Rules Governing Pharmacy Benefit Manager Licensure and Regulation

Comments Received Prior to Hearing

09/20/2021
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Comments on Proposed Rules

On August 16, 2021, the Department of Commerce published in the State Register its Notice of Intent to adopt rules following a public hearing. A 30-day comment period followed the publication of the Notice, closing on September 16, 2021 at 4:30 PM. The Department received six official comments submitted either through the Department’s eComment web site hosted by the Office of Administrative Hearings (OAH) or submitted directly to the office of the Administrative Law Judge (ALJ) proceeding over the hearing, in addition to an annotated copy of the proposed rules from one stakeholder submitted first to Commerce, all of which are incorporated into this document.

The Department held its hearing on September 20, 2021, and the post-hearing comment period runs from September 21 through October 8, 2021. For five business days after this period the Department and interested persons may respond to any new information submitted during the written submission period and the record then is closed.

Overview of Comments Submitted

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Minnesota Chamber of Commerce Comments

Bentley Graves - Director, Health Care & Transportation Policy
September 16, 2021

The Honorable Kimberly Middendorf  
Office of Administrative Hearings

OAH Docket No. 21-9009-37561

RE: Proposed adoption of new rules addressing PBM licensure, regulation, creating Minnesota Rules, chapter 2737; Revisor’s ID Number: R-04625

Judge Middendorf:

Thank you for the opportunity to comment on the proposed adoption of new rules addressing Pharmacy Benefit Manager (PBM) licensure, regulation, creating Minnesota Rules, chapter 2737; Revisor’s ID Number: R-04625.

The Minnesota Chamber of Commerce (the Chamber) is a statewide business organization, representing more than 6,000 employers of all sizes across the state. The vast majority of Chamber members offer health insurance coverage to their employees. This health insurance coverage generally includes coverage for prescription drugs—a benefit that is typically managed by a PBM. As such, PBMs exist as a partner to many of our member companies to deliver enhanced health outcomes, with better value and lower costs.

During the 2019 legislative session, the Chamber was actively engaged in the negotiations around SF 278, which was ultimately passed by the Legislature and signed into law by Governor Walz to bring reforms and increased transparency to the role that PBMs play in the prescription drug supply chain.

One of the key components of our involvement in the discussion and debate on SF 278 during the 2019 session was to ensure that employers and their employees were able to continue to enjoy the cost-saving benefits both of pharmacy networks and mail order programs for prescription drugs. The statutory language around these two key issues that now resides in 62W.07 was carefully, thoughtfully, and precisely crafted and comprehensively negotiated with legislators and stakeholders. This was necessary to strike a critical balance between ensuring the continuation of these critical cost-containment tools and the desire of legislators and many stakeholders to ensure enrollees were given
choice in how and where to fill their prescriptions by establishing a “level playing field” between PBM owned outlets and other, non-owned network outlets.

Comments on 2737.1200, Subp. 2
The rule omits important statutory language found in 62W.07(c). The statute goes to great lengths to make clear that a PBM satisfies the requirements of the 62W.07(c) exemption by ensuring its enrollees’ access to the same incentives at other NETWORK pharmacy outlets that are not owned by the PBM AND that have agreed to accept the same pricing terms, conditions, and requirements related to the cost of the prescription that govern the PBM’s network agreement with the outlet it owns. This is language that was carefully and purposefully included in the statute to ensure PBMs and health carriers maintained their ability to leverage networks as a cost-reduction tool, benefitting plan sponsors and enrollees. If the rule were adopted as written, without any reference to – or clear incorporation of – this important statutory language, the rule would run counter to statute and would undermine and create significant ambiguity around the extent to which pharmacy networks may be used in Minnesota.

Further, while it is true that the hallmark of this section of statute is to allow more choice for enrollees, the Department of Commerce’s (the Department) attempt to enshrine a “like for like” requirement in the rule would frustrate this statutory goal. For example, the statutory language requires that an in-network, non-owned retail pharmacy be allowed to compete with a PBM’s own mail order pharmacy. The language in this rule does not. The proposed rule would not provide the level playing field between the PBMs and the local independent pharmacists – and the increased choice for enrollees – that the statutory language was carefully and intentionally crafted to create. It does not provide local, in-network retail pharmacists the ability to give their patients “the same deal” that those patients may be offered through their PBM’s own mail order pharmacy.

Comments on 2737.1200, Subp. 4
As noted above, the statutory language found in 62W.07(b) and (c) is clear and explicit: a PBM cannot penalize, require, or provide financial incentives to an enrollee as an incentive to use an OWNED outlet (retail, mail order, specialty, or other owned outlet) UNLESS the PBM offers the enrollee the SAME incentives when using a NON-OWNED NETWORK outlet (retail, mail order, specialty, or other network non-owned outlet) that has agreed to accept the SAME pricing terms, conditions, and requirements related to the cost of the prescription (both for the drug and the dispensing of the drug) that are in the PBM’s network agreement with the owned outlet.

Given the clear language in 62W.07(b) and (c), the Department is overstepping its authority in 2737.1200, Subp.4 in attempting to prohibit a PBM from offering financial incentives to use a single mail order pharmacy that is an owned pharmacy and that is the single mail order pharmacy in its network. Such a move attempts to establish in rule the limitation of 62W.07(b) but WITHOUT the statutory exception that exist in 62W.07(c). Again, the statute is clear. A PBM may offer financial incentives to use an owned mail order pharmacy so long as those incentives are also available to an enrollee at other network outlets that have agreed to the same pricing and dispensing terms, conditions, and
requirements. Not only is there no limitation in statute that equates to the limitation proposed by the Department in 2737.1200, Subp. 4(1), it is clear the statutory language does not contemplate one.

**Comments on 2737.1500; 2737.1600; and 2737.1800**
Each of these sections of the proposed rule includes limitations on contractual agreements. However, in each case, it seems the underlying statutory language is quite clear about what is and is not permitted. Any contractual agreement that runs counter to those statutory requirements is unlawful and already within the enforcement purview of the Department. We would request additional clarification from the Department as to why these provisions were included in the rule when no statutory ambiguity appears to exist.

Again, thank you for the opportunity to provide comment. Please do not hesitate to contact me for clarification or discussion at 513-377-0029 or bgraves@mnchamber.com.

Respectfully submitted,

Bentley Graves  
Director, Health Care & Transportation Policy  
Minnesota Chamber of Commerce
Sanford Health Comments

Cory Brown – System Vice President, Government Affairs
September 15, 2021

Administrative Law Judge Kimberly Middendorf
Office of Administrative Hearings
600 North Robert Street, P.O. Box 64620
Saint Paul, Minnesota 55164-0620

Re: Proposed Rules Governing Pharmacy Benefits Management (PBM) Licensure and Regulation, Minnesota Rules, Chapter 2737; Revisor's ID Number R-04625, OAH docket number 21-9009-37561

Dear Judge Middendorf,

On behalf of Sanford Health and Sanford Health Plan, we are pleased to provide comments on the Proposed Rules Governing Pharmacy Benefits Management (PBM) Licensure and Regulation. Sanford Health is a non-profit integrated health system headquartered in the Dakotas – with a substantial presence in Western Minnesota. We are one of the largest health systems in the nation with 46 hospitals, 1,400 physicians, and more than 200 Good Samaritan Society senior care locations in 26 states and ten countries. Additionally, Sanford Health Plan proudly serves approximately 220,000 members across the Dakotas, Minnesota and Iowa.

The proposed rules currently under consideration serve to supplement and reinforce the recently passed PBM Licensure and Transparency law passed by the Minnesota legislature in 2019. We generally support efforts that bring transparency to prescription drugs to consumers; however, laws and regulations that place duplicative licensure requirements on health plans are counterproductive to reducing overall healthcare spending. We would encourage examination of the overall proposed PBM regulatory scheme and statutory adjustments to capture the true intent of this regulation and to avoid inefficiencies that may lead to increased costs.

Sanford Health is supportive of the proposed 2737.1300 rule, which protects pharmacies from being harmed due to their participation in the federal 340B Drug Pricing Program. The 340B Drug Pricing Program is crucial to ensuring that patients have access to prescription drugs. A crucial component of the program is the ability for 340B entities, which are many of Minnesota’s federally qualified health centers, critical access hospitals, rural health clinics, and disproportionate share hospitals, to contract with pharmacies to provide access to 340B drugs to their patients. By protecting the right to participate in 340B contracting relationships for pharmacies, these rules will ensure that pharmacies are able to participate in the 340B program without potentially endangering their PBM relationships. We are supportive of inclusion in the final rules.

Respectfully Submitted

Corey Brdwn
System Vice President, Government Affairs – Sanford Health
Prime Therapeutics Comments

Alex Sommer – Government Affairs Principal
September 16, 2021

Hon. Kimberly Middendorf
Office of Administrative Hearings

OAH Docket No: 71 9003-36416

Re: In the Matter of the Proposed Rules Governing Pharmacy Benefits Management Licensure and Regulation, Minnesota Rules, Chapter 2737
Revisor’s ID Number R-04625

BACKGROUND

Prime Therapeutics, LLC (Prime) is a pharmacy benefit manager (PBM) based in Eagan, MN, owned by 18 not-for-profit Blue Cross and Blue Shield insurers, subsidiaries or affiliates of those insurers, including Blue Cross and Blue Shield of Minnesota. At Prime, our mission is to help people get the medication they need to feel better and live well. A central tenet of that mission is holding down prescription drug costs for our health plan clients and members. On behalf of Prime, I respectfully submit these initial comments regarding the proposed rules governing PBM licensure and regulation and look forward to further discussing these and other concerns at the September 20th hearing.

In 2019, the Minnesota Pharmacy Benefit Manager Licensure and Regulation Act (the Act), Minn. Stat. § 62W, was enacted. While the Act granted the Department of Commerce (the Department) regulatory and rulemaking authority, the Act’s requirements are detailed and specific not only to their intent, but to the exact requirements. Minnesota law is clear on this subject: “When the words of a law in their application to an existing situation are clear and free from all ambiguity, the letter of the law shall not be disregarded under the pretext of pursuing the
spirit.”¹ Should it be deemed necessary for the Department to engage in rulemaking in areas where the legislature spoke with specificity, the Department’s rules must align with the statutory language, filling in only where necessary to “effectuate the intention of the legislature.”² Here, the Department’s proposed rules regularly venture into those areas where the legislature acted with adequate specificity as to warrant no further rulemaking. In doing so, the Department has confused or flatly contradicted the clear requirements outlined in § 62W, the effects of which would likely have significant consequences for Minnesotans. In the discussion below, I highlight areas illustrating where the Department (1) goes beyond the scope of its rulemaking authority, (2) contradicts the language and/or legislative intent manifest in the Act, and/or (3) includes language that is unnecessary to fulfill its regulatory authority under the Act.³

**DISCUSSION**

The following section includes references to specific problematic sections and short discussions of each, as well as Prime’s suggested actions with respect to those sections. As noted above, the overarching concern is the Department reaching into areas beyond its scope of authority, whether by way of unnecessary rulemaking or contradictions with the enabling statute.

**2737.0400– Business License Requirements; Initial Application**

- Subp. 2(D)(6) requires a PBM to disclose delinquent tax obligations, bankruptcies, demands or judgments for overdue money. Requiring disclosure of informal and unadjudicated demands for money from any party or person is overly broad and may not be possible for the PBM to know and therefore report accurately. At line 3.14, “or demand” should be deleted. Additionally, lines 3.16 and 3.17 are superfluous and should be deleted.

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¹ Minn. Stat. § 645.16
² Id.
³ Minn. R. 1400.2100 (B) and Minn. R. 1400.2100 (D) should inform this review of the Department’s proposed rules. Subsection B requires a rule be disapproved if the rule “is not rationally related to the agency’s objective or the record does not demonstrate the need for or reasonableness of the rule.” Subsection D requires disapproval if a rule “exceeds, conflicts with, does not comply with, or grants the agency discretion beyond what is allowed by, its enabling statute or other applicable law.”
Subp. 3 requires PBMs to meet a deadline based on the speed of another entity’s actions (Minnesota Department of Health (MDH) review). The timeline should be based on a PBM’s submission to MDH, not by when MDH completes its review. Prime suggests this should be amended to read: “Pharmacy benefits managers must submit a network adequacy report to MDH no less than 90 days prior to the desired license effective date.”

2737.0700 - Enforcement by Commissioner – Subp. 2

In proposed section 2737.0700, the Department defines a wide universe of relevant laws and regulations for the Commissioner’s consideration when taking enforcement action against a PBM. As written, the proposed rules apply to areas of law (e.g., pharmacy laws) that are not relevant to the operation of a PBM. Further, this section would essentially grant the Commissioner quasi-enforcement authority with respect to laws entirely outside the Department’s jurisdiction (e.g., state pharmacy laws, federal law). Prime suggests that this section either be removed or otherwise amended to include only those bodies of law that are both directly applicable to PBMs in their capacity as PBMs and within the Department’s scope of authority.

2737.0800 – Adequate Network
2737.0900 – Accessible Network

Under these two sections, the Department proposes rules that are (1) at odds with the plain reading of § 62W.05 and (2) unreasonable and unnecessary within the context of how pharmacy networks operate, as they do not effectuate the legislative intent of ensuring adequate access to retail pharmacy services.

§ 62W.05 requires a PBM to “provide an adequate and accessible pharmacy network . . . that meet the relevant requirements in section 62K.10.” In the SONAR, the Department claims
“[n]either of these terms is defined in the statute.” While § 62W.05 may not specifically define “network adequacy,” the relevant statute, § 62K.10 outlines specific criteria and standards out for determining network adequacy. This section, and thus § 62W.05 by way of pointing to §62K.10 as the reference for network adequacy, does not lack clarity as to what is meant by “network adequacy.”

