

**In the Matter of Proposed Adoption of New Rules Governing  
Pharmacy Benefit Manager (PBM) Licensure and Regulation,  
creating Minnesota Rules, chapter 2737; Revisor's ID  
Number: R04625, OAH Docket No. 21-9009-37561.**

**Initial Response to Comments Submitted During the Pre-Hearing Public  
Comment Period, at the September 20, 2021 Public Hearing, and During the  
Post-Hearing Public Comment Period up to October 6, 2021**

**October 8, 2021**

## I. Introduction

This document provides an initial response to the comments received in the above referenced rulemaking docket. During the pre-hearing comment period seven (7) comments were received. At the September 20, 2021 hearing there were three (3) public comments—each commenter represented an organization that submitted written comments which largely mirrored the comments presented at the hearing. As of October 6, 2021,<sup>1</sup> there were nine (9) responses on the OAH eComments webpage.<sup>2</sup>

### A. Notice and Public Hearing

The Minnesota Commerce Department (Commerce) published its Notice of Intent to Adopt Rules with a Hearing (Notice) regarding the above-referenced proposed rulemaking docket in the State Register on August 16, 2021 (46 SR 137). The Notice provided for the submission of comments from August 17, 2021, through September 16, 2021. The public was also allowed to make comments at the September 20, 2021 hearing. Additionally, the post-hearing comment period was extended until 4:30 p.m. on October 8, 2021, by order of Administrative Law Judge Middendorf.

Commerce has presented information demonstrating that the proposed rules are needed and reasonable as required by Minn. Stat. §§14.131 and 14.14, subd. 2, through an affirmative presentation of facts at the hearing, and in the Statement of Need and Reasonableness (SONAR).

### B. Goals of Rulemaking

Commerce is proposing adoption of these rules to address the following needs: first, create clarity for industry and Minnesotans of the meaning of key statutory provisions; second, increase predictability in the enforcement of the PBM statute; and third, provide greater detail to the processes required by statute, e.g., licensure and data reporting.

### C. Organization of Commerce's Review and Response to Comments

This document supplements the SONAR, previously filed in this matter. This document contains Commerce's initial response to comments submitted during the pre-hearing public comment period, at the September 20, 2021 public hearing, and during the post-hearing public comment period up to October 7, 2021.

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<sup>1</sup> Comments made after October 6, 2021, will be addressed in Commerce's final response submitted during the rebuttal period.

<sup>2</sup> Although there were nine replies to the request for post-hearing comments, some of those were duplicative and submitted by the same person or organization.

The comments received, to date, include both positive and negative feedback. Some commenters believe the rules have not gone far enough, and others that the rules have gone too far. Generally, the comments addressed one to three of the proposed rules, however, some commenters chose to address each proposed rule in their comment. As the proposed rules would create a new chapter, Commerce has chosen to organize its response by each proposed rule rather than by each comment received. This approach will allow for comments that are substantially the same to be addressed only once.

In order to increase clarity, the following tables are provided: Table 1, a list of the comments received, is provided to indicate who commented, when they commented and which proposed rules they addressed, as well as providing a short title for each comment to be used the subsequent section, Response to Comments; Table 2, a list of commonly used acronyms found in the SONAR, the comments, and this response.

**Table 1. List of Comments Received.**

Commenter	Short Title	Comment Period	Proposed Rules Addressed
Minnesota Chamber of Commerce	Chamber Comment	Pre-Hearing	2737.1200 2737.1500 2737.1600 2737.1800
Sanford Health	Sanford Comment	Pre-Hearing	2737.1300
Prime Therapeutics	Prime Comment	Pre-Hearing	2737.0400 2737.0700 2737.0800 2737.0900 2737.1200
Pharmaceutical Care Management Association (PCMA)	PCMA Comment	Pre-Hearing	2737.0100 2737.0300 2737.0400 2737.0500 2737.0600 2737.0700 2737.0800 2737.0900 2737.1000 2737.1100 2737.1200 2737.1500 2737.1600 2737.1700 2737.1800

Minnesota Council of Health Plans	MCHP Comment	Pre-Hearing	2737.0100 2737.0300 2737.0400 2737.0800 2737.0900 2737.1100
Minnesota Pharmacists Association, Minnesota Society of Health-system Pharmacies	Pharmacist Comment	Pre-Hearing	2737.0300 2737.0400 2737.0700 2737.0800 2737.0900 2737.1000 2737.1100 2737.1200 2737.1300 2737.1400 2737.1500 2737.1600 2737.1700 2737.1800
Gary Boehler, Dakota Drug <sup>3</sup>	Dakota Drug Annotated Statute	Pre-Hearing	n/a
Sarah Derr, Pharmacists Association, Minnesota Society of Health-system Pharmacies	Pharmacist Hearing Comment	Hearing	2737.0300 2737.0400 2737.0700 2737.0800 2737.0900 2737.1000 2737.1100 2737.1200 2737.1300 2737.1400 2737.1500 2737.1600 2737.1700 2737.1800
Michelle Mack, Pharmaceutical Care	PCMA Hearing Comment	Hearing	2737.0100 2737.0300

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<sup>3</sup> Mr. Boehler submitted an extensive list of concerns with the statute. Many of his comments were similar to those raised by other stakeholders throughout the rulemaking process. However, Commerce wishes to keep the responses in this document specific to the public comments on the proposed rule.

Management Association			2737.0400 2737.0500 2737.0600 2737.0700 2737.0800 2737.0900 2737.1000 2737.1100 2737.1200 2737.1500 2737.1600 2737.1700 2737.1800
Alex Sommer, Prime Therapeutic	Prime Hearing Comment	Hearing	2737.0400 2737.0700 2737.0800 2737.0900 2737.1200
Jill McCormack, National Association of Chain Drug Stores <sup>4</sup>	NACDS Comment	Post-Hearing	2737.0300 2737.0700 2737.0800 2737.0900 2737.1000 2737.1100 2737.1200 2737.1300 2737.1700 2737.1800
Brooke Davis <sup>5</sup>		Post-Hearing	n/a
Mark Whittier <sup>6</sup>	Whittier Comment	Post-Hearing	2737.1200
Kaitlyn John <sup>7</sup>		Post-Hearing	n/a

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<sup>4</sup> Mrs. McCormack resubmitted the comment with an updated signature page.

<sup>5</sup> This comment concerns the importance of wound care in nursing homes, which is not germane to the proposed rules.

<sup>6</sup> Mr. Whittier entered three separate responses on the OAH eComments page, however, Commerce treats them as a single comment, which includes an attached document with annotated statutes and rules.

<sup>7</sup> This comment concerned the use of CBD, which is not germane to the proposed rules.

Buck Humphrey, Pharmacists Association, Minnesota Pharmacy Alliance	Pharmacists Post- Hearing Comment	Post-Hearing	2737.0100
			2737.0300
			2737.0400
			2737.0500
			2737.0700
			2737.0800
			2737.1100
			2737.1600
			2737.1700
			2737.1800

**Table 2. List of Commonly used Acronyms**

APA	Administrative Procedures Act
AWP	Average Wholesale Price
ALJ	Administrative Law Judge
BCGP	Board Certification in Geriatric Pharmacy
BS	Bachelor of Science
CFR	Code of Federal Regulations
ERISA	Employee Retirement Income Security Act of 1974
FAPhA	Fellow of the American Pharmacists Association
HMO	Health Maintenance Organization
JD	Juris Doctorate
MA	Master of Arts
MAC	Maximum Allowable Cost
MCO	Managed Care Organizations
MDH	Minnesota Department of Health
MMB	Minnesota Management and Budget
MN	Minnesota
MORS	Minnesota Office of the Revisor of Statutes
OAH	Office of Administrative Hearings
PBM	Pharmacy Benefits Manager
PharmD	Doctor of Pharmacy
PhD	Doctor of Philosophy
RPh	Registered Pharmacist
SONAR	Statement of Need and Reasonableness
TPA	Third Party Administrator
WAC	Wholesale Acquisition Cost

## II. Response to Comments

Commerce provides specific responses to comments below grouped by the proposed rule number.

### A. 2737.0100

**Summary of Comments:** The comments raise concerns about three terms in the definitions section: aggregate, doing business in Minnesota, and owned pharmacy.

**Raised by:** PCMA Comment, MCHP Comment, Pharmacists Post-Hearing Comment

**Response: Aggregate.** The term aggregate is used two (2) times in the rules and only in sections relating to transparency reporting. The rules also very clearly state that the definitions in 2377.0100 apply to this particular chapter.

**Doing Business in Minnesota.** Perhaps no phrase has elicited more communication with Commerce about §62W than the phrase doing business in Minnesota. The phrase appears in the statute in relation to PBMs' responsibility to submit transparency reports to the Commissioner. In the initial two years that PBMs have submitted these reports, PBMs have routinely sought clarity from Commerce about when a plan sponsor is doing business in Minnesota. Moreover, Commerce received additional questions about the meaning of §62W.03's directive that "no person shall perform, act, **or do business in this state** as a pharmacy benefit manager . . ." without first obtaining a license. (62W.03, subd. 1 (emphasis supplied)).

Both the legislature and Commerce recognize that PBMs serve multiple plan sponsors, and that these plan sponsors may be outside of Minnesota. The law seeks only the information for those plan sponsors that are doing business in Minnesota. In 2737.1000 and 2737.1100, Commerce's proposed rules make plain which plan sponsor's data needs to be submitted to the plan sponsor and/or the Commissioner. Similarly, the use of the phrase doing business in 2737.0200 and 2737.0400 seeks only to provide a predictable and clear metric upon which industry can rely to make compliance determinations. As the SONAR notes, Minnesota has a number of border communities which raise questions around whether or not the plan sponsor, for whom the PBM acts, is doing business in Minnesota, thus subjecting the PBM to the jurisdiction of Commerce.

With respect to the relative clarity of the proposed definition, Commerce appreciates the concern raised by the PCMA comment, and is proposing to update the definition to more precisely reflect the basis for the definition articulated above:

Subp. 3. Doing business in Minnesota. "Doing business in Minnesota" means a PBM is in contract to perform pharmacy benefits services with a plan sponsor that is either (1) is a Minnesota entity, or (2) makes a contract or engages in a

terms of service agreement with a Minnesota resident that is performed in whole or in part by either party in Minnesota.

With respect to PCMA’s concern about clause (2), Commerce does not share the concern. As is noted in the SONAR, this formulation is used elsewhere in Minnesota statutes without causing the sort of confusion envisioned in the PCMA comment. See SONAR at 9 (quoting Minn. Stat. §5325, subd. 4(b) and Minn. Stat. §626.18, subd. 1 (e)). This clause merely states that a plan sponsor is doing business if the plan sponsor is itself a Minnesota entity, or if the plan sponsor makes a contract with a Minnesota resident that will require either the resident or the plan sponsor to perform all or part of that contract in Minnesota. This definition serves as a limiting device to alleviate PBMs from having to (1) register for a license or (2) submit transparency reports for its client—the plan sponsor—where that client is not a Minnesota entity, and whose only connection to Minnesota is an enrollee who performs all work outside of Minnesota.

**Owned Pharmacy.** The proposed definition of owned pharmacy is useful because §62W’s regulation of pharmacy ownership interests is not unidirectional. That is, the statute applies to a “health carrier or pharmacy benefit manager [that] has an ownership interest in a pharmacy or [a] pharmacy [that] has an ownership interest in [a] pharmacy benefit manager.” (62W.07(b),(d)). The proposed definition allows for rules that are easier to read, inasmuch as the rules do not constantly require the caveat that a rule applies to both pharmacies owned by PBMs and PBMs’ owned by pharmacies. As noted by the Pharmacists Post-Hearing comment, this definition also ensures the rules are consistent with the statutory language.

#### B. 2737.0200

**Summary of Comments:** None.

**Raised by:** N/A

**Response:** None

#### C. 2737.0300

**Summary of Comments:** The PCMA comment raises two concerns: (1) the use of the term pharmacy management services in subpart one, and (2) the scope of Commerce’s rulemaking authority in subpart 2.

The NACDS and Pharmacists comments urged inclusion of this rule, noting that allowing managed care organizations (MCOs)—and their PBMs— in contract with DHS to provide Medicaid services to Minnesotans should not grant them the exemption from regulation by Commerce.



The MCHP comment suggested the inclusion of a statutory reference to subpart 1 to bring greater clarity as to when the exemption applies, and also sought clarification on the scope of subpart 2.

**Raised by:** PCMA Comment, NACDS Comment, MCHP Comment, Pharmacist Comment, Pharmacists Post-Hearing Comment

**Response:** **Subpart 1.** Commerce does not believe, contrary to the PCMA comment’s argument, that the term pharmacy management services is confusing. The words, having not been defined elsewhere, have their plain meaning.

One of the key features of §62W’s definition of a PBM is that the services listed must be provided as part of a contract with a plan sponsor. The statute specifically exempts DHS from the definition of plan sponsor. The rationale for why is made clear in the SONAR. The need for the rule is explained with specific reference to DHS’s fee-for-service role. DHS and the other state programs highlighted in the SONAR all perform the types of tasks outlined §62W.02, sub. 15, however, unlike entities performing those pharmacy management services in the private sector, these agencies and state actors are subject to more stringent oversight and transparency rules and regulations.

With respect to what the rules mean where it reads “directly provides,” again Commerce believes these words to have their ordinary meaning. Directly providing would mean where no intermediary—a PBM—is used to perform the pharmacy management services. This would be in accord with the rationale explained above and in the SONAR.

Commerce appreciates the feedback in the MCHP comment, and proposes to add a statutory reference to subpart 1:

Where an agency of the state of Minnesota directly provides pharmacy management services, the agency is extended the exemption granted to the Department of Human Services under Minnesota Statutes, section 62W.06, subdivision 16.

**Subpart 2.** The PCMA Comment appears to misapprehend the intent of subpart 2, which makes clear that a PBM providing PBM services to a MCO operating under contract with DHS is not relieved of the requirements of §62W by virtue of the MCO’s contract with DHS. DHS administers the managed care programs that provide coverage for eligible Minnesotans. DHS achieves this by contracting with MCOs who provide health care services. Thus, the rule merely clarifies that DHS’s role in the managed care space is not akin to that of a plan sponsor, and so any PBM hired by an MCO must abide by all applicable portions of §62W. As noted by the NACDS comment, this rule is beneficial to ensure that Minnesotans receiving managed care benefits are afforded the protections of §62W.

With respect to the MCHP comment’s request for clarification, it is Commerce’s belief that the exemption for DHS should be limited to state agencies engaged directly in pharmacy

management services, while the managed care organizations should not be entitled to the exemption. The Pharmacists and NACDS comments both echo this distinction, requesting inclusion of the rule.

#### D. 2737.0400

**Summary of Comments:** The PCMA comment and the Prime Comment take exception with a number of proposed disclosure requirements, arguing that they are inappropriate inasmuch as they request PBMs to disclose allegations of misconduct rather than final adjudications of misconduct. Additionally, the PCMA comment raises concerns about the types of information requested and the fee charged. The Prime Comment also raises a concern about the interplay between deadlines at MDH—related to the network adequacy review—and deadlines at Commerce. The PCMA and MCHP comments raise concerns about ongoing reporting requirements. The Pharmacist comment suggests a lower license fee to increase access to the Minnesota Market for smaller PBMs.

**Raised by:** PCMA Comment, Prime Comment, MCHP Comment, Pharmacist Comment, Pharmacists Post-Hearing Comment

**Response: Allegations/Adjudications.** The kinds of information requested by Commerce in its initial application for PBM licensure, as detailed in the rules, is consistent with other license applications and disclosure forms used by Commerce. In each case, the applicant is asked to describe the allegations/demand. The statute and the rules provide that the Commissioner may seek additional information, and the statute provides that the Commissioner must state the basis for the denial of an application. An applicant aggrieved by such a decision would have the same remedies available to it as any other license applicant. The type of behavior sought by the application is the type that the statute indicates can form the basis for suspension, revocation, or probationary status. §62W.03, subd. 4(a)(1).

**Information Requests.** The applications for an initial or renewal license ask what would seem, to Commerce, to be quite basic questions: who are you working for and for how many enrollees do you provide services. The PCMA comment does not advance any reason why establishing a rule requesting such information is not reasonable.

Likewise, the objection to subpart 5 by the PCMA and MCHP comments is unpersuasive. Commerce, after consulting with industry stakeholders—and recognizing the annual nature of renewal—decided to limit the scope of the request for updated information to only those categories which it believed material: subparts 2(C-E). The basis for the included categories is discussed in depth in the SONAR. Commerce believes that the proposed rule is necessary and reasonable.

**Limits of Network Adequacy Report.** The PCMA comments suggests that the proposed rule which makes the restrictions placed on a PBM's network by MDH applicable to the license issues by Commerce is beyond the authority of the Commissioner of Commerce. The PCMA

comment misapprehends the nature of the network adequacy process, and its proposed remedy would render the network adequacy inquiry meaningless. The PCMA comment appears to suggest that the network adequacy report issued by MDH is unrelated to the licensure of a PBM. If MDH reviews a network and determines that the network is only adequate in certain counties, but the Commissioner of Commerce is unable to enforce those restrictions, then the entire network adequacy process would be meaningless.

More to the point, the authority for the rule is found in §62W.04, subd. (4)(b) which expressly provides the Commissioner of Commerce the power to subject a license to certain restrictions. The proposed rule, then, appropriately clarifies that where MDH has determined the PBM's network is insufficient to meet the requirements of §62W.05, the license shall be subject to the restrictions determined by MDH.

**Fees.** The statute sets the fee for the license and requires that that amount be deposited into the general fund. The rule simply establishes that in the event the third party service provider retained by the commissioner to administer the application process charges an administrative fee, that the fee will be in addition to the \$8500, as that amount must be deposited in the general fund.

**Network Adequacy Deadlines.** The rules attempt to provide new applicants as much guidance as possible to ensure that a new PBM will be able to begin operations without delay. As noted in the SONAR, an application for an initial license is not complete without a Network Adequacy Report approved by MDH. MDH, however, is not subject to the same time constraints that Commerce is, under the text of the statute. This subpart thus makes clear that the onus is on the entity seeking licensure as a PBM to first have the network reviewed by MDH, and upon receipt of an approval or limited network report from MDH, submit its application for a PBM license. Additionally, Commerce recognizes the concern raised by the Prime comment is a serious one, and as such, with respect to the renewal process, it proposes 2737.0600, subpart 5, which allows for license continuity in an event where a PBM has filed for a renewal on a timely basis but the application has not yet been approved.

## **E. 2737.0500**

**Summary of Comments:** The PCMA comment raises similar concerns as noted in the prior section, which are fully addressed above. Additionally, the PCMA comment argues that the rules are impermissible inasmuch as the form and manner of the application for license renewal are subject to Minn. Stat. §14.

**Raised by:** PCMA Comment, Pharmacists Post-Hearing Comment

**Response:** The statute that the PCMA comment claims Commerce is departing from states: "To renew a license, an applicant must submit a completed renewal application **on a form**

**prescribed by the commissioner[.]”<sup>8</sup>** Minn. Stat. §62W.03, subd 3. It is unclear from this language how a rule, that repeats what is already in statute, is a departure from that statute. More to the point, the concern that animates the PCMA comment—that future renewal applications could change wildly—is actually a basis to adopt the proposed rules, which create clarity and specificity around what areas the license application must include.

#### F. 2737.0600

**Summary of Comments:** The PCMA Comment argues that subpart 4 impermissibly curtails the due process rights of applicants.

**Raised by:** PCMA Comment

**Response:** The proposed rules set forth the process for an agency hearing on the denial of a license. After that hearing the agency issues a final determination. The rules clarify when a license decision is final and subject to contested case proceedings. Contrary to the PCMA comment, this process is intended to provide additional due process to applicants. As the SONAR notes none of the remedies of chapter 14 are removed.

#### G. 2737.0700

**Summary of Comments:** The PCMA and Prime comments argue that the enumerated legal references vary too greatly from the “limited” basis on which a license may be suspended, revoked or placed in probationary status. The NACDS comment notes in its comment that this proposed rule is beneficial to ensure PBM compliance with the statute and rules.

**Raised by:** PCMA Comment, NACDS Comment, Prime Comment, Pharmacists Post-Hearing Comment

**Response:** As the SONAR notes, the list of statutory bases for suspension, revocation, and probation are actually quite extensive: violations of federal and state law sounding in fraud, consumer complaints, failure to pay an application fee, and failure to comply with any provision of §62W.

The Pharmacists Post-Hearing Comment aptly notes: “The statute does not limit the federal and state laws that Commerce should monitor to enforce that statute. We submit that Commerce

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<sup>8</sup> The PCMA comment states that it is “likely” that manner and form would themselves be rules, and subject to Minn. Stat. §14. Subd. 4. In that chapter, rule is defined as “every agency statement of general applicability and future effect, including amendments, suspensions, and repeals of rules, adopted to implement or make specific the law enforced or administered by that agency or to govern its organization or procedure.” Commerce disagrees that an agency would be required to undergo rulemaking to implement license application forms, and the PCMA comment includes no legal authority which would support such a conclusion.

has been given in the statute not only the right, but the responsibility to assure that their licensees comply with any law related to the operation of a PBM and the pharmacies that PBMs own and operate.” As the SONAR states, Commerce engaged industry and stakeholders to try to arrive at a rule that would provide some level of details as to what federal and state laws would be examined by the Commissioner.

With respect to Subpart 2.E, it was never the intention of Commerce to imply that the rules would allow Commerce to assume regulatory oversight of each enumerated statute, law, regulation and/or rule. Rather, Commerce intended that if the appropriate regulatory body made a determination as to a violation of the enumerated statutes, laws, regulations, or rules, the Commissioner could consider such a violation as part of the renewal process.

In reviewing the comments made about this proposed rule it is clear that the current rule creates confusion. In order to alleviate these concerns, Commerce proposes the following edit to Subp. 2 A (line 8.14):

A. failure to comply with relevant state and federal law, as determined by the relevant regulatory body:

The PCMA comment requests additional rules that would limit §62W.05, subd. 4(a)(2). Commerce believes that the statutory language is drafted sufficiently clear. The PCMA comment also argues that the statute itself is unconstitutionally vague. Commerce does not believe that the rulemaking process is the appropriate venue to adjudicate that argument.

## H. 2737.0800

**Summary of Comments:** As with 2737.0900, this proposed rule elicited substantial feedback. The issues can be divided into three broad categories: (1) authority to promulgate rules; (2) pharmacy type for network adequacy; and (3) distance requirements. Issues 1 and 2 will be addressed in this section, while issue 3 will be addressed below in the section pertaining to 2737.0900.

Commenters focusing on the authority of Commerce tended to note that the network adequacy review was performed by MDH, and as such should not be subject to rulemaking by Commerce.

A number of commenters pointed out that the language of Subp. 1 was confusing, as the first part appears to indicate all pharmacy types must be included, but that the use of ‘or’ on line 10.5 suggests otherwise.

The Prime comment suggested that the reference to §62K.10 only applied to retail networks. The MCHP comment proposed an edit to subpart 2.

**Raised by:** PCMA Comment, NACDS Comment, Prime Comment, MCHP Comment, Pharmacist Comment, Pharmacists Post-Hearing Comment

**Response:** **Authority to Promulgate Rules.** More than one comment contained an argument that Commerce could not promulgate rules relating to network adequacy because the network adequacy provisions governed MDH. This, however, ignores the plain language of the law giving rise to Commerce’s rulemaking authority, Section 20 of Minnesota Session Laws – 2019, Regular Session, Chapter 39 explicitly provides:

Sec. 20. RULEMAKING AUTHORITY.

The commissioner of commerce may adopt permanent rules for license application and renewal requirements, forms, procedures, **network adequacy**, and reporting procedures and compliance, for pharmacy benefit manager licensing under Minnesota Statutes, chapter 62W. The commissioner must not adopt rules to implement Minnesota Statutes, chapter 62W, under any other grant of rulemaking authority. If the commissioner of commerce does not adopt rules by January 1, 2022, rulemaking authority under this section is repealed. Rulemaking authority under this section is not continuing authority to amend or repeal rules. Notwithstanding Minnesota Statutes, section 14.125, any additional action on rules after adoption must be under specific statutory authority to take the additional action.

(emphasis supplied). There should be no doubt that Commerce has the authority to adopt rules relating to PBM network adequacy.

**Pharmacy Types for Network Adequacy.** The wide range of comments on the ‘relevant’ portion of 62K.10 that should be applied to MDH’s network adequacy review highlights the need for greater clarity on this particular issue, and indeed this appears to be why the legislature singled out network adequacy as an area Commerce should engage during the rulemaking process.

As discussed below, it is important to note that the language in §62W.05, subd. 1, that directs the adequacy review to §62K.10 notes that that section of statute contains relevant requirements, plural. To that end, Commerce agrees with the NACDS and Pharmacists comments that one such relevant portion of §62K.10, is subdivision 4. This subdivision requires that “[e]ach designated provider network must include a sufficient number and type of providers . . . to ensure that covered services are available to all enrollees without unreasonable delay.” Commerce proposes to delete the ‘or’ on line 10.5. This errant ‘or’ defeats the purpose of the pharmacy type requirement. Many commenter’s agreed that the ‘or’ on line 10.5 should be deleted. In the same way that a primary care physician is not the only health care provider an enrollee may need, a retail pharmacy is not the only pharmacy an enrollee may need. Different pharmacies serve different needs, and it is imperative that enrollees have access to each type of pharmacy, in order to have an adequate network. Commerce’s rule, with the deletion of the ‘or’ on line 10.5, does exactly that.

The Prime comment’s argument that the exclusion of mail order for the calculation of an adequate network under §62K.10 means the statute only addresses retail pharmacies assumes too much. If the legislature intended only retail pharmacies to be subject to network adequacy review they could have stated as such. There are, as the rules indicate, more than two types of pharmacies. What is clear is that the physical location of mail order pharmacy was not intended to be part of the analysis of an adequate network. If, as the Prime comment suggests, all that §62W.05 commands is the application of one part of §62K.10 (the mileage requirements) the legislature would have stated the “relevant requirement” in §62K.10, not the “relevant requirements.” It is clear that more than simply a measure of where retail pharmacies are located is called for by the statute. Contrary to the Prime Comment, Commerce believes that the legislature certainly intended that Minnesotans have access to specialty pharmacies and home infusion pharmacies when they deal with serious illness.

**Subpart 2.** Subpart two is consistent with MDH’s authority in §62W.05, subd. 2, which grants MDH the authority to issue waivers to the network adequacy requirement. Specifically, the statute requires that in order for a waiver to be granted, the requesting PBM provide information on the steps taken to remedy the shortcoming. In the context of a network failing to have certain types of pharmacies, e.g., home infusion, it is imperative that MDH be able to ascertain if the PBM has a plan to provide the requisite services to enrollees should the need arise.

## I. 2737.0900

**Summary of Comments:** Commenters submitted a wide range of feedback on this rule. Commenters tended to focus on the importance of having a nearby pharmacy. Many comments noted that 90% of Americans have a retail pharmacy within 5 miles of their home. Table 3 summarizes the proposed distances for retail pharmacies and the authority for such a proposal.

**Table 3. Suggested Network Adequacy Parameters.**

Commenter	Proposed Distance	Authority
NACDS Comment	2 Miles (urban) 5 Miles (suburban) 15 Miles (rural)	§62K.10, subd. 4, 42 CFR §423.120
Pharmacist Comment	2 Miles (urban) 5 Miles (suburban) 15 Miles (rural)	§62K.10, subd. 4, 42 CFR §423.120
Prime Comment	60 Miles/60 Minutes	§62K.10, subd. 3.
Commerce	30 Miles/30 Minutes	§62K.10, subd. 2.

**Raised by:** PCMA Comment, NACDS Comment, Prime Comment, MCHP Comment, Pharmacist Comment

**Response:** This proposed rule, along with 2737.0800, elicited substantial feedback. Commerce’s proposed rule relied on the statutory language (referring to the relevant portions of §62K.10) and the grant of rulemaking authority over network adequacy, to arrive at the proposed rule. Commerce believes that the proposed rule was necessary and reasonable, for the reasons articulated in the SONAR. However, after reviewing the comments made, and in consultation with MDH, Commerce has decided to strike this proposed rule (2737.0900).

The comment by Prime Therapeutics is persuasive. As noted above, §62W.05 instructs MDH to use the relevant portions of §62K.10. While Commerce believes that pharmacy services are more akin to primary care than “specialty physician services, ancillary services, specialized hospital services” that are mentioned in subdivision 3, the term ancillary services is a defined term in the Minnesota Rules governing HMOs:

Subp. 3a. Ancillary services. "Ancillary services" means laboratory services, radiology services, durable medical equipment, **pharmacy services**, rehabilitative services, and similar services and supplies dispensed by order or prescription of the primary care physician, specialty physician, or other provider authorized to prescribe those services.

Minn. R. 4685.0100 (emphasis supplied). In light of the comments submitted, and the existence of Minn. R. 4685.0100, Commerce is withdrawing proposed rule 2737.0900.

The NACDS and Pharmacists comments raise important concerns that should be addressed, however, the best method for such a change would be a statutory modification.

## **J. 2737.1000**

**Summary of Comments:** The PCMA Comment implores Commerce to remove timelines for disclosure by PBMs to plan sponsors of the data required under §62W.06 and remove the subpart 2. B.

**Raised by:** PCMA Comment, Pharmacist Comment

**Response:** As noted in the SONAR, the public engagement process undertaken by Commerce as part of its rulemaking process laid bare that the PBM-plan sponsor relationship is the least in need over additional oversight by Commerce. The rules reflect an attempt to balance that reality with the need to create fixed clear rules around the statutorily required duties the two parties owe one another, and to provide a predictable metric for the parties to reference when in dispute about the relevant statutory obligations.

While Commerce recognizes that it is likely to become common practice for a PBM to require a nondisclosure agreement prior to releasing the plan sponsor transparency reports, the statute itself does not make execution of a non-disclosure mandatory. To that end, Commerce thinks it would be inadvisable to enshrine in the rules a requirement by a plan sponsor to sign such an



agreement, where the statute only allows for a PBM to make it mandatory. The statute is sufficiently clear on this issue, that a PBM which elects to require a non-disclosure agreement signed by a plan sponsor, may withhold the transparency reports until such an agreement is signed.

#### K. 2737.1100

**Summary of Comments:** The PCMA comment suggests that format of the reports submitted to the commissioner should be subject to rulemaking requirements contained in Minnesota Statute chapter 14. The MCHP comment requests an addition to subpart 4. The Pharmacists comment includes extensive feedback on the first transparency reports published in 2020 by Commerce, as well as proposed two edits to the proposed rules.

**Raised by:** PCMA Comment, MCHP Comment, Pharmacist Comment, Pharmacists Post-Hearing Comment

**Response:** The rules specifically limit the information sought in the forms prescribed by the commissioner to the categories of information authorized by statute. There is no basis to believe that the standardization of format of a data submission tool comes within the definition of rulemaking.

With respect to the MCHP comment, Commerce believes the addition is unnecessary. As noted in the SONAR, Commerce initially intended to create its own therapeutic category system. Feedback from multiple stakeholders suggested that was a bad approach, and that the better approach, now in the rules, would be to select an existing system. Had Commerce elected to build its own system, the proposed edits in the MCHP comment containing a mandatory consultation with PBMs and plan sponsors would likely have been advisable. However, by electing to use a “preexisting and commonly used” system, which is consistent with industry standards and periodically reviewed, Commerce believes the rule has sufficient protections to ensure against the use of a problematic systems.

The Pharmacists comment requests that subpart 3 specify the conditions under which a PBM would have no data to report. The Pharmacists comment suggests limiting language that a PBM can only claim to be exempt from reports where it had no claims in the state. Commerce believes this definition would not capture other reasons why PBMs may not report. During the rulemaking process it became evident to Commerce that PBMs often supply very narrow services and may subcontract out other PBM activities. In these cases, more than one PBM may service a plan sponsor doing business in Minnesota. Recognizing this, Commerce crafted a rule that would allow capture of multiple reasons for not being subject to reporting. The modification proposed by the Pharmacists comment would potentially lead to Commerce receiving reports covering the same underlying transactions from multiple sources. Moreover, Commerce believes that the way the rule is currently drafted is sufficient to capture the type of non-reporters sought by the Pharmacists comment proposal.

Similarly, Commerce does not believe the replacement of the word ‘like’ with uniform in subpart 4 makes the rule any clearer.

## L. 2737.1200

**Summary of Comments:** Some Comments support the proposed rules, notably the NACDS comment, which offered proposed changes to the rule. The NACDS comment notes that in a number of areas the rules may not sufficiently describe the behavior the legislature sought to prohibit. The Pharmacists comment, while supportive, seeks specific revisions throughout the subpart. The Whittier comment raises concerns about fairness across pharmacy type, rather than within pharmacy type.

Other commenters, notably the PCMA comment, believe the statutory language is sufficiently clear.

Additionally, the Prime and Chamber comments request that the statutory language requiring a non-owned network pharmacy accept the same pricing terms, conditions and requirements as the owned pharmacy in order to offer the same deal. The Chamber also calls into question the like for like nature of subpart 2.

**Raised by:** PCMA Comment, NACDS comment, Prime Comment, Chamber Comment, Pharmacist Comment, Whittier Comment

**Response: Subpart 1.** The proposed language in the Pharmacists comment does not appear, to Commerce, to add to the existing subpart. The current language already makes clear that if a network—which as noted above must contain a mix of pharmacy types—is made up only of owned pharmacies then the PBM is requiring its enrollees to use its owned pharmacies.

**Subpart 2.** The Whittier comment seeks to change the rules, because “If the proposed rules stay as written [PBMs] will still be able to charge lower copays thru their mail order owned pharmacies to incentivize funneling business AWAY from local MN pharmacies of ALL types.” Commerce understands this concern but believes that its ability to make rules to prevent this would run afoul of §62W.07 (e), which allows PBMs to vary copays and quantity limits based on mail versus retail status—subject to restrictions.

**Subpart 3.** The Pharmacists comment essentially proposes to invert sentence structure in the paragraphs A and B of subpart 3. That is, the current rule says a PBM can only impose limits on an owned pharmacy when it has already placed those limits on a non-owned pharmacy. The proposed change would have the order reversed, requiring that a PBM may only impose refill limits on a non-owned where the limits have already been placed on an owned pharmacy. Commerce agrees that these suggestions are beneficial, as this wording better reflects the statutory language. Subpart 3 differs from subpart 2, in that this section deals with limitations, rather than incentives/benefits.

As such Commerce is proposing the following edits:

Subp. 3. Use of quantity and refill limits. A pharmacy benefit manager whose network includes owned retail or owned mail order pharmacies may use quantity and refill limits only as provided in this subpart.

A. Retail. A pharmacy benefit manager or health carrier may only impose quantity limits or refill frequency limits at a nonowned ~~an owned~~ retail pharmacy when ~~where~~ the pharmacy benefit manager or health carrier has imposed ~~provides the enrollee access to a nonowned retail pharmacy with~~ the same limits at its owned retail pharmacies.

B. Mail order. A pharmacy benefit manager or health carrier may only impose quantity limits or refill frequency limits at a nonowned ~~an owned~~ mail order pharmacy when ~~where~~ the pharmacy benefit manager or health carrier has imposed ~~provides the enrollee access to a nonowned retail pharmacy with~~ the same limits at its owned mail order pharmacies.

**Subpart 4.** The NACDS and Pharmacists comments raise a valid concern that, as drafted, a PBM could evade the rule by including two owned mail order pharmacies. In response, Commerce proposes to make the following edits to the subpart 4 of the proposed rule:

Subp. 4. ~~Single~~ Exclusively owned mail order pharmacy networks. If a pharmacy benefit manager administers a network with ~~a single~~ only mail order ~~pharmacies~~ pharmacy that ~~is are~~ are ~~an owned~~ pharmacies ~~pharmacy~~, the pharmacy benefit manager is prohibited from (1) offering financial incentives to use the mail order ~~pharmacies~~ pharmacy, or (2) imposing limits on an enrollee's access to medication.

Commerce does not believe the additional edits proposed by NACDS are necessary as this rule is specifically designed to address mail order pharmacies, and potential network arrangements that would frustrate the intent of §62W.07.

As discussed above with respect to network adequacy, there are multiple types of pharmacies that provide different types of services to enrollees depending on their need. As Commerce noted in the SONAR, and as recognized by comments like the Chamber comment, the hallmark of this section of the PBM law is to allow enrollees greater choice and flexibility in the pharmacy at which they choose to fill their prescriptions. Subparts 2 and 4 are needed to prevent frustration of that aim. This rule's requirement that the incentives (or disincentives) be made available at the same type of pharmacy is the best way to achieve the legislative aim of the law.

Commerce does not think the rules require the additional clause—from the statute—proposed by the Prime Comment, however, Commerce does not see that the inclusion would compromise the rule.

#### M. 2737.1300

**Summary of Comments:** The Sanford and Pharmacists comments offer support for this rule. The Pharmacists comment seeks additional language in the rule to prohibit certain actions by PBMs which the Pharmacists suggest are designed to dissuade participation in the 340B program.

**Raised by:** Sanford Comment, Pharmacist Comment

**Response:** Commerce believes that the rule as proposed is sufficient to clarify the meaning of §62W.07(f), and while the additional provisions suggested by the Pharmacists comment may add additional protections, doing so would place Commerce beyond the scope of the statute as drafted.

#### N. 2737.1400

**Summary of Comments:** None.

**Raised by:** N/A

**Response:** None

#### O. 2737.1500

**Summary of Comments:** The PCMA comment requests that the word paper in the rules be changed to print, to mirror the language in the statute. The Chamber does not see the need for rulemaking in this area, particularly on the question of contracting around the provisions of the §62W.08.

The Pharmacist comment seeks clarification about which party would determine the format of the MAC price list. The Pharmacist comment additionally recommends that Commerce adopt additional requirements for the MAC price list.

**Raised by:** PCMA Comment, Chamber Comment, Pharmacist Comment

**Response:** Commerce agrees as to the PCMA comment and proposes to replace the word paper on line 16.7 with the word print.

Commerce believes putting prohibitions on abrogating the statutory requirements of the statute into the rules is necessary to effectuate the overall aims of the PBM law. Allowing PBMs to contract around these provisions would obviously frustrate the law.

With respect to the question of who chooses the format of the list: Commerce’s rule provides that the PBM must allow a pharmacy to review the list in any of the three (3) formats: electronic, telephonic or print/paper. The rule is written to provide the pharmacy with access to all three depending on which the pharmacy would like.

As to adding additional requirements for the list, Commerce is constrained by the text of the statute.

#### P. 2737.1600

**Summary of Comments:** The PCMA Comment requests that subpart 1.B. reform or remove the requirements that audit appeals processes—established by requirement of 62W.09, subd. 4—be disclosed each time a pharmacy under audit is provided with an appealable audit report. The Chamber does not see the need for rulemaking in this area, particularly on the question of contracting around the provisions of the §62W.09.

**Raised by:** PCMA Comment, Chamber Comment, Pharmacists Post-Hearing Comment

**Response:** As noted in the SONAR, multiple stakeholders provided feedback that the establishment of written appeals processes was central to making the provisions of §62W.09 effective. Commerce’s proposed rule achieves the aim of effectuating the legislative intent of the law, while minimally burdening PBMs. The written appeals process will already be written, and the rule only requires that the process be provided alongside any report issued by an entity doing an audit at the same time they deliver a report which could be appealed.

Commerce believes putting prohibitions on abrogating the statutory requirements of the statute into the rules is necessary to effectuate the overall aims of the PBM law. Allowing PBMs to contract around these provisions would obviously frustrate the law.

#### Q. 2737.1700

**Summary of Comments:** Many commenters expressed a concern about Commerce’s proposed formula for determining what is an “allowable claim amount.” Commenters proposed alternative language. The NACDS and Pharmacist comments definition: “full point of sale reimbursement amount contracted between the pharmacy benefits manager and the pharmacy[.]” The PCMA comment definition: “the health plan contracted rate for purposed of compliance with Minn. stat. §62W.12”

**Raised by:** PCMA Comment, NACDS comment, Pharmacist Comment, Pharmacists Post-Hearing Comment

**Response:** The differing versions of what constitutes an allowable claim amount evidences the need for rulemaking on this issue. The goal of §62W.12 is to ensure that at the point of sale the enrollee has the lowest cost to acquire their prescription drug.

In order to provide greater clarity, Commerce proposes the following edit:

The allowable claim amount is equivalent to the net amount the pharmacy receives from the pharmacy benefit manager for dispensing the prescription, the health carrier or pharmacy benefits manager has agreed to pay the pharmacy for the prescription medication.

This new definition incorporates elements from both the NACDS comment and PCMA comment's definitions.

#### R. 2737.1800

**Summary of Comments:** Commenters disagreed on whether this rule was necessary. The PCMA comment argued that the statute was clear enough. Alternatively, the NACDS and Pharmacists comments argued that the proposed rule, while a good idea, could be improved. The Chamber does not see the need for rulemaking in this area, particularly on the question of contracting around the provisions of the §62W.13. The Pharmacists comment also suggests edits to subpart 3 to improve clarity.

**Raised by:** PCMA Comment, NACDS Comment, Chamber Comment, Pharmacist Comment, Pharmacists Post-Hearing Comment

**Response:** This proposed rule is designed to ensure that PBMs do not retroactively claw back fees related to performance or quality related performance metrics. The rule helps to bridge §62W.09 governing pharmacy audits, and §62W.13, governing retroactive adjustments. The audit provisions set the parameters around how and when a PBM may seek to recoup improperly paid benefits to the pharmacy. The retroactive adjustment provisions set forth when a PBM may seek a claw back, however, that statute references only two conditions for a claw back: a clerical error and as part of an audit. The proposed rules make explicit what is implicit: other types of claw backs are impermissible, specifically the types of claw backs that are regularly seen in the industry and which have repeatedly been brought to the attention of Commerce during the rulemaking process, and the first years of the statute's existence.

The proposed rules are necessary to prevent PBMs from using their larger bargaining power to require smaller pharmacies—or pharmacies not owned by the PBM—to waive their rights under §62W.13. That said, Commerce believes adopting the additional language proposed in the Pharmacists comment would push the rule beyond its authority.

Commerce believes putting prohibitions on abrogating the statutory requirements of the statute into the rules is necessary to effectuate the overall aims of the PBM law. Allowing PBMs to contract around these provisions would obviously frustrate the law.

With respect to subpart 3, Commerce does not think the proposed addition of “positive reward” enhances the rule, however, Commerce does agree with the Pharmacists comment that the second sentence in subpart 3 does not add value to the rules and may in fact cause confusion. To that end, Commerce proposes to delete the second sentence in subpart 3:

Subp. 3. Fees not subject to adjustment. Payment for quality performance metrics included in a prescription drug plan that are based on a pharmacy's quality performance and calculated on prescription count are not retroactive claim adjustments. ~~Retroactive adjustments must not include payments to the pharmacy based on meeting certain performance metrics and must not be based on related prescription count.~~

## S. Rules Not Proposed

Some commenters raised a concern that Commerce had not proposed any rules around certain statutory provisions. Those comments are addressed below, with reference to the portion of the statute that the commenter believes needs rules.

### i. §62W.04

**Summary of Comments:** This portion of the PBM law requires that “A pharmacy benefit manager must exercise good faith and fair dealing in the performance of its contractual duties.” Commenters stated that this portion of the law needed rules. The Pharmacists comment cites to a series of alleged business practices by PBMs that would violate §62W.04. Both the business practices identified, incentivizing use of pharmacies owned by the PBM, and claims adjustments, are addressed in other portions of the statute and rules.

The Pharmacist Comment suggests that the final rules “should include a definition of exercising of good faith and fair dealings for PBMs, contracted pharmacies and discussion of enforcement, including how a pharmacy in Minnesota can seek enforcement relief.”

Similarly, the Whittier comment proposes that a rule should be proposed specifically prohibiting below cost reimbursement as an act of bad faith.

Alternatively, the Whittier comment made the following suggested rule proposal:

PBMs cannot contract with pharmacies at rates BELOW ACQUISITION COSTS on Brand Rx products or generic Rxs as this would be in BAD FAITH! I have attached this section of 62W.04.

**Raised by:** Pharmacist Comment, Pharmacist Hearing Comment, Whittier Comment

**Response:** Commerce believes that the language in §62W.04 is sufficiently clear, and as such, rulemaking around this section of the statute is unnecessary. Commerce engaged the advisory committee on this issue: whether the rules should define good faith and fair dealing. While the conversation was spirited, with some members arguing in favor of defining the term, and others arguing against it. Ultimately, Commerce believes that the term “good faith and fair dealing” is a legal term that has a specific meaning. Commerce believes that the legislature was aware of this when it selected the phrase and intended that the phrase would have the meaning ordinarily attributed to it by a court of law in Minnesota. In light of that belief, Commerce chose not to propose any rules around §62W.04.

## ii. ERISA Jurisdiction

**Summary of Comments:** Commenters sought specific rules around the scope of Commerce’s enforcement of §62W.01, *et seq.*

**Raised by:** PCMA Comment, Pharmacist Hearing Comment

**Response:** In its SONAR, Commerce provided a detailed analysis of the interaction between ERISA preemption and PBM regulation. As noted in the SONAR, this area of law is currently evolving, with the most recent pronouncement coming from the United States Supreme Court, which upheld Arkansas’s PBM law over a claim of ERISA preemption. That said, and as Commerce has noted throughout the rulemaking process, rulemaking is not the appropriate mechanism for determining preemption questions.<sup>9</sup>

## III. Conclusion

Commerce has addressed the many concerns and questions raised during the hearing and comment periods. Commerce has shown that the rules are needed and reasonable. Commerce respectfully submits that adoption of these rules should be recommended.

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<sup>9</sup> In its pre-hearing comment and in comment at the hearing, PCMA implied that Commerce stated that the rules would not “impact ERISA plans.” (Tr. 33:21-22). This is inaccurate. Commerce took the position that the rules were not the appropriate place to address preemption. When Commerce convened the Advisory Committee, it stated at the first meeting, that the committee’s work would not address the question of whether the ERISA preempted any portions of 62W. To the extent that PCMA’s statement is intended to evidence a shift in position by Commerce or indicate that Commerce is using the rules to establish jurisdiction, that would be incorrect.