II(6) results in the improper taking or damage of private property rights in violation of the Montana Constitution and § 2-10-101 et seq., MCA, and also asserted that CSI has not conducted the impact assessment required by § 2-10-105, MCA.

RESPONSE 25: New Rule II(6) does not constitute an improper taking or damage of private property rights in violation of the Montana Constitution and § 2-10-101 et seq., MCA. Further, § 2-10-101 et seq., MCA, including the impact assessment

under § 2-10-105, MCA, does not apply because New Rule II(6) does not affect “private property” as defined in § 2-10-103, MCA.

COMMENT 26: A commentor expressed concern that proposed New Rule II(6) prohibited a PBM from steering members to pharmacies in which the PBM has an ownership interest will negatively impact health insurers' efforts to lower costs and improve the quality of care.

RESPONSE 26: The proposed rule did not prohibit a PBM from using a pharmacy or steering enrollees or injured workers to a pharmacy in which it has an ownership interest. Rather, the proposed rule stated that the PBM cannot require the use of a pharmacy in which it has an ownership interest.

COMMENT 27: A commentor asserted that proposed New Rule II(6) was “inconsistent with the other Montana insurance code network adequacy standards.”

RESPONSE 27: The adopted rules are not inconsistent with the standards in the health benefit plan network adequacy rule. Nothing in the Act requires that other network adequacy requirements align precisely with the network adequacy requirements for PBMs.

COMMENT 28: A commenter asserted that proposed New Rule II(6) exceeded CSI's rulemaking authority. The commenter asserted that the Act limited CSI's rulemaking authority to only consider “relative availability of physical pharmacies in a geographic area.” § 33-2-2409(2), MCA. The commenter asserted that the paragraph should be removed from the adopted rules.

RESPONSE 28: Proposed New Rule II(6) does not exceed the statutory rulemaking authority. When determining the sufficiency and adequacy of a pharmacy network, consideration is given to the availability of retail pharmacies. CSI recognizes that the availability of retail pharmacies may vary by geographic service area.

COMMENT 29: A commentor stated that proposed New Rule II(7) should be stricken because a PBM that meets the criteria for network adequacy should not have its rationale reviewed for not contracting with pharmacies that are not included in their network.

RESPONSE 29: Proposed New Rule II(7) was included to provide flexibility to a PBM to refuse to contract with a pharmacy that fails to meet the legitimate and reasonable selection criteria established by the PBM. That information may be relevant with respect to CSI's review of a pharmacy network where a PBM can show that it was unable to contract with a particular pharmacy because of the pharmacy's unwillingness to meet the PBM's legitimate and reasonable selection criteria.

COMMENT 30: A commentor suggested a wording change to proposed New Rule II(8)(a) to limit pharmacy directory access to a PBM's enrollees and only to their pharmacy network and no other network offered by the PBM. The commentor

suggested this change would prevent confusion because pharmacy networks are specific to an insurance plan.

RESPONSE 30: Allowing the directory to be accessible by the general public, not just enrollees, would be an important consideration for potential enrollees and injured workers of a workers' compensation carrier to consider the sufficiency and adequacy of a pharmacy network. Clear identification of the pharmacy networks in the directory will prevent confusion about the application of those networks to a specific benefit plan.

COMMENT 31: A commentor stated that it is unclear whether, related to proposed New Rule II(9), a PBM can have a restricted network that does not meet the threshold percentage.

RESPONSE 31: The adopted rule clarifies that the percentage threshold is one criterion that may be considered in assessing network sufficiency and adequacy.

7. The effective date of this rulemaking is January 1, 2022.

/s/ Robert Stutz
Robert Stutz
Rule Reviewer

/s/ Mary Belcher
Mary Belcher
Deputy State Auditor

Certified to the Secretary of State December 14, 2021