Beyond the plain language of §62W.05 and §62K.10, the Department’s proposed rules are unreasonable and unnecessary when considered in the context of how pharmacy networks operate. Separately determining the adequacy of each PBM network offering is not sensible considering the role of a PBM’s pharmacy network offerings in the health insurance marketplace. To elaborate, a network tied to a particular health plan is generally made up of multiple PBM network offerings that complement each other to create the plan’s desired network. That network, at the plan level, is what determines an enrollee’s ultimate access to pharmacy services. Reviewing each network offering at the PBM level ignores this and would create a duplicative review process in furtherance of a standard differing from that defined by the legislature.

The legislature included §62W.05 to ensure adequate access to retail pharmacies. This is perhaps most clearly illustrated by the fact that they prohibited mail-order pharmacies from being included in the determination of network adequacy. Instead of furthering this objective, the Department proposes a new standard that requires the inclusion of six different types of pharmacies in each of a PBM’s pharmacy network offerings, including mail-order pharmacy. This contradiction illustrates that the proposed rules are wholly different from what the

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4 Minn. Dept. of Commerce, Insurance Division, 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 – Statement of Need and Reasonableness, pg. 15 (July 2021).
legislature intended – comprehensiveness of each network offering was never the intended standard, but rather access to retail pharmacy. Considering the legislature’s intended focus on retail pharmacy and no indication that the legislature contemplated or intended a new standard other than existing one as currently applied under §62K.10, these sections of the proposed rule are in direct conflict with both the letter and the spirit of the enabling statute. Prime suggests the regulatory standard align with that defined in statute, i.e., adequate access to retail pharmacies based on MDH’s analysis pursuant to §62K.10.

Specific to accessibility under 2737.0900, the Department proposes §62K.10 subd. 2 as the relevant standard for pharmacy services. Currently, §62K.10 subd. 3 is the relevant standard and Prime suggests that remain as the relevant standard. If the legislature intended a tighter geographical standard to apply to pharmacy services, it would have amended §62K.10 to include pharmacy in subd. 2. It did not. Where the legislature specifically enumerates certain entities, the exclusion of others is plainly intentional. The legislature directly acknowledges this in §62k.10 subd. (3) where it states that the looser standard will apply to “specialty physician services, ancillary services, specialized hospital services, and all other health services not listed in subdivision 2.” The statutory language does not leave room for interpretation: services not specifically listed, such as pharmacy services, are subject to the standard in subd. 3.

2737.1200 – Pharmacy Ownership Interest

In this section, the proposed rules again speak to an area where there rulemaking is not necessary because it directly alters the meaning and intent of the legislature with respect to financial incentives offered to owned and non-owned retail pharmacies. §62W.07 prohibits PBMs from offering financial incentives to enrollees who utilize the PBM’s owned pharmacies;
however, under the law, this does not apply where the PBM offers the same incentives to enrollees at non-owned pharmacies that have “agreed to accept the same pricing terms, conditions, and requirements . . . that are in the agreement with a network pharmacy in which the pharmacy benefit manager has an ownership interest.”\(^5\) Importantly, the proposed rules do not include the aforementioned language; rather, they simply state that a PBM must offer the same financial incentives at any non-owned pharmacy as they do at an owned pharmacy.

Here again, the Department makes a material change – this time, by way of omission. The effect of this improper omission would be significant – the utility of a pharmacy network in Minnesota, and thus the savings driven by a managed network of pharmacies, would be greatly diminished. Without those savings, the cost of offering a prescription drug benefit in Minnesota would skyrocket for Minnesota plan sponsors and the cost of prescription drugs would similarly increase for Minnesota enrollees (whether directly at the pharmacy counter and/or through increased premiums due to the overall cost increases to the plan sponsors).

Prime suggests the statutory language be mirrored in the rule; specifically, the rule must include the statutory language tying financial incentives at non-owned pharmacies to the pharmacy “agree[ing] to accept the same pricing terms, conditions, and requirements . . . that are in the agreement with a network pharmacy in which the pharmacy benefit manager has an ownership interest.”

**CONCLUSION**

When the legislature enacted SF 278 in 2019, it codified very specific requirements that require little in the way of clarifying rulemaking. The Department’s proposed rules ignore this and advance new regulatory standards outside the scope of their rulemaking authority and/or in

\(^5\) Minn. Stat. § 62W.07(c)
conflict with the letter and intent of the enabling statute. The goal of this rulemaking should be to establish a regulatory framework that provides sufficient clarity as to enforcement of the law and how entities subject to the requirements can comply. As written, these proposed rules go beyond the rulemaking authority delegated or otherwise contemplated by the legislature when it passed SF 278. Prime appreciates the opportunity to comment on these proposed rules and looks forward to further discussing this and addressing any questions at the September 20th hearing.

Respectfully,

Alex Sommer
Government Affairs Principal
Prime Therapeutics
Pharmaceutical Care Management Association
Comments

Michelle Mack – Director, State Affairs
September 16, 2021

SUBMITTED ELECTRONICALLY VIA PORTAL

The Honorable Kimberly Middendorf  
Office of Administrative Hearings

OAH Docket No: 71 9003-36416

Re: In the Matter of the Proposed Rules Governing Pharmacy Benefits Management (PBM) Licensure and Regulation, Minnesota Rules, Chapter 2737
Revisor’s ID Number R-04625
Initial Comments from PCMA

Dear Judge Middendorf:

On behalf of the Pharmaceutical Care Management Association (“PCMA”), we respectfully submit these initial comments regarding the proposed rules governing pharmacy benefits management (“PBM”) licensure and regulation. PCMA is the national trade association for PBMs, which administer prescription drug plans for more than 266 million Americans with health coverage provided through Fortune 500 employers, health insurance plans, labor unions, and Medicare Part D. PBMs are engaged by clients including health insurers, government agencies, unions, school districts, and large and small employers, to manage pharmacy benefits pursuant to health insurance benefits and contracts.

Background:

The Pharmacy Benefit Management statute, Chapter 62W is a very comprehensive and detailed statute, that in most respects can be read to be self-executing, and in need of little rulemaking. Indeed, the enabling statute evidences a sparse role for rulemaking. Section 20 of Laws 2019 Chapter 39 contains the following quite unusual provision:

“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
The draft rule proposed by the Department is troublesome in several respects. In many instances the rules inappropriately propose to add substantive provisions not authorized by the statute or within the jurisdiction of the Department. In other instances, the Department is proposing to avoid necessary rulemaking by proposing to later impose critical requirements by updating their website or other methods non-compliant with the Chapter 14 rulemaking and the express requirements of the rulemaking authority granted in Chapter 39 quoted above. From a due process prospective, the Department’s proposed appeal procedure from the Commissioner’s substantive licensing decisions is very troubling. Fortunately, Chapter 14 again rescues this infirmity by requiring determinations of this magnitude to be subject to an independent contested case review in lieu of the Department’s proposed internal, informal, and rushed process.

Due to the extensive nature of these rules and the issues raised thereby, PCMA will appear at the September 20th hearing, and at that time will respectfully request that you extend to 20 calendar days the period for initial response, and correspondingly extend the rebuttal comment period. In addition, we request to receive a copy of your report upon issuance and would like to be informed of the date that the agency adopts the rules and files them with the Secretary of State.

The following constitutes PCMA’s initial comments on the proposed rules. For ease of following, these comments will serially follow the rule in chronological order.

2727.0100 DEFINITIONS:

Subp. 2. Aggregate. "Aggregate" means the sum total of the particular reporting element at the national drug code level.

The proposed rules define “aggregate” in terms of drug codes for purposes of reporting to the Department, but the statute uses aggregate in other ways, e.g., aggregate fees and aggregate payments. For example, in the statute, the term “aggregate retained rebates” is defined so it is recommended that, if necessary, the term “aggregate” be modified so that it is limited to the narrow definition that is likely intended.

Subp. 3. Doing business in Minnesota. "Doing business in Minnesota" means a plan sponsor (1) is a Minnesota entity, or (2) makes a contract or engages in terms of service agreement with a Minnesota resident that is performed in whole or in part by either party in Minnesota.

The proposed rules refer only to a “pharmacy benefit manager doing business in Minnesota,” yet the definition defines only when a “plan sponsor” is doing business in Minnesota. This creates confusion in that it defines the term for a plan sponsor, but the rule refers to the term only in the context of a PBM. It is not clear in the PBM context whether item (1) and (2) refer to the PBM or the plan sponsor with which a PBM contracts. In addition, under (2), it is not clear whether “Minnesota resident” refers to an enrollee that...
is a Minnesota resident and, if so, what the meaning is of “either party”, since an enrollee would not perform services for a plan sponsor or a PBM. The determination of whether a PBM does business in Minnesota should be based on its activities alone, and not on the activities of the entity or plan sponsor on whose behalf the activities are performed given the latter may perform activities in Minnesota unrelated to the PBM. PCMA would propose deleting this definition and instead the Department should rely on the plain and well-established meaning of the term.

Subp. 5. **Owned pharmacy.** "Owned pharmacy" means (1) a pharmacy, whether retail, mail order, specialty, or other, or a pharmacy provider in which a pharmacy benefit manager has a direct or indirect ownership interest, or (2) a pharmacy provider has an ownership interest, whether direct or indirect, in the pharmacy benefit manager.

The proposed rules definition of “owned pharmacy” is not needed as the statute is clear that any ownership interest by a PBM includes direct and indirect and term “pharmacy” is defined by law. PCMA recommends that this definition be removed.

**2737.0300 GOVERNMENT PROGRAMS.**

Subpart 1. **Governmental agencies providing pharmacy management services.** 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.

In this subpart, the term, “pharmacy management services” is used. This term is not defined or used elsewhere in the proposed rules nor in the statute. PCMA recommends the term be changed to “pharmacy benefit management”. In addition, we are unclear as to what “directly provides” means and request that clarification be provided. For example, does this mean the state agency contracts directly with a PBM in lieu of going through a managed care organization or does it mean the state agency would be managing its own PBM?

Subpart 2. **Managed care plans in contract with state agencies.**

The statutory definition of “plan sponsor” specifically excludes the Department of Human Services (DHS). It does not carve-out DHS plans or plans sponsored by DHS as the proposed rule is attempting to do here. Therefore, the Department does not have the authority to extend the applicability of a statute. This is outside the scope of the statute and should be deleted.
2737.0400 BUSINESS LICENSE REQUIREMENTS; INITIAL APPLICATION.

Subp. 2. D(2) in the proposed rules includes “any contract or other business relationship terminated for alleged misconduct on the part of any owner, partner, officer, or director of the applicant”.

The proposed rules request information about whether the applicant has ever had a business relationship terminated due to “alleged misconduct” relative to pharmacy benefit management business. Regulatory action must be made based on legally established facts, not mere allegations. While disputes between parties often contain unfounded allegations, they are not legal findings. For clarity and objectivity, this term should be removed, and the standard should be: “terminated due to a legal finding of fraud or other illegal activity.”

Subp. 2. D(6) requires an applicant to “fully describe any delinquent tax obligation, bankruptcy, or demand or judgment for overdue money by an insurer, insured, pharmacy, or any other claimant, whether involving fraud, misappropriation of funds, failure to exercise good faith and fair dealing in the performance of contractual duties, or for any other reason”.

The proposed rules request an applicant describe any “demand”. Similar to “alleged misconduct” above, regulatory action must be based on legally established facts. Additionally, use of “demand” in this context is impermissibly vague. PCMA suggests that a period be inserted after “claimant” on line 3.15 and lines 3.16 and 3.17 be stricken.

Subp. 2. E. in the proposed rules require an applicant to “provide the identities of any plan sponsors for whom the applicant provides pharmacy benefit manager services in Minnesota”.

The proposed rule requires the identities of “any plan sponsor” which is overly broad. In some instances, PBMs may not know all the plan sponsors if they are “downstream” from the plan sponsor with whom they have contracted. PCMA suggests the language read “any plan sponsors in Minnesota with whom the pharmacy benefit manager directly contracts to provide pharmacy benefit management services.”

Subp. 2. F. requires an applicant to “provide the total number of insureds residing in Minnesota for each plan sponsor for which the applicant provides services.”

PCMA recommends that this be removed as this information is something each health plan in the state should already be reporting, if required by law, which would make it duplicative, and they would have the most current and accurate information.
Subp. 3. Network adequacy report.

The last sentence of this paragraph suggests that any restrictions determined by the Department of Health, “may become part of any license issued” by the Department. To avoid jurisdictional confusion and overreach, PCMA suggests this last sentence be deleted. The Department has no authority to enforce restrictions determined by the Health Department pursuant to 62K.

Subp. 4. Fee. in the proposed rules indicates that an “additional administration fee may be charged by the service provider retained by the commissioner.”

The statute is very clear that upon initial application or renewal the only fee required is a nonrefundable fee of $8,500. No additional application or renewal fees are allowed. Subp. 4 should be deleted.

Subp. 5. Updated information required.

For clarification, PCMA suggests that the word “materially” be inserted in this subpart before the instance of the word “changes” when used in lines 4.12 and 4.15. To do otherwise, would needlessly burden both the Department and the PBM’s with address changes, minor errata filings etc.

2737.500 BUSINESS LICENSE REQUIREMENTS; RENEWAL APPLICATION

Subpart 1. Renewal application.

Minn. Stat. 62W.03, subd. 3(c)(1) and (2) state that “(c) The Commissioner may deny the renewal of a license for any of the following reasons: (1) the PBM has been determined by the Commissioner to be in violation or noncompliance with federal or state law; or (2) the PBM has failed to timely submit a renewal application and the information required under paragraph (a).” The statute does not reference or authorize the Commissioner to consider those items referenced in 2737.0700 subp. 2, which will be later addressed in these comments. The proposed rules seem to require essentially an annual compliance audit to receive a renewal greatly beyond the criteria contained in Chapter 62W. PCMA recommends that the renewal process follow the law and not be in the form of an annual compliance review.

On line 5.4 the proposed rule states, “Renewal applications must be submitted in the manner and form prescribed by the commissioner,” PCMA believes the application and forms should be part of this rulemaking proceeding. Given the many instances where the draft rules are departing from the statute, it is highly likely that the “manner and form” of the applications on their own will meet the definition of a “Rule” contained in Minn. Stat.
14. The Department should be required to submit these documents into this record for review and comment as part of this rulemaking proceeding.

**Subp. 3. Fee.** in the proposed rules indicates that an “additional administration fee may be charged by the service provider retained by the commissioner.”

As was stated earlier, the statute is very clear there is a nonrefundable fee of $8,500. There is no authority for the Department to levy additional fees. This subpart should be removed.

**Subp. 4. Updated information required.**

As was stated earlier, for clarification, PCMA suggests that the word “materially” be inserted in this subpart before the instance of the word “changes” when used in lines 4.12 and 4.15. To do otherwise would needlessly burden both the Department and the PBM’s with address changes, minor errata filings etc.

**2737.0600 REVIEW BY COMMISSIONER.**

**Subp. 4. Appeals Process.**

The proposed summary appeal process is totally lacking in fundamental due process and does not comply with the requirements of Minnesota’s Administrative Procedure Act Chapter 14. The proposed hearing IS the proceeding when the licensure or renewal will be contested. Chapter 14 requires this hearing to be a contested case before an Administrative Law Judge.

The definition of a contested case is as follows:


“"Contested case" means a proceeding before an agency in which the legal rights, duties, or privileges of specific parties are required by law or constitutional right to be determined after an agency hearing. "Contested case" does not include hearings held by the Department of Corrections involving the discipline or transfer of inmates or other hearings relating solely to inmate management.’

The legal rights, duties, and privileges of a PBM applicant for initial or renewal licensure are constitutionally entitled to a contested case rather than the summary, virtually ad hoc procedure set forth in Subdivision 4. Section 14.57(a) correspondingly requires the proceeding to be a contested case before the Office of Administrative Hearings.
ENFORCEMENT BY COMMISSIONER.

There are a number of problems with this subpart as there is a significant departure from the enabling statute.

62W.03 Subd. 3(c)(1-2) sets forth the limited basis upon which the Commissioner may deny the renewal of a license. Reference to the limited scope of renewal denial should be acknowledged in the rule.

Subp. 2. Basis for suspension, revocation, or probation.

The lengthy list of state and federal laws for which compliance is required set forth in Subp. 2 greatly departs from the four items cited in 62W.03 Subd. 4. The basis for enforcement action must conform to the four items in the statute. Many of the items cited in the draft rule are beyond the jurisdiction of the Department or the scope of the Chapter 62W. Additionally, it should be noted that clause (2) of Subdivision 4 which states: "(2) the commissioner has received consumer complaints that justify an action under this subdivision to protect the safety and interests of consumers;" is constitutionally suspect as void for vagueness. It would be advisable for the rule to clarify that the complaints must have matured through a contested case or other proceeding which provides a licensee with the due process to which they are entitled.

The overreach of this section is exemplified by "Subp. 2. E. compliance with federal pharmacy laws, including but not limited to the following laws, regulations, and guidance, as applicable to the plan sponsor or product that the pharmacy benefit manager serves. PBMs are not "pharmacies" and federal agencies have oversight of a PBMs activity in federal programs - not the Minnesota Department of Commerce.

This subpart should be narrowed in scope to conform to the statute and provide assurance that the consumer complaint basis referenced in clause (2) will provide fundamental due process to the licensees.

ADEQUATE NETWORK.

Chapter 62W.05 defers network adequacy determinations to the Department of Health. The Department of Commerce does not have the authority to regulate network adequacy. These two sections should be stricken.

TRANSPARENCY REPORTS TO PLAN SPONSORS.

Subp. 2. Time to respond.

PCMA recommends that the Department not set a deadline but rather allow a given PBM and plan sponsor to agree on a timetable between themselves. Many of the required disclosures are already occurring, and it would be most efficient to
allow parties to continue disclosures in accordance with existing, agreed-upon
disclosure schedules. In the alternative, if the Department sets a deadline, PCMA
proposes that it be 90 days from the date of the plan sponsor’s request to allow
sufficient time for the PBM to review the request, gather responsive information,
and submit the information to the plan sponsor. Given the sheer volume of claims
at issue, there are situations in which 60 days would not be sufficient to perform the
required tasks.

Additionally, we believe that in order to be consistent with the statute, the
proposed rule should include under “[a] formal request is made when…” that, if
required by a PBM, the plan sponsor must execute a nondisclosure agreement
pursuant to Minn. Stat. 62W.06.

Subp. 2. B. states: the “plan sponsor provides evidence of perceived
negligence with respect to a contractual duty between the pharmacy benefit
manager and plan sponsor during the last contractual year.”

This language is gratuitous, vague, and unnecessary. The statute states
that the PBM “must disclose” transparency information “upon the request of the
plan sponsor”. A plan sponsor does not need a reason to request the report.
PCMA would suggest this be deleted.

2737.1100 TRANSPARENCY REPORTS TO COMMISSIONER.

PCMA believes the commissioner’s transparency report requirements contained in Subp.
1 and Subp. 4 should be spelled out and contained in this rule. The Department should not be
allowed to impose changes which are mandates of the information and requirements set forth in
Subp.1 and 4 by annual website postings. The depth and breadth of information being sought in
subpart 1 and mandated in subpart 2 meet the definition of a rule:


"Rule" means 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.

2737.1200 PHARMACY OWNERSHIP INTEREST; PHARMACY SERVICES.

Subp. 2. Exemptions to prohibitions.

PCMA believes that the statute, 62W.07 is written in sufficient detail that no rulemaking is
necessary to give effect to the provisions of this section. To do otherwise risks the rules misstating
the statute. For example, 62W.07(d) prohibits a PBM or health carrier from “imposing limits,
including quantity limits or refill frequency limits, on an enrollee’s access to medication that differ
based “solely” on ownership interest. This does mean that a PBM can vary limits based on other considerations. PCMA believes the statute is sufficiently clear and detailed such that 2737.1200 is not necessary.

2737.1500 MAXIMUM ALLOWABLE COST PRICING.

Subpart 1. A. Form.

The manner in which PBMs must allow pharmacies the PBM contracts with is inconsistent with the statute. The term “paper” is used in the proposed rule and the statute uses the term “print”. PCMA suggests the proposed rule be consistent with the statute.

2737.1600 PHARMACY AUDITS.

Subpart 1. B. Electronic availability. This rule require that information regarding the written appeals process be provided at the commencement of the audit, in addition to any time that entity being audited is provided a report that could be appealed.

Upon entering a contract with a pharmacy, PBMs provide pharmacies a Provider Manual that includes all of this information. To avoid unreasonable duplication, it is suggested that it should be sufficient to provide this information in the contract or the provider manual.

2737.1700 ALLOWABLE CLAIM AMOUNT.

The proposed rule creates a definition for “allowable claim amount”.

The term “allowable claim amount” is found in the statute that pertains to Point of Sale (Minn. Stat. 62W.12(2)) requirements and should be defined based within the context of the patient cost share, consistent with the statute and not the pharmacy reimbursement, which is a separate and distinct contractual reimbursement rate that is not connected to patient cost share. PCMA suggests the language in lines 17.8 and 17.9 be deleted and replaced with “the allowable claim amount is defined as the health plan contracted rate for purposes of compliance with Minn. Stat. 62W.12.”

2737.1800 RETROACTIVE ADJUSTMENTS.

Subpart 1. Contracts.

The statute clearly outlines what is prohibited as it relates to retroactive adjustments. Therefore, we are unclear as to why the proposed rules are adding additional requirements that are beyond the scope of law. PCMA suggests deleting this subpart because it is unnecessary.
Subp. 2. Billing Errors.

PCMA contends that this requires a great amount of detail for something that is a “technical billing error.” As with all errors, when a billing error is made, it is not always caught immediately. Therefore, PCMA suggests deleting this subpart as it creates additional administrative work.

RUTLEDGE V. PCMA AS Referenced in the SONAR.

At the beginning of this rulemaking proceeding before the US Supreme Court issued the Rutledge v. Pharmaceutical Care Management Association, 141 S. Ct. 474 (2020) (Rutledge) decision, Department staff indicated that these rules would not impact ERISA plans Following Rutledge, the Statement of Need and Reasonableness (SONAR) noted that, “What the Rutledge decision makes clear, is that Commerce need not construct separate rules or procedures for application as to health plans subject to ERISA.” This summary conclusion is an overbroad simplification of Rutledge and has great implications on how it applies to the proposed rules. The ALJ’s authority in this proceeding does not extend to declarations of unconstitutionality. However, a misunderstanding of Rutledge as it applies to these rules could be very important in assessing these rules vulnerability to constitutional challenge in the future. Therefore, PCMA is providing the following ERISA background information on the Supreme Court’s Decision, as well as the scope and impact of Rutledge:

I. ERISA Preemption Background

In order to understand the scope and significance of Rutledge, it is important to understand the context, purpose, and background of ERISA preemption. Congress enacted ERISA to provide a “uniform regulatory regime over employee benefit plans.” 29 U.S.C. §1001, et. seq.; Aetna Health Inc., 542 U.S. at 248. ERISA does not mandate “any given set of minimum benefits, but instead controls the administration of benefit plans” and leaves selection and design of plan benefits to plan administrators. New York State Conf. of Blue Cross & Blue Shield Plans v. Travelers Ins. Co., 514 U.S. 645, 651 (1995) (“Travelers”). “[B]y mandating certain oversight systems and other standard procedures” pursuant to uniform federal rules, ERISA “make[s] the benefits promised by an employer more secure” for employees while at the same time reducing the administrative burdens for multi-state employers. Gobeille v. Liberty Mut. Ins. Co., 136 S. Ct. 936, 943 (2016).

In order to achieve this objective, Congress included an express preemption clause in ERISA, which preempts “any and all State laws insofar as they may now or hereafter relate to any employee benefit plans.” 29 U.S.C. §1144(a). ERISA’s preemption clause is “comprehensive,” Gobeille, 136 S. Ct. at 943. Congress “intended to preempt the field for Federal regulations, thus eliminating the threat of conflicting or inconsistent State and local regulation of employee benefit plans.” Shaw v. Delta Air Lines, 463 U.S. 85, 99 (1983) (quoting 120 Cong. Rec. 29933 (Aug. 22, 1974). Congress sought to ensure that “employee benefit plan regulation would be ‘exclusively a federal concern.’” Davila, 542 U.S. at 208. “States are precluded from regulating in a field that Congress, acting within its proper authority has determined must be regulated by its exclusive

Consistent with this Congressional intent, the Supreme Court has construed the words “relate to” in ERISA’s express preemption provision to mean state laws that have either a “connection with” or a “reference to” ERISA plans. *Gobeille*, 136 S. Ct. at 943. The Act only implicates “connection with” preemption. State laws have a “connection with” ERISA plans in several circumstances.


*Second*, “state laws dealing with the subject matters covered by ERISA” also have a connection with ERISA plans and are preempted. *Shaw*, 463 U.S. at 98; *Rutledge*, 141 S. Ct. at 482 n.2 (distinguishing laws that “overlap with ‘fundamental components of ERISA regulation’”). In *Gobeille*, for example, the Court explained that “ERISA’s reporting, disclosure, and recordkeeping requirements for welfare benefit plans are extensive.” 136 S. Ct. at 944. The Court thus concluded that a state law that “compels [the disclosure of] detailed information” by third-party administrators to state authorities was preempted. *Id* at 945. Congress’s intent to provide ERISA plan administrators a uniform set of rules makes it clear Congress carved out these decisions as the exclusive domain of federal authorities, not for the states. *Id*.

*Third*, state laws that “‘govern[] a central matter of plan administration’ have a connection with ERISA plans and are preempted. *Gobeille*, 136 S. Ct. at 943 (quoting *Egelhoff v. Egelhoff ex rel. Breiner*, 532 U.S. 141, 148 (2001)). “Plan administration includes ‘determining the eligibility of claimants, calculating benefit levels, making disbursements, monitoring the availability of funds for benefit payments, and keeping appropriate records in order to comply with applicable reporting requirements.’” *PCMA v. District of Columbia*, 613 F.3d 179, 185 (D.C. Cir. 2010).

II. The Supreme Court’s Decision in *Rutledge*

*Rutledge* did not change the framework set forth above for determining whether a law bears an impermissible “connection with” ERISA plans. Rather, it applied the above framework to the law at issue in that case, Arkansas’s Act 900, which regulates MAC lists for generic-drug reimbursements. Act 900 is a drug pricing law: its provisions operate together to set a price floor for generic prescription drugs. The price floor is the “pharmacy acquisition cost,” which was defined as “the amount that a pharmaceutical wholesaler charges for a pharmaceutical product
as listed on the pharmacy’s billing invoice.”1 Ark. Code Ann. § 17-92-507(a)(6). Act 900 sets the price floor using several mechanisms aimed at the same goal. First, Act 900 requires PBMs to update MAC lists within seven calendar days from “an increase of ten percent (10%) or more in the pharmacy acquisition cost from sixty percent (60%) or more of the pharmaceutical wholesalers doing business in” Arkansas. Ark. Code Ann. § 17-92-507(c)(2). Second, the law requires PBMs to disclose their MAC lists to pharmacies and promptly disclose any list updates. Id. § 17-92-507(c)(1), (3). Third, PBMs must “[p]rovide a reasonable administrative appeal procedure” that allows pharmacies to challenge MAC-based reimbursements below the invoice price and requires the PBM to increase the reimbursement to invoice price unless the PBM can prove that the pharmacy could have obtained the drug from its primary wholesaler at the MAC price. Id. § 17-92-507(c)(4). Fourth, the law permitted a pharmacy to forgo the appeal process and simply “decline to provide” the prescribed drug to a patient on the plan’s terms if the MAC-based reimbursement is less than the pharmacy’s invoice price. Id. §17-92-507(e).

The Supreme Court held that ERISA did not preempt Act 900. The Court’s reasoning rested on its long-standing precedent in Travelers. 514 U.S. 645 (1995). In Travelers, the Court held that a New York law requiring hospitals to add a surcharge to the bill for patients covered by commercial insurers, but not patients covered by Blue Cross and Blue Shield insurers was a “basic rate regulation” not preempted under ERISA. Id. at 667, n.6, 668. Although the New York law in Travelers made Blue Cross “more attractive” and “thus ha[d] an indirect economic effect on choices made by insurance buyers, including ERISA plans,” those indirect economic effects did not trigger ERISA preemption because differential charges merely affected “a plan’s shopping decisions.” Id. at 659-60. The state law did not “bind plan administrators to any particular choice” and thus did not “function as a regulation of an ERISA plan itself.” Id.

On this basis, the Court in Rutledge deemed Act 900 “merely a form of cost regulation” that “requires PBMs to reimburse pharmacies for prescription drugs at rates equal to or higher than the pharmacy’s acquisition cost,” and was therefore not preempted. 141 S. Ct at 481. Recognizing that an indirect economic influence does not dictate preemption, the Court found that the effect of Act 900 is not “so acute that it will effectively dictate plan choices,” therefore leaving open the possibility that some indirect economic influence could dictate plan choice, leading to preemption. Id. Further, the Court compared those provisions of Act 900 that required PBMs to recalculate and reprocess pharmacy claims to other state-laws mechanisms for enforcing judgements for breach of contract, which the Court has previously held as permissible under ERISA. Id. (citing Mackey v. Lanier Collection Agency & Service, Inc., 486 U.S. 825, 831-32 (1988)). In this way, Rutledge did not change existing law regarding the scope of ERISA preemption. Instead, it applied long-standing precedent to laws regulating the use of MAC pricing.

III. The Scope and Impact of Rutledge

The Court specifically distinguished the Arkansas MAC law at issue in Rutledge from those state PBM laws that interfere with benefit design. Rutledge, 141 S. Ct. at 480 (ERISA preemption

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1 This price does not accurately reflect a pharmacy’s cost for generic drugs, which is frequently reduced by post-invoice discounts such as prompt pay discounts and rebates.
is “primarily concerned with preempting laws that require providers to structure benefit plans in particular ways, such as by requiring payment of specific benefits, or by binding plan administrators to specific rules for determining beneficiary status”). Further, Rutledge reinforced the principle that laws directed at third parties rather than plans themselves may be preempted by rejecting without discussion the argument that only plans may invoke ERISA preemption. See Gobeille, 136 S. Ct. at 947 (holding Vermont law regulating ERISA third-party plan administrator preempted by ERISA). In so doing, the Court left open the possibility that a panoply of potential state PBM laws, such as those that regulate plan design, benefit selection, and other central matters of plan administration, may still be preempted.

After Rutledge, ERISA preemption principles that prevent states from regulating plan design or central matters of plan administration remain intact. Rutledge was narrowly tailored to the Arkansas law at issue in the case. Therefore, it only limits ERISA preemption of PBM laws that are rate regulations similar to Act 900.2

Rutledge does not make it clear that there need not be separate rules or procedure for application as to health plans subject to ERISA. The scope of ERISA preemption was not narrowed by Rutledge.

We thank you for the opportunity to comment.

Please contact me should you have any questions or comments.

Sincerely,

Michelle D. Mack
Director, State Affairs
Cell:  202-579-3190

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2 Notably, however, the Court did not take a policy position on Act 900. It did not agree with Arkansas that it was a prudent law. In fact, the Court acknowledge that Act 900 would increase prescription drug costs.
Minnesota Council of Health Plans Comments

Lucas Nesse – President and CEO
September 16, 2021

Administrative Law Judge Kimberly Middendorf
Office of Administrative Hearings
600 North Robert Street, P.O. Box 64620
Saint Paul, Minnesota 55164-0620

RE: Proposed Rules Governing Pharmacy Benefits Management (PBM) Licensure and Regulation, Minnesota Rules, Chapter 2737; Revisor’s ID Number R-04625, OAH docket number 21-9009-37561

Dear Judge Middendorf,

Thank you for the opportunity to provide comments in response to the Minnesota Department of Commerce’s proposed rules governing Pharmacy Benefits Management (PBM) licensure and regulation published in the Minnesota State Register on August 16, 2021. The Minnesota Council of Health Plans (“Council”) is the trade organization representing five of Minnesota’s nonprofit health plans – Blue Cross Blue Shield of Minnesota, HealthPartners, Medica, Sanford Health, and UCare. Collectively, our members help approximately 4.4 million Minnesotans access the health care they need.

The Council would like to thank those at the Minnesota Department of Commerce (“the Department”) for the thoughtful engagement on the PBM legislation and the continued engagement through this rulemaking process. Specifically, the Council appreciates the inclusion of health plans, PBMs, and other key stakeholders in the implementation work group. We believe the Department’s thoughtful front-end engagement has helped reduce unintended impacts on Minnesotans and we appreciate the opportunity to comment on the rulemaking with the same goal. The Council respectfully submits the following comments on the proposed rules.

2737.0100 – DEFINITIONS

The Council is concerned the Department’s definition of “Doing business in Minnesota,” as written in Subpart 3 (lines 1.9-1.12) extends beyond the scope of the Rutledge v. PCMA decision. In addition to ERISA pre-emption concerns with the definition, the Council also has concerns about a third-party administrator or employer’s ability to operationalize sub-bullet 2 of Subpart 3 (lines 1.10-1.12). While we appreciate the Department’s attention to further clarify what it means to be “doing business in Minnesota” for purposes of the section, we believe the definition as currently drafted would create additional confusion and a significant operational burden for plan sponsors and the Department.
The Council kindly requests clarification with regard to the exemptions provided to the Department of Human Services (“DHS”). First, the Council recommends that the exemption granted DHS as a Plan Sponsor in Minn. Stat. § 62W.02, subdivision 16 be included in Subpart 1. Unlike Subpart 2, there is no statutory reference in Subpart 1. The Council notes that the Statement of Need and Reasonableness (“SONAR”) provides at page 10 that Subpart 1 is designed to clarify when a government entity may rely on the statutory exemption from the Plan sponsor definition, which expressly exempts DHS from the definition of “Plan Sponsor.” The language of proposed Subpart 1 specifically refers to “[g]overnmental agencies providing pharmacy management services” so we recommend that the language be clarified in Subpart 1 to reflect the statutory authority as well as the statutory reference.

Page 10 of the Department’s SONAR, regarding Subpart 1 states:

“Subpart 1 proposes to extend the plan sponsor exemption granted to the Minnesota Department of Human Services (DHS) to other government agencies who directly provide pharmacy management services for themselves and other governmental agencies in the same manner that DHS does in its fee-for-service role.”

In Subpart 2, we request clarification regarding the (non) exemption to DHS contractors and to whom it applies given DHS contracts with several entities to administer programs.

In the next paragraph on page 10 of the SONAR regarding Subpart 2, the Department states:

“Subpart 2 makes clear that this proposed rule does not extend the exemptions to non-governmental health plan providers, in contract with DHS, for the provision of managed care under the Medical Assistance and Minnesota Care programs.”

The Council requests the language in Subpart 2 be clarified to include which entities are included within the reference to “managed care plans,” and fall within the exemption and those that do not. The Department states in the SONAR that PBMs in contract with Managed Care Organizations (“MCOs”) or Health Maintenance Organizations (“HMOs”) would not be exempt, but does not state whether the MCO or HMO, in contract with DHS to administer Medical Assistance and Minnesota Care programs, are exempt from the definition of Plan sponsor. More importantly, we note that the proposed Subpart 2 does not mention other entities in contract with DHS, including but not limited to County Based Purchasers, and Integrated Health Partnerships, all of which contract with DHS and serve enrollees in managed care plans. If the intent of the rule is to clarify that “managed care plans” that contract with DHS are not entitled to the Plan sponsor exemption granted to DHS by Section 62W.02, subd. 16, then we recommend that the language of the rule specifically include all the different type of entities that contract with DHS to serve enrollees in managed care plans. We share the Department’s goal to not “frustrate the legislature’s intent” and recommend the rules provide clarification on which entities are impacted by these proposed rules.
2737.0400 – BUSINESS LICENSE REQUIREMENTS; INITIAL APPLICATION
Regarding network adequacy reporting in Subpart 5 (lines 4.11-4.17), the proposed rule requires that if any of the information provided on the network adequacy report changes at any time following submission, the applicant must provide updated information to the Minnesota Department of Health (“MDH”) within 30 days of the date the applicant becomes aware of the changed information. The Council suggests the Department update this language to require that applicants provide updated information only for “meaningful” or “substantive” changes to help reduce administrative burden for applicants and MDH.

2737.0800 – ADEQUATE NETWORK
The Council seeks technical clarification on the “Pharmacy Type” requirements listed in Subpart 1 (lines 9.23-10.6). The subpart states that a network is adequate if it contains at least one of each of six types of pharmacies. However, the language on line 10.5 of the draft rules uses “or” in its list of the six types of pharmacies, which could suggest not all types are required. We encourage the Department to make a technical correction to resolve this potential inconsistency. Subpart 1 should also be updated to clarify that it does not require the inclusion of a pharmacy type that is specifically excluded or prohibited by law or by contract with a state agency and that Subpart 2 does not require an explanation for an exclusion of a pharmacy type when excluded for the same reason(s).

Subpart 2 requires that the PBM “describe how an enrollee requiring services from the excluded pharmacy type may access them.” Rather than clarifying a component of the statute, this language seems to expand requirements under the statute. The network adequacy waiver under the rule only requires that the PBM “(1) demonstrate with specific data why the pharmacy benefit manager is not able to meet the requirements; and (2) include information as to the steps that were and will be taken to address network adequacy.” Therefore the Council respectfully suggests the following changes to Subpart 2:

Subp. 2. Plan to provide services. If a pharmacy benefit manager does not include a pharmacy type listed in subpart 1, the pharmacy benefit manager must provide the Department of Health an explanation why the pharmacy type is excluded, and describe how an enrollee requiring services from the excluded pharmacy types may access them.

2737.0900 – ACCESSIBLE NETWORK; RETAIL PHARMACY
The Council seeks to understand why the Department is using 62K.10 for the purpose of determining network accessibility. There are restrictions on mail order pharmacies elsewhere in the statute, but the Council believes these pharmacies can satisfy time and distance standards of this section in the proposed rules.
2737.1100 – TRANSPARENCY REPORTS TO COMMISSIONER

Under Minnesota Statute 62W.06, and reinforced by this section starting on line 11.13, PBMs must submit certain cost information to the Department, which in turn is published on a public site. The Council acknowledges that transparency is important for members to make informed decisions in their healthcare.

There may be several entities that perform a portion of the identified responsibilities of a PBM in Minnesota Statute Chapter 62W.02, subdivision 15 for a single health plan. Data submitted by health plans or other entities under this statute and the proposed rule would be duplicative of the data submitted by PBMs which contract with health plans. The output of that duplicative data may ultimately paint an inaccurate picture of the prescription drug market. In such a circumstance, the Council believes each entity should only be responsible for reporting on the items in 62W.06 that correspond to the duties that they perform. Entities should not be asked to report on duties that they do not perform or to duplicate reporting information from a PBM or other entity also reporting to the Department.

Regarding Subpart 4, the Council requests consultation with “experts in the field” be strengthened to encourage the commissioner to consult with plan sponsors and PBMs who have expertise in commonly used therapeutic categories. This will ensure any classification system created by the department is consistent with industry standards. We respectfully request the following changes:

Subp. 4. Therapeutic categories. The commissioner must select a preexisting and commonly used therapeutic classification system to group drugs into like categories. The commissioner must consult with state agencies and other experts in the field, including plan sponsors and PBMs in order to determine the best classification system. The commissioner must publish the classification system on the department’s website at the same time transparency report templates are published. The classification system must be consistent with industry standards and must be reviewed on a periodic basis.

Thank you once again for the opportunity to provide these comments. The Council advocates for statutes and rules that are clear, concise, and not duplicative so as to minimize administrative costs, licensing fees, and otherwise duplicate reporting – which ultimately may be reflected in overall healthcare spending. Please do not hesitate to contact me if you have any questions or would like to discuss the Council’s comments in more detail.

Sincerely,

[Signature]

Lucas Nesse
President & CEO
Minnesota Council of Health Plans
Minnesota Pharmacy Alliance and Minnesota Society of Health-Systems Pharmacists Comments

Sarah Derr, PharmD – Executive Director

Tamara Bezidcek, PharmD, BCPS, FMSHP – Co-Chair
September 16, 2021

Administrative Law Judge Kimberly Middendorf
Office of Administrative Hearings
600 North Robert Street
Saint Paul, Minnesota 55164-0620

Submitted electronically at https://minnesotaoah.granicusideas.com/discussions

Re: Proposed Rules Governing Pharmacy Benefits Management (PBM) Licensure and Regulation, Minnesota Rules, Chapter 2737; Revisor’s ID Number R-04625, OAH docket number 21-9009-37561

Dear Judge Middendorf:

The Minnesota Pharmacy Alliance (MPA) and the Minnesota Pharmacy Association represent a majority of pharmacists and pharmacies in Minnesota, from health system pharmacies and pharmacists, to regional chain pharmacies like Thrifty White and Sterling Drug, to grocery store pharmacies settings like Hy-Vee and Cub to over 180 independently owned pharmacies throughout Minnesota. Pharmacies will be the most visited health care setting for Minnesotans this year and your local community pharmacist has been and will be the health care professional you will see most frequently in the months and years to come. Pharmacies, on average, are within 5 miles of their patients throughout Minnesota and pharmacists continue to be on one of the most trusted health professionals you or I will come in contact with this week.

Ensuring that Minnesota patients have access to pharmacy health services is essential to our fundamental quality of life and a cornerstone to a healthy community. Which is why it is so important that the Minnesota Commerce Department’s rules on PBM licensure and regulation are clear, well written and not misunderstood. The statutory language found in Chapter 62W and these rules will be the foundation for PBM regulation and the relationship between PBMs, patients and pharmacies going forward. The practice of pharmacy and the business of pharmacy is defined, at its most basic transaction model, as a contract with a payer to cover a patient’s cost of goods and services received from a pharmacists and pharmacy. The Minnesota Legislature set out to define and regulate how that transaction relationship will work in Minnesota as a matter of law.

Minnesota patients have seen the most pharmacy closures in the nation over the past 5 years and a significant loss of pharmacy health services over the past 10 years. Impact to patient care and a loss of patient access to critical pharmacy health care services in communities is real and the disparity between
access in densely populated regions of the state versus smaller towns and cities as well as core urban areas is stark. Many pharmacies are closing their doors because they can’t get reimbursed for their cost of goods. The Minnesota Legislature in 2019 enacted the Minnesota PBM Licensure and Regulation legislation, now MN-Chapter 62W, with very specific intent. Each word and sentence as well as definitions and consequences were contemplated and decided upon by many stakeholders with the goals in mind of creating greater transparency for patients and pharmacies, a defined set of pharmacy and payor relationship rules and put in place prohibitions on certain PBM practices that disadvantage community pharmacy and in many cases under pay pharmacies for their product and services which undermines the practice of pharmacy and impacts patient access to critical health care services.

In order to ensure that Minnesotans have access to pharmacy health services and that Minnesota pharmacies stay in business and to further clarify and define for the entities the Commerce Department and Department of Health are charged with licensing and regulating under the Act, we urge you to consider the following when finalizing the Department’s rules governing Minnesota Chapter 62W – Proposed Rules Governing Pharmacy Benefits Management (PBM) Licensure and Regulation, Minnesota Rules, Chapter 2737; Revisor’s ID Number R-04625, OAH docket number 21-9009-37561

On behalf of the Minnesota Pharmacy Association (MPhA) and the Minnesota Pharmacy Alliance (MPA) and our member pharmacies operating throughout Minnesota, we are pleased to have the opportunity to comment on the Minnesota Commerce Department’s (“Commerce”) proposed rules to provide industry and other stakeholders with clarity and predictability in the implementation and enforcement of the Minnesota Pharmacy Benefit Management (PBM) Licensure & Regulation Act passed in 2019 – Section 20 of Minnesota Session Laws – 2019, Regular Session, Chapter 39 (codified in Minnesota Statutes, chapter 62W). We have written our comments in the form of general observations and suggested modifications to specific rule provisions as well as questions about Commerce’s proposed definitions and rule language. Finally, we conclude with some observations and discussion.

The Minnesota PBM Licensure and Regulation Act was painstakingly written and language was specifically selected to convey exactly what the Legislature intended for Commerce to regulate and enforce. One of the core principles of the Act is found in 62W.04 which reads:

“62W.04 PHARMACY BENEFIT MANAGER GENERAL BUSINESS PRACTICES.
(a) A pharmacy benefit manager must exercise good faith and fair dealing in the performance of its contractual duties. A provision in a contract between a pharmacy benefit manager and a health carrier or a network pharmacy that attempts to waive or limit this obligation is void.

(b) A pharmacy benefit manager must notify a health carrier in writing of any activity, policy, or practice of the pharmacy benefit manager that directly or indirectly presents a conflict of interest with the duties imposed in this section.”

However, other than one mention in § 2727.0400, Subp. 4, d of a PBM having to report a tax delinquency or previous judgement Good Faith and Fair dealings in a PBM’s initial application to do business in the State of Minnesota – the rules proposed by Commerce are silent about PBMs regulated and licensed in Minnesota being required to “...exercise good faith and fair dealings in the performance of its contractual duties” – not using deceptive practices with pharmacies or patients. There is no mention of PBMs treating all contracted parties/pharmacies similarly and not different.
This is especially important when considering how PBMs reimburse their own pharmacies versus non-owned pharmacies contracted in a network. For example PBMs routinely offer an incentive within their benefits plan design for patients to use a provider that is more expensive to the plan sponsor than other providers within the plan’s network, telling a plan sponsor to incentivize member patients to utilize a PBM owned pharmacy even though the incentive would actually cost the plan more money. Another example of bad faith and unfair dealings between PBMs and contracted network pharmacies are claims adjustments by PBMs longer than 6-12 months after the point of sale transaction. Multiple pharmacies have reported claw backs and claims adjustments more than 36 months after the point-of-sale transaction by PBMS serving members in Minnesota. These are just 2 examples of several PBM business practices that would not meet any reasonable definition of good faith or fair dealings. However, if the rules are silent and Commerce is not defining what is “exercising good faith and fair dealings” or giving examples of what is not “exercising good faith and fair dealings” and doesn’t speak to enforcing 62W.04, how can PBMs be expected to stop or not implement these unfair practices.

Commerce’s silence on defining and enforcing 62W.04 should be reconsidered. Any final Commerce rules governing 62W 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. Mentioning enforcement of 62W.04 should be included in the rules under § 2737.0200: Authority, Scope and Purpose, added to the Enforcement section, § 2737.0700 or should be discussed and defined in its own-new subpart.

Another area where the Commerce proposed rules are silent is in declaring whether or not the Minnesota Commerce Department intends to regulate or believes that it has the authority to regulate and hold accountable to Minnesota Chapter 62W self-funded health plans contracting with a PBM for services. Or does Commerce believe that PBMs managing self-funded benefit plans are not eligible for regulation because the plan they are managing is exempted by federal ERISA provisions? We believe that in fact, this past October (2020) in PCMA versus Rutledge, the U.S. Supreme Court ruled unanimously that states can regulate PBMs and/or health insurance carriers and their business dealings, pricing and business relationships even if the benefits plan and the contracted PBM in question is contract with a self-funded plan.

The Commerce rules relating to 62W, the PBM Licensure and Regulation Act, should not be silent on either of these very important issues. Below are our specific comments, questions and suggestions for Commerce consideration. Please let us know if you have any questions or would like additional information about any of our comments or legislator intent.

I. Definitions, Authority, Scope and Purpose and Government Programs (§ 2737.0100 - .0300)

MPhA and MPA has no other comments about these provisions. However, we believe that Commerce’s proposed rule definitions under § 2737.0300, “Government Programs” is satisfactory. The “Managed Care plans” definitional language is very clear that managed care organizations contracting with the State of Minnesota to provide pharmaceutical – pharmacy services benefits to members covered under Medical Assistance (MN-Medicaid) or MNCare are not exempted from having to be licensed or regulated under the Act. The Legislature was very specific when addressing the question of whether or not managed care insurers and their contracted PBMs would be covered by the 2019 law. The intent is clear that they are covered and not exempted from the law simply because they are managing Medicaid beneficiary contracts. Medicaid managed care beneficiaries are afforded the same protections as other Minnesotans under the 2019 law and Commerce’s rules and regulations.
II. Business License Requirements; Initial Application (§2737.400)
As it relates to a PBM’s registration fees, we would observe that the requirement to be licensed in Minnesota to do business, § 2737.0400, Subp. Fee, Application: $8500 may prevent smaller PBMs from entering the market? Should the fee for a PBM license be prorated for very small PBMs? However, we are not certain if Commerce has the authority to prorate the fee based on volume or another metric.

III. Enforcement by Commissioner (§ 2737.0700)
Commerce has proposed specific enforcement provisions and penalties in proposed § 2373.0700 as well as a number of other sections in the proposed rules. The need to ensure PBM compliance with the statute and implementing regulations is critically important. We urge Commerce to adopt all enforcement provisions as proposed.

IV. Adequate and Accessible Networks (§ 2737.0800, 2737.0900)
Under proposed § 2737.0800 and § 2737.0900, Commerce has proposed to define network adequacy such that a PBM need to have only one of each type of pharmacy in the network, and refers to Minnesota Statutes § 62K.10, Subpart 2, as the standard for network accessibility. MPhA and MPA urge Commerce to reconsider these proposed standards, as they are severely inadequate to meet patients’ needs for pharmacy network adequacy and accessibility.

When read together, the proposed language of these sections would require only one of each pharmacy type in the network within 30 miles or 30 minutes of enrollees. We believe that this will cause great inconvenience to Minnesotans. Presently, on average, 90% of all Americans have access to a retail pharmacy within five miles of their home. Commerce’s proposed standards could require Minnesotans to drive past multiple pharmacies in order to reach the one network pharmacy that is within 30 miles or 30 minutes of their home.

Rather than § 62K.10, Subdiv. 2, we believe that the applicable statutory section is § 62K.10, Subdiv. 4, which 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.” Considering that the vast majority of Americans routinely seek healthcare services at their local neighborhood pharmacy, we believe that Minnesotans would find having to drive 30 minutes or 30 miles to find a network pharmacy to be an unreasonable delay.

We believe this allows for Commerce to use the following appropriate standard for network adequacy and accessibility which can be found at 42 CFR § 423.120, which are the federal government’s standards for the Medicare Part D program. Notably, the federal standards for pharmacy access require a pharmacy within two, five, or 15 miles, depending on the setting:

- **At least 90 percent** of Medicare beneficiaries, on average, in urban areas ...
- **live within 2 miles** of a network pharmacy that is a retail pharmacy or a pharmacy described under paragraph (a)(2) of this section.
- **At least 90 percent** of Medicare beneficiaries, on average, in suburban areas ...
  - **live within 5 miles** of a network pharmacy that is a retail pharmacy or a pharmacy described under paragraph (a)(2) of this section.
• **At least 70 percent** of Medicare beneficiaries, on average, in rural areas ... live **within 15 miles** of a network pharmacy that is a retail pharmacy or a pharmacy described under paragraph (a)(2) of this section. (emphasis added)

We urge Commerce to look to access and adequacy standards set for Medicare Part D beneficiaries for guidance when developing such standards for Minnesotans. The proposed rules would impose undue hardships on Minnesota enrollees to access pharmacy care services when compared to Medicare beneficiaries.

If Commerce chooses to stay with the 30/30 network adequacy standard, then they should include language stipulating that if a PBM network includes pharmacies with a financial or other incentive to use a pharmacy or pharmacies, then both the network of pharmacies with an incentive and the network of pharmacies without an incentive must meet the 30 miles or 30 minutes requirement.

**Additionally, § 2737.0800. Subp. 1 E says, "Long Term Care; or...". Since every category of pharmacy as defined in the rules is required shouldn't the "or" in this sentence be "and"?**

V. **Transparency Reports (§ 2737.1000, 2737.1100)**

With respect to proposals at §§ 2737.1000 and 2737.1100 to provide clarity for PBMs with as to their responsibilities for providing transparency reports to plan sponsors and the Commissioner. Several PBMs (13 in 2020) in the past have not filed these statutorily required reports due to claims that the statutory provisions are unclear. While we understand that Commerce is bound by the statutory confidentiality requirements with regard to the information provided in the reports, we ask that the Commerce work to ensure that PBMs and plan sponsors comply with their relevant statutory and contractual confidentiality requirements and that the statutorily required information be provided to Commerce so that a lay person can understand what has been reported.

Also, Commerce should further define and when receiving the Transparency report not simply publish raw numbers and information provided by the PBM, but rather a consistent set of reporting information that meets the requirements under the law. Commerce should standardize and provide specific examples to the reporting PBMs about what information they provide will meet the expectation and requirement of the Department of Commerce. For example, one of the 2020 PBM Transparency reports included “negative” data – negative rebate information. Another example is the broad use of different sources and different drug therapy categories. Commerce should clearly spell out which single source data source they can use and which therapeutic categories PBMs can use when reporting for their Transparency reports. Without being able to compare Transparency reports with the same source and definitional variables, there is no way to functionally utilize the data reported in each Transparency report. The Legislature’s intent was for a lay person to be able to compare the Transparency reports and, most importantly, to have licensed PBMs in Minnesota provide the specific information called for in 62W in a usable and readable format – i.e transparent.

If the 2020 PBM Transparency Reports are any indication of what the public will see in the future, we urge Commerce to require PBMs reporting to utilize a more uniform set of definitions and a more consistent use of terms when reporting. For example, what is the definition of “a rebate” and/or “retained or passed through rebates?” Various PBMs have reported using their own, non-commonly understood, definitions.
Commerce should review the data and information given in each PBM Transparency report, audit the report/data to make sure it is comparable and standardized. If it is not satisfactory based on the statute and rules then Commerce should inquire with the PBM and require them to resubmit in the format and standard called for. Reports not standardized and comparable are useless and do not meet the legislative intent.

2737.1100 TRANSPARENCY REPORTS TO COMMISSIONER.
General comments:

The transparency reports provided to the Dept. of Commerce by PBMs in December 2020 did not meet the legislative intent of the enabling statute. First, thirteen PBMs did not submit a report and it is not clear what the enforcement procedures are for submitting reports and what the consequences are for non-compliance with this provision.

Subp. 3 should require a PBM to make a distinction between having no relevant claims to report versus a claim of being exempt from reporting claims data that would otherwise appear to be relevant.

The submissions reported by PBMs to the Dept of Commerce (DOC) in December 2020 were reported almost verbatim as submitted with typographical errors, formatting problems, and other anomalies that made the reports virtually useless. These reports, as presented to the public, did not meet the legislative intent of this transparency reporting requirement. If anything, the reports presented to the public added confusion and opacity to the public’s ability to understand and interpret the information presented. For example, one PBM reported ‘negative’ amounts for rebates. It is not clear what these negative amounts meant and if they were really negative or merely a typographical or formatting error with a dash (‘-‘) in front of the numbers reported. The Dept. of Commerce must play more than a ministerial role by simply reporting whatever the PBM submits. The DOC should evaluate, clarify, standardize, and analyze the data submitted to assure its accuracy and responsiveness to the reporting requirements. DOC staff, or their delegate, should check with the reporting entity (PBNs) to clarify data that does not appear to be responsive to the reporting requirements.

The DOC was to select a preexisting and commonly used therapeutic classification system to group drugs into like categories. Instead, the DOC template allowed the PBMs to select among 3 or more formats. As a result of the lack of direction as specified in the proposed regulation, the categories submitted by the 16 responding PBMs were widely disparate and not comparable contrary to the legislative intent. The commissioner must select a ‘single’ preexisting and commonly used therapeutic classification system to group drugs into like ‘uniform’ categories. The therapeutic categories actually reported by PBMs to the DOC in the December 2020 submissions were not at all comparable or uniform and did not allow any meaningful comparison across PBMs.

Revisions recommended for Subp.3:
A distinction should be made between having no claims versus having claims but assertion of being exempt from reporting. The following language makes this distinction.

Subp. 3. **Notice of no data to report.** A pharmacy benefit manager that claims to be exempt from the requirement to submit the transparency reports under Minnesota Statutes, section
62W.06, subdivision 2, must, no later than the date the reports are due, submit to the commissioner a statement specifying the basis for nonreporting.

- A pharmacy benefit manager that has no data to report is an entity that has had no claims in the state of Minnesota subject to Minnesota Statutes, section 62W.06, subdivision 2. Such a PBM must, no later than the date the reports are due, submit to the commissioner a statement specifying that there are no claims subject to reporting.

- A pharmacy benefit manager that has claims it considers to be exempt from the requirement to submit the transparency reports under Minnesota Statutes, section 62W.06, subdivision 2, must, no later than the date the reports are due, submit to the commissioner a statement specifying the basis for nonreporting.

Subp. 4. **Therapeutic categories.** The commissioner must select a single preexisting and commonly used therapeutic classification system to group drugs into like uniform categories. The commissioner may consult with state agencies and other experts in the field in order to determine the best classification system. The commissioner must publish the classification system on the department’s website at the same time transparency report templates are published. The classification system must be consistent with industry standards and must be reviewed on a periodic basis.

**IX. Networks with only PBM-Owned Pharmacies (§ 2737.1200, Subp. 1)**

Under proposed § 2737.1200, Subpart 1 and, Commerce has proposed to define when a PBM “requires” an enrollee to use a pharmacy pursuant to Minnesota Statute § 62W.07(b) with respect to the statutory prohibition that a PBM shall not establish a network of pharmacies that includes only pharmacies directly or indirectly owned by the PBM.

We and our pharmacy colleagues across the state are concerned that the proposed language could allow a PBM to establish networks that include only one type of pharmacy not directly or indirectly owned by the PBM, and include only other types of pharmacies owned directly or indirectly by the PBM. For example, PBMs commonly establish networks to the detriment of beneficiaries that require beneficiaries to use one, PBM-owned, specialty pharmacy for all specialty pharmacy services. This practice would still be allowed under the proposed rules. To remedy this concern, we urge Commerce to amend this section as follows:

- **Subpart 1. Networks with only owned pharmacies.** A pharmacy benefit manager requires an enrollee to use a pharmacy if the pharmacy benefit manager establishes a network of pharmacies that includes only pharmacies directly or indirectly owned by the pharmacy benefit manager, or if the pharmacy benefit manager establishes a network of pharmacies that excludes types of pharmacies that are not directly or indirectly owned by the pharmacy benefit manager.

Our proposed underlined additions would ensure that beneficiaries that rely on one type of pharmacy, such as a specialty pharmacy, are not forced to use only the PBM-owned pharmacy. This was the intent of legislators when they wrote the very clear delineation on PBM owned pharmacy preferential treatment and unfair practices provisions of the legislation.
X. **Use of Quantity and Refill Limits (§ 2737.1200, Subp. 3)**

Under proposed § 2737.1200, Subpart 3, Commerce has proposed that a PBM or health carrier may only impose quantity limits or refill frequency limits at their owned pharmacies where the PBM or health carrier provides the enrollee access to a non-owned pharmacy with the same limits.

This is not what the Legislature intended and we believe that proposed rules would allow PBMs to only impose limits on itself where it has already done so to other, non-owned pharmacies. Considering its business interests, PBMs are more likely, and commonly do, impose limits on other pharmacies that they do not impose on their own pharmacies. We believe the proposed language would impose a prohibition without any real effect.

Rather, we urge the Division to reverse the impact of its proposal, as follows (also suggested by the NACDS comments):

- **Retail.** A pharmacy benefit manager or health carrier may only impose the same quantity limits or refill frequency limits at an a non-owned retail pharmacy where that the pharmacy benefit manager or health carrier provides the enrollee access to a nonowned has already imposed at an owned retail pharmacy with the same limits.

- **Mail order.** A pharmacy benefit manager or health carrier may only impose the same quantity limits or refill frequency limits at an a non-owned mail order pharmacy where that the pharmacy benefit manager or health carrier provides the enrollee access to a nonowned has already imposed at an owned mail order pharmacy with the same limits.

Our proposed underlined and strikethrough edits should ensure that enrollees receive the same types of benefits at a non-PBM-owned pharmacy as they would at a PBM-owned pharmacy.

XI. **Pharmacy Ownership Interest (§ 2737.1200, Subp. 4)**

**2737.1200 Subp. 4 Single Mail Order Pharmacy Networks**

We appreciate the intent of this language, however, as the language stands, a PBM could circumvent this restriction if they were to offer a network with two or more owned mail order pharmacies. Because the potential for abuse exists in other pharmacy categories as well, we also believe this restriction should apply to ALL categories of network pharmacies. We suggest the following changes to the language:

Subp. 4. Single mail order pharmacy networks with owned pharmacies. If a pharmacy benefit manager administers a network with a single one or more owned retail, specialty, home infusion, mail order or long term care pharmacies, but does not include non-owned pharmacies of the same category, mail order pharmacy that is an owned pharmacy, the pharmacy benefit manager is prohibited from (1) offering financial incentives to use the mail order pharmacy, owned pharmacies or (2) imposing limits on an enrollee’s access to medication.

In addition, throughout .1200, Subp. 2, A-C the final portion of the last sentence of each lettered subpart reads “...the same incentive at a nonowned mail order pharmacy.” We urge Commerce to
change each final sentence in A-C to be substituted with language that reads: “...the same incentive at nonowned pharmacies.”

“...at a...” implies one nonowned pharmacy, the intent is to make sure the same incentive is offered or not offered at nonowned pharmacies, not just one.

XII. Section 340B Participants (§ 2737.1300)

MPhA and MPA appreciate Commerce’s proposals at § 2737.1300 to clarify PBM requirements with respect to pharmacies that contract to provide services to the 340B patients. Specifically, under Subpart 3, the Division proposes to prohibit a PBM from requiring that 340B participants agree to terms and conditions specific to the 340B program in order to access network status. Commerce’s proposal should help ensure that 340B patients receive the same level of benefits as other, non-340B enrollees.

However, considering some recent PBM actions that impose requirements on pharmacies that jeopardize pharmacies’ abilities to serve 340B patients, we urge Commerce to further clarify that among the terms and conditions that PBMs are prohibited from imposing on 340B participants are “requiring pharmacies to provide the PBM with information in any medium the PBM chooses,” and “requiring pharmacies to provide PBMs with information about 340B claims that cannot be determined at the point-of-sale.” For example, PBMs will commonly adjudicate a claim at point-of-sale but then require the pharmacy to resubmit the claim at a later time with additional information to which the pharmacy may not have access. We ask that Commerce include these types of terms and conditions in the prohibitions of § 2737.1300 because they are among the 340B specific factors that limit pharmacy access to network status, and because they violate the intent of § 62W.13 that prohibit PBMs from imposing retroactive adjustments on pharmacy after the claim has been adjudicated at the point-of-sale.

XVII. Maximum Allowable Cost Pricing, (§ 2737.1500 Subp. 1B)

Electronic availability: this section of the rules should clarify that whichever of the 3 formats the pharmacy requests a MAC list(s) to be provided to the requester is determined by the patient or pharmacy requesting the updated MAC Pricing list. Or does the PBM determine which format it will provide the MAC pricing list in? The Legislature’s intent was to make MAC pricing as transparent as possible and that included making the format in which the MAC price list is received up to the pharmacy or patient, not the PBM. The rules should clarify this and be clear that the requester specifies the format in which they would like to receive the MAC list. The PBM does not get to decide that they will only provide the list in the format they determine.

And

MAC Pricing, (§ 2737.1500 Subp. 1, C and D)

Date updated and updated items: In order to be meaningful, this requirement must be more robust and not only inform the reviewer when the MAC list was last updated, but rather when a specific drug on the MAC pricing list was updated, the price’s effective date and what the previous price was and the last date when the previous price was good through. PBMs should be required to provide dates that prices were updated, the drug prices that were updated on each date and the previous and updated price for each drug must be available to network pharmacies. Further, the pricing list should be available in real-time so that a pharmacy and the patient can utilize the information to determine at the point of sale.
XVIII. Allowable Claim Amount (§ 2737.1700)
Under proposed § 2737.1700, Commerce is proposing to implement Minnesota Statute § 62W.12 by defining the “allowable claim amount” to be equivalent to the net amount the pharmacy receives from the pharmacy benefit manager for dispensing the prescription. We are very concerned that the proposed provision could be interpreted by PBMs to exclude the cost of the medication product from the calculation of “allowable claim amount,” because the definition mentions only the service of dispensing the prescription. This does not capture all variables of the reimbursement equation.

To remedy our concerns, we request Commerce define the “allowable claim amount” to be the “full point-of-sale reimbursement amount contracted between the pharmacy benefit manager and the pharmacy.”

Allowable Claim Amount: The prohibition of retroactive adjustments is essential to this requirement, since the allowable claim amount must be known at the point of sale if it is to be used as a metric for determining the amount the patient is to pay at the point of sale.

XIX. Retroactive Adjustments (§ 2732.1800)
We generally support Commerce’s proposal under § 2732.1800 to implement the provisions of Minnesota Statute § 62W.13, which prohibit retroactive payment adjustments on pharmacies by PBMs. However, we believe that the language should be improved to help ensure that PBMs do not circumvent the intent with creative contractual language. Often, PBMs will impose on pharmacies retroactive adjustments and declare that the payment claw back is actually just an adjustment to meet contractually obligated aggregate payment rates or payment amounts. In essence, the PBM will claw back payment pursuant to a contractual provision that merely redefines retroactive adjustments as a different type of payment adjustment or “administrative fee”. To help prevent these types of PBM activities, we recommend the following edits:

Subpart 1. Contracts. Minnesota Statutes, section 62W.13, must not be waived or modified by contract, including any contractual provision that would lead to the adjustment of pharmacy reimbursement after a claim has been adjudicated at point-of-sale. Prohibited contractual provisions include any requirement for a pharmacy to agree to reduction is reimbursement based on obligated aggregate payment rate or obligated aggregate payment amount.

We appreciate the Commerce’s consideration of our proposed amendment to help ensure that PBMs comply with relevant statutory and regulatory requirements, and are not able to circumvent their intent with creative contractual provisions.

XX. Retroactive Adjustments (§ 2737.1800, Subp. 3)
Fees not subject to adjustment: The first sentence defines quality performance metrics that are allowed under 62W.13. We encourage Commerce to slightly modify this language so that it reads (line 17.17) “Payments as a positive reward performance metrics...” The second sentence in § 2737.1800, Subp. 3 contradicts and confuses the first sentence? We would suggest eliminating the second sentence and we would encourage Commerce to add a final sentence in this section that reads: “Any other fees may not be adjusted or imposed after the point-of-sale.”

XXI. Conclusion
MPhA and MPA thanks the Minnesota Commerce Department for your attention and consideration of our comments. We also want to thank you for the opportunity to provide our perspectives on
rules to implement the 2019 PBM Licensure and Regulation Act – now MN-Chapter 62W. if we can provide further assistance, please do not hesitate to contact Buck Humphrey: hubert4@gmail.com; 612-889-6515

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62W.01 CITATION.
This chapter may be cited as the "Minnesota Pharmacy Benefit Manager Licensure and Regulation Act."

History: 2009 c. 39 s. 1.
62W.02 DEFINITIONS.

Subdivision 1. Scope. For purposes of this chapter, the following terms have the meanings given.

Subd. 2. Aggregate retained rebate. "Aggregate retained rebate" means the percentage of all rebates received by a pharmacy benefit manager from a drug manufacturer for drug utilization that is not passed on to the pharmacy benefit manager's client.

Subd. 3. Claims processing service. "Claims processing service" means the administrative services performed in connection with the processing and adjudicating of claims relating to pharmacy services that includes:

(1) receiving payments for pharmacy services;
(2) making payments to pharmacists or pharmacies for pharmacy services; or
(3) both clauses (1) and (2).

Subd. 4. Commissioner. "Commissioner" means the commissioner of commerce.

Subd. 5. Enrollee. "Enrollee" means a natural person covered by a health plan and includes an insured, policyholder, subscriber, contract holder, member, covered person, or certificate holder.

Subd. 6. Health carrier. "Health carrier" has the meaning given in section 62A.01, subdivision 2.

Subd. 7. Health plan. "Health plan" means a policy, contract, certificate, or agreement defined in section 62A.01, subdivision 3.

Subd. 8. Mail order pharmacy. "Mail order pharmacy" means a pharmacy whose primary business is to receive prescriptions by mail, fax, or through electronic submissions, dispense prescription drugs to enrollees through the use of the United States mail or other common carrier services, and provide consultation with patients electronically rather than face-to-face.

Subd. 9. Maximum allowable cost price. "Maximum allowable cost price" means the maximum amount that a pharmacy benefit manager will reimburse a pharmacy for a group of therapeutically and pharmaceutically equivalent multiple source drugs. The maximum allowable cost price does not include a dispensing or professional fee.

Subd. 10. Multiple source drugs. "Multiple source drugs" means a therapeutically equivalent drug that is available from at least two manufacturers.

Subd. 11. Network pharmacy. "Network pharmacy" means a retail or other licensed pharmacy provider that directly contracts with a pharmacy benefit manager.

Subd. 12. Other prescription drug or device services. "Other prescription drug or device services" means services other than claims processing services, provided directly or indirectly, whether in connection with or separate from claims processing services, including:

(1) negotiating rebates, discounts, or other financial incentives and arrangements with drug manufacturers;
(2) disbursing or distributing rebates;
(3) managing or participating in incentive programs or arrangements for pharmacy services;
(4) negotiating or entering into contractual arrangements with pharmacists or pharmacies, or both;
(5) developing prescription drug formularies;
(6) designing prescription benefit programs; or
(7) advertising or promoting services.

Subd. 13. Pharmacist. "Pharmacist" means an individual with a valid license issued by the Board of Pharmacy under chapter 151.

Subd. 14. Pharmacy or pharmacy provider. "Pharmacy" or "pharmacy provider" means a place of business licensed by the Board of Pharmacy under chapter 151 in which prescription drugs are prepared, compounded, or dispensed under the supervision of a pharmacist.
Subd. 15. Pharmacy benefit manager. (a) "Pharmacy benefit manager" means a person, business, or other entity that contracts with a plan sponsor to perform pharmacy benefits management, including but not limited to:
(1) contracting directly or indirectly with pharmacies to provide prescription drugs to enrollees or other covered individuals;
(2) administering a prescription drug benefit;
(3) processing or paying pharmacy claims;
(4) creating or updating prescription drug formularies;
(5) making or assisting in making prior authorization determinations on prescription drugs;
(6) administering rebates on prescription drugs; or
(7) establishing a pharmacy network.
(b) Pharmacy benefit manager does not include the Department of Human Services.

Subd. 16. Plan sponsor. "Plan sponsor" means a group purchaser as defined under section 62J.03; an employer in the case of an employee health benefit plan established or maintained by a single employer; or an employee organization in the case of a health plan established or maintained by an employee organization, an association, joint board trustees, a committee, or other similar group that establishes or maintains the health plan. This term includes a person or entity acting for a pharmacy benefit manager in a contractual or employment relationship in the performance of pharmacy benefit management. Plan sponsor does not include the Department of Human Services.

Subd. 17. Rebates. "Rebates" means all price concessions paid by a drug manufacturer to a pharmacy benefit manager or plan sponsor, including discounts and other price concessions that are based on the actual or estimated utilization of a prescription drug. Rebates also include price concessions based on the effectiveness of a prescription drug as in a value-based or performance-based contract.

Subd. 18. Retail pharmacy. "Retail pharmacy" means a chain pharmacy, a supermarket pharmacy, an independent pharmacy, or a network of independent pharmacies, licensed under chapter 151, that dispenses prescription drugs to the public.

Subd. 19. Specialty drug. "Specialty drug" means a prescription drug that:
(1) cannot be routinely dispensed at a majority of retail pharmacies;
(2) is used to treat chronic and complex, or rare medical conditions;
(3) has special storage, handling, or distribution requirements that typically cannot be met by a retail pharmacy; and
(4) meets at least three of the following criteria:
(i) requires complex and extended patient education and counseling;
(ii) requires intensive monitoring;
(iii) requires clinical oversight; and
(iv) requires product support services.

Subd. 20. Specialty pharmacy. "Specialty pharmacy" means a pharmacy that specializes in dispensing specialty drugs for patients with serious health conditions requiring complex therapies and high cost biotech and injectable medications. A pharmacy benefit manager or health carrier may require a specialty pharmacy to be accredited as a specialty pharmacy from one of the following accreditors:
(1) Utilization Review Accreditation Commission (URAC);
(2) Accreditation Commission for Health Care, Inc.; or
(3) Joint Commission Accreditation Commission.

History: 2019, c 39 , s 2
62W.03 LICENSE TO DO BUSINESS.

Subdivision 1. General. (a) Beginning January 1, 2020, no person shall perform, act, or do business in this state as a pharmacy benefit manager unless the person has a valid license issued under this chapter by the commissioner of commerce.

(b) A license issued in accordance with this chapter is not transferable.

Subd. 2. Application. (a) A pharmacy benefit manager seeking a license shall apply to the commissioner of commerce on a form prescribed by the commissioner. The application form shall include at a minimum the following information:

(1) the name, address, and telephone number of the pharmacy benefit manager;

(2) the name and address of the pharmacy benefit manager agent for service of process in this state; and

(3) the name, address, official position, and professional qualifications of each person responsible for the conduct of affairs of the pharmacy benefit manager, including all members of the board of directors, board of trustees, executive committee, or other governing board or committee; the principal officers in the case of a corporation; or the partners or members in the case of a partnership or association.

(b) Each application for licensure must be accompanied by a nonrefundable fee of $8,500. The fees collected under this subdivision shall be deposited in the general fund.

(c) Within 30 days of receiving an application, the commissioner may require additional information or submissions from an applicant and may obtain any document or information reasonably necessary to verify the information contained in the application. Within 90 days after receipt of a completed application, the network adequacy report required under section 62W.05, and the applicable license fee, the commissioner shall review the application and issue a license if the applicant is deemed qualified under this section. If the commissioner determines the applicant is not qualified, the commissioner shall notify the applicant and shall specify the reason or reasons for the denial.

Subd. 3. Renewal. (a) A license issued under this chapter is valid for one year. To renew a license, an applicant must submit a completed renewal application on a form prescribed by the commissioner, the network adequacy report required under section 62W.05, and a renewal fee of $8,500. The fees collected under this paragraph shall be deposited in the general fund. The commissioner may require a renewal applicant to submit additional information to clarify any new information presented in the renewal application.

(b) A renewal application submitted after the renewal deadline date must be accompanied by a nonrefundable late fee of $500. The fees collected under this paragraph shall be deposited in the general fund.

(c) The commissioner may deny the renewal of a license for any of the following reasons:

(1) the pharmacy benefit manager has been determined by the commissioner to be in violation or noncompliance with federal or state law, or

(2) the pharmacy benefit manager has failed to timely submit a renewal application and the information required under paragraph (a).

In lieu of a denial of a renewal application, the commissioner may permit the pharmacy benefit manager to submit to the commissioner a corrective action plan to cure or correct deficiencies.

Subd. 4. Oversight. (a) The commissioner may suspend, revoke, or place on probation a pharmacy benefit manager license issued under this chapter for any of the following circumstances:

(1) the pharmacy benefit manager has engaged in fraudulent activity that constitutes a violation of state or federal law;

(2) the commissioner has received consumer complaints that justify an action under this subdivision to protect the safety and interests of consumers;

(3) the pharmacy benefit manager fails to pay an application license or renewal fee; and

(4) the pharmacy benefit manager fails to comply with a requirement set forth in this chapter.

(b) The commissioner may issue a license subject to restrictions or limitations, including the types of services that may be supplied or the activities in which the pharmacy benefit manager may be engaged.

Subd. 5. Penalty. If a pharmacy benefit manager acts without a license, the pharmacy benefit manager may be subject to a fine of $5,000 per day for the period the pharmacy benefit manager is found to be in violation. Any penalties collected under this subdivision shall be deposited in the general fund.

Subd. 6. Enforcement. The commissioner shall enforce this chapter under the provisions of chapter 45.
62W.04 PHARMACY BENEFIT MANAGER GENERAL BUSINESS PRACTICES.

(a) A pharmacy benefit manager must exercise good faith and fair dealing in the performance of its contractual duties. A provision in a contract between a pharmacy benefit manager and a health carrier or a network pharmacy that attempts to waive or limit this obligation is void.

(b) A pharmacy benefit manager must notify a health carrier in writing of any activity, policy, or practice of the pharmacy benefit manager that directly or indirectly presents a conflict of interest with the duties imposed in this section.

History: 2019 c 39 § 4

Commented [GB23]: Good faith and fair dealing are four words PBMs do not live by today in MN or any other state. Subparagraph (a) is meaningless. PBMs continually, and unilaterally waive or limit existing contracts in place. From my perspective the answer is to require fiduciary responsibility to any plan sponsor, and secondarily, to require the Commerce Commissioner to grant any approval to contract changes being made that are unilateral by the PBM, e.g silent acceptance clauses, or when a call or email is made to any PBM requesting change and is told “this contract is non-negotiable.” Happens every day.

Commented [GB24]: I believe any letter than is written to a health carrier or plan sponsor should also be sent to the Commerce Commissioner’s office. Hence my reason for adding additional staff with significant PBM contracting experience to the staff that is FULLY funded by PBM registration fees. That expertise is sorely needed to stop some of the heinous activities being dumped on patients and pharmacies by PBMs.
Office of the Revisor of Statutes

2020 Minnesota Statutes

62W.05 PHARMACY BENEFIT MANAGER NETWORK ADEQUACY.

Subdivision 1. Requirements. (a) A pharmacy benefit manager must provide an adequate and accessible pharmacy network for the provision of prescription drugs that meet the relevant requirements in section 61K.02. Mail order pharmacies must not be included in the calculations of determining the adequacy of the pharmacy benefit manager's pharmacy network under section 62K.07.

(b) A pharmacy benefit manager must submit to the commissioner a pharmacy network adequacy report describing the pharmacy network and pharmacy accessibility in this state, with the pharmacy benefit manager's license application and renewal, in a manner prescribed by the commissioner.

Subd. 2. Network adequacy waiver. A pharmacy benefit manager may apply for a waiver from the commissioner of health if the pharmacy benefit manager is unable to meet the network adequacy requirements under subdivision 1. A waiver application must be submitted to the commissioner of health on a form prescribed by the commissioner of health and must:

1. Demonstrate with specific data why the pharmacy benefit manager is not able to meet the requirements.
2. Include information as to the steps that were and will be taken to address network adequacy.

If a waiver is granted by the commissioner of health, the waiver shall automatically expire after three years. If a renewal of the waiver is sought, the commissioner of health shall consider steps that the pharmacy benefit manager has taken over the past three-year period to address network adequacy.

Subd. 3. Accreditation standards. A pharmacy benefit manager must not require pharmacy accreditation standards or recertification requirements to participate in a network that are inconsistent with, more stringent than, or in addition to federal and state requirements for licensure as a pharmacy in this state unless authorized under this chapter.

History: W 97 c 39 s 5

Commented [GB25]: The network adequacy should be based on the guidelines CMS has established, and not the simple rule of thumb that PBMs use which is 15 miles from pharmacy door to pharmacy door. Guidelines are far more stringent and need to be adopted by MN as well. Guidelines from CMS are intended for Medicare Part D recipients and MN should require nothing less. It is time to stop them from contracting exclusively with big box stores, or in the case of CVS Caremark, contracting with their own CVS pharmacies, an example of steering and using preferred networks to exclude those pharmacies the PBMs don’t want. We can stop that in MN.

Commented [GB26]: The #1 reason for a PBM not getting network adequacy is because of their heinous and unilateral contracts. Waivers should not be granted. Either they comply with MN statute or don’t participate. That is their modus operandi; show a little bit of the same!

Commented [GB27]: No waivers should ever be granted, and three years is ridiculous. Any PBM can resolve issues in a matter of 90 days or less it is chooses to. Three years is just a gift to the PBMs to let them continue to do what they do best – take advantage of every situation they can.

Commented [GB28]: Hence this ties back to specialty drug accreditation in Subd. 20 and appears to conflict with language written there where it says a PBM may require special accreditation for specialty drugs. This Subd. 3 says it correctly.
62W.06 PHARMACY BENEFIT MANAGER TRANSPARENCY.

Subdivision 1. Transparency to plan sponsors. (a) Beginning in the second quarter after the effective date of a contract between a pharmacy benefit manager and a plan sponsor, the pharmacy benefit manager must disclose, upon the request of the plan sponsor, the following information with respect to prescription drug benefits specific to the plansponsor: 

(1) the aggregate wholesale acquisition costs from a drug manufacturer or wholesale drug distributor for each therapeutic category of prescription drugs;

(2) the aggregate wholesale acquisition costs from a drug manufacturer or wholesale drug distributor for each therapeutic category of prescription drugs available to the plan sponsor's enrollees;

(3) the aggregate amount of rebates received by the pharmacy benefit manager by therapeutic category of prescription drugs. The aggregate amount of rebates must include any utilization discounts the pharmacy benefit manager receives from a drug manufacturer or wholesale drug distributor;

(4) any other fees received from a drug manufacturer or wholesale drug distributor;

(5) whether the pharmacy benefit manager has a contract, agreement, or other arrangement with a drug manufacturer to exclusively dispense or provide a drug to a plan sponsor's enrollees, and the application of all consideration or economic benefits collected or received pursuant to the arrangement;

(6) prescription drug utilization information for the plan sponsor's enrollees;

(7) de-identified claims level information in electronic format that allows the plan sponsor to sort and analyze the following information for each claim:

(i) whether the claim required prior authorization;

(ii) the amount paid to the pharmacy for each prescription, net of the aggregate amount of fees or other assessments imposed on the pharmacy, including point-of-sale and retroactive charges;

(iii) any spread between the net amount paid to the pharmacy in item (ii) and the amount charged to the plan sponsor;

(iv) whether the pharmacy is, or is not, under common control or ownership with the pharmacy benefit manager;

(v) whether the pharmacy is, or is not, a preferred pharmacy under the plan;

(vi) whether the pharmacy is, or is not, a mail order pharmacy; and

(vii) whether enrollees are required by the plan to use the pharmacy;

(8) the aggregate amount of payments made by the pharmacy benefit manager to pharmacies owned or controlled by the pharmacy benefit manager on behalf of the sponsor's plan;

(9) the aggregate amount of payments made by the pharmacy benefit manager to pharmacies not owned or controlled by the pharmacy benefit manager on behalf of the sponsor's plan; and

(10) the aggregate amount of the fees imposed on, or collected from, network pharmacies or other assessments against network pharmacies, including point-of-sale fees and retroactive charges, and the application of those amounts collected pursuant to the contract with the plan sponsor:

(b) A pharmacy benefit manager may require a plan sponsor to agree to a nondisclosure agreement that specifies that the information reported under this section is proprietary information. The pharmacy benefit manager is not required to disclose the information to the plan sponsor until the plan sponsor has executed the nondisclosure agreement, if required by the pharmacy benefit manager.

Subd. 2. Transparency report to commissioner. (a) Beginning June 1, 2020, and annually thereafter, each pharmacy benefit manager must submit to the commissioner a transparency report containing data from the prior calendar year as it pertains to plan sponsors doing business in Minnesota. The report must contain the following information:

(1) the aggregate wholesale acquisition costs from a drug manufacturer or wholesale drug distributor for each therapeutic category of prescription drugs for all of the pharmacy benefit manager's plan sponsor clients, and these costs net of all rebates and other fees and payments, direct or indirect, from all sources;

(2) the aggregate amount of all rebates that the pharmacy benefit manager received from all drug manufacturers for all of the pharmacy benefit manager's plan sponsor clients. The aggregate amount of rebates must include any utilization discounts the pharmacy benefit manager receives from a drug manufacturer or wholesale drug distributor;
(3) the aggregate of all fees from all sources, direct or indirect, that the pharmacy benefit manager received for all of the pharmacy benefit manager's plan sponsor clients;

(4) the aggregate retained rebates and other fees, as listed in clause (3), that the pharmacy benefit manager received from all sources, direct or indirect, that were not passed through to plan sponsors;

(5) the aggregate retained rebate and fees percentage;

(6) the highest, lowest, and mean aggregate retained rebate and fees percentage for all of the pharmacy benefit manager's plan sponsor clients; and

(7) de-identified claims level information in electronic format that allows the commissioner to sort and analyze the following information for each claim:

   (i) the drug and quantity for each prescription;
   (ii) whether the claim required prior authorization;
   (iii) patient cost-sharing paid on each prescription. This data is classified pursuant to paragraph (d);
   (iv) the amount paid to the pharmacy for each prescription, net of the aggregate amount of fees or other assessments imposed on the pharmacy, including point-of-sale and retroactive charges. This data is classified pursuant to paragraph (d);
   (v) any spread between the net amount paid to the pharmacy in item (iv) and the amount charged to the plan sponsor. This data is classified pursuant to paragraph (d).

(b) Within 60 days upon receipt of the transparency report, the commissioner shall publish the report from each pharmacy benefit manager on the Department of Commerce’s website, with the exception of data considered trade secret information under section 13 37. The transparency report must be published in such a way as to not disclose the identity of a specific plan sponsor, the prices charged for a specific prescription drug or classes of drugs, or the amount of any rebates provided for a specific prescription drug or classes of drugs.

(c) For purposes of this subdivision, the aggregate retained rebate and fee percentage must be calculated for each plan sponsor for rebates and fees in the previous calendar year as follows:

   (1) the sum total dollar amount of rebates and fees from all drug manufacturers for all utilization of enrollees of a plan sponsor that was not passed through to the plan sponsor; and

   (2) divided by the sum total dollar amount of all rebates and fees received from all sources, direct or indirect, for all enrollees of a plan sponsor.

(d) Data, documents, materials, or other information in the possession or control of the commissioner of commerce that are obtained by, created by, or disclosed to the commissioner pursuant to paragraph (a), clause (7), items (iii), (iv), and (v), are classified as confidential, protected nonpublic, or both. Those data, documents, materials, or other information are not subject to subpoena, and are not subject to discovery or admissible in evidence in any private civil action. However, the commissioner may use the data, documents, materials, or other information in the furtherance of a regulatory or legal action brought as a part of the commissioner’s official duties. The commissioner shall not otherwise make the data, documents, materials, or other information public without the prior written consent of the pharmacy benefit manager. Neither the commissioner nor any person who received data, documents, materials, or other information while acting under the authority of the commissioner are permitted or required to testify in any private civil action concerning data, documents, materials, or information subject to this paragraph that are classified as confidential, protected nonpublic, or both.

Subd. 3. Penalty. The commissioner may impose civil penalties of not more than $1,000 per day per violation of this section. 

History: 2010 c 90 s 9. 

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62W.07 PHARMACY OWNERSHIP INTEREST; PHARMACY SERVICES.

(a) A pharmacy benefit manager that has an ownership interest either directly or indirectly, or through an affiliate or subsidiary, in a pharmacy must disclose to a plan sponsor that contracts with the pharmacy benefit manager any difference between the amount paid to that pharmacy and the amount charged to the plan sponsor.

(b) A pharmacy benefit manager or health carrier is prohibited from penalizing, requiring, or providing financial incentives, including variations in premiums, deductibles, co-payments, or coinsurance, to an enrollee as an incentive to use a retail pharmacy, mail order pharmacy, specialty pharmacy, or other network pharmacy provider in which a pharmacy benefit manager has an ownership interest or in which the pharmacy provider has an ownership interest in the pharmacy benefit manager.

(c) Paragraph (b) does not apply if the pharmacy benefit manager or health carrier offers an enrollee the same financial incentives for using a network retail pharmacy, mail order pharmacy, specialty pharmacy, or other network pharmacy in which the pharmacy benefit manager has no ownership interest and the network pharmacy has agreed to accept the same pricing terms, conditions, and requirements related to the cost of the prescription drug and the cost of dispensing the prescription drug that are in the agreement with a network pharmacy in which the pharmacy benefit manager has an ownership interest.

(d) A pharmacy benefit manager or health carrier is prohibited from imposing limits, including quantity limits or refill frequency limits, on an enrollee's access to medication that differ based solely on whether the health carrier or pharmacy benefit manager has an ownership interest in a pharmacy or the pharmacy has an ownership interest in the pharmacy benefit manager.

(e) Nothing in paragraph (d) shall be construed to prohibit a pharmacy benefit manager from imposing different limits, including quantity limits or refill frequency limits on an enrollee's access to medication based on whether the enrollee uses a mail order pharmacy or retail pharmacy so long as the enrollee has the option to use a mail order pharmacy or retail pharmacy with the same limits imposed in which the pharmacy benefit manager or health carrier does not have an ownership interest.

(f) A pharmacy benefit manager or health carrier must not prohibit an entity authorized to participate in the federal 340B Drug Pricing Program under section 340B of the Public Health Service Act, United States Code, title 42, chapter 6A, or a pharmacy under contract with such an entity to provide pharmacy services from participating in the pharmacy benefit manager's or health carrier's provider network. A pharmacy benefit manager or health carrier must not reimburse an entity or a pharmacy under contract with such an entity participating in the federal 340B Drug Pricing Program differently than other similarly situated pharmacies. A pharmacy benefit manager that contracts with a managed care plan or county-based purchasing plan under contract with the commissioner of human services under chapter 256B or 256L must comply with this paragraph only if the entity or contracted pharmacy can identify all claims eligible for 340B drugs at the time of initial claims submission at the point of sale. This paragraph does not preclude a pharmacy benefit manager that contracts with a managed care plan or county-based purchasing plan under contract with the commissioner of human services under chapter 256B or 256L from reimbursing an entity or pharmacy identified in this paragraph at a lower rate for any prescription drug purchased by the entity or pharmacy through the federal 340B Drug Pricing Program.

History: 2021 c 39 s 7.

Commented [GB52]: This needs to be done on a claim by claim basis and not in the aggregate. A plan sponsor deserves the right to see ANY markup on a claim, and especially so on generics and specialty drugs, where the biggest spread pricing appears to be occurring.

Commented [GB53]: This language will allow a PBM to “sub-contract” with another PBM not falling into the above language. Language should be simplified and state that no PBM may coerce or require any patients to use any mail order pharmacy or preferred pharmacy outside of that patient’s local pharmacy with any preferential copay or incentive.

Commented [GB54]: This is particularly common today with days’ supply limitations or the number of fills a patient may obtain locally before being forced to either a mail order pharmacy or an owned/affiliated pharmacy of the PBM.

Commented [GB55]: Paragraph (e) is not needed with paragraph (d) and the language changes offered. If paragraph (e) remains in place, then language needs to be added saying that a patient may not be coerced by differing copays between a local pharmacy or the mail order pharmacy.

Commented [GB56]: I am confused by paragraph (f). I am not sure what it says. Multiple states have passed legislation forbidding PBMs to interfere with contracts between a pharmacy and the contracted HRSA entity as many PBMs are reducing rates for those contracted pharmacies to their own network rates, yet the contracts are between the contracted entity and the pharmacy(ies). PBMs have no right to get in between those contracts and that language should be made clear in 62W.
62W.075 THERAPEUTIC ALTERNATIVE PRESCRIPTION DRUG.

A pharmacy benefit manager or health carrier must not require, or demonstrate a preference for, a pharmacy to dispense a therapeutically equivalent or therapeutically alternative drug that costs the enrollee more out-of-pocket than the prescribed drug, unless the substitution is made for medical reasons that benefit the patient. Before a substitution is made under this section, the pharmacy must obtain approval from the prescribing practitioner and must inform the enrollee of the reason for the substitution.

History: 1W93, 39 § 8.

Commented (GB57): This is an extremely common practice of PBMs everywhere and costs plan sponsors, patients, and taxpayers hundreds of millions of dollars across the country. Specify specifically DAW 9 and negative formularies removing less costly drugs for more expensive alternatives is expressly forbidden in Minnesota.
62W.076 SPECIALTY PHARMACY.

A pharmacy benefit manager that contracts with a specialty pharmacy must disclose to an enrollee, upon request, the enrollee's out-of-pocket costs at the specialty pharmacy for the prescription drug referenced by the enrollee and the enrollee's out-of-pocket cost at a network retail pharmacy that is identified by the enrollee that is within the enrollee's health plan network.

History: 2019 c 39 s 2

Commented [GB58]: Eliminate the words “upon request” and make this mandatory for all PBM. Nobody ever thinks to ask this question, especially a patient. Open this up for more transparency.
62W.077 PREFERRED NETWORK.

A pharmacy benefit manager that uses a preferred network of pharmacies must disclose to an enrollee upon request the enrollee's out-of-pocket cost at the preferred pharmacy for the prescription drug referenced by the enrollee and the enrollee's out-of-pocket cost at a nonpreferred pharmacy identified by the enrollee that is within the enrollee's health plan network.

History: 1999 c 138 s 63

Commented [GB59]: This needs to be done during the re-enrollment period and not after the fact when it is too late for a patient to move to a better plan or one with more transparency.
62W.08 MAXIMUM ALLOWABLE COST PRICING.

(a) With respect to each contract and contract renewal between a pharmacy benefit manager and a pharmacy, the pharmacy benefits manager must:

1. provide to the pharmacy, at the beginning of each contract and contract renewal, the sources utilized to determine the maximum allowable cost pricing of the pharmacy benefit manager;

2. update any maximum allowable cost price list at least every seven business days, noting any price changes from the previous list, and provide a means by which network pharmacies may promptly review current prices in an electronic, print, or telephonic format within one business day at no cost to the pharmacy;

3. maintain a procedure to eliminate products from the list of drugs subject to maximum allowable cost pricing in a timely manner in order to remain consistent with changes in the marketplace;

4. ensure that the maximum allowable cost prices are not set below sources utilized by the pharmacy benefits manager; and

5. upon request of a network pharmacy, disclose the sources utilized for setting maximum allowable cost price rates on each maximum allowable cost price list included under the contract and identify each maximum allowable cost price list that applies to the network pharmacy. A pharmacy benefit manager must make the list of the maximum allowable costs available to a contracted pharmacy in a format that is readily accessible and usable to the network pharmacy.

(b) A pharmacy benefit manager must not place a prescription drug on a maximum allowable cost list unless the drug is available for purchase by pharmacies in this state from a national or regional drug wholesaler and is not obsolete.

(c) Each contract between a pharmacy benefit manager and a pharmacy must include a process to appeal, investigate, and resolve disputes regarding maximum allowable cost pricing that includes:

1. a 15-business-day limit on the right to appeal following the initial claim;

2. a requirement that the appeal be investigated and resolved within seven business days after the appeal is received; and

3. a requirement that a pharmacy benefit manager provide a reason for any appeal denial and identify the national drug code of a drug that may be purchased by the pharmacy at a price at or below the maximum allowable cost price as determined by the pharmacy benefit manager.

(d) If an appeal is upheld, the pharmacy benefit manager must make an adjustment to the maximum allowable cost price no later than one business day after the date of determination. The pharmacy benefit manager must make the price adjustment applicable to all similarly situated network pharmacy providers as defined by the plan sponsor.

History: 2019 c. 39 s. 1
62W.09 PHARMACY AUDITS.

Subdivision 1. Procedure and process for conducting and reporting an audit. (a) Unless otherwise prohibited by federal requirements or regulations, any entity conducting a pharmacy audit must follow the following procedures:

1. a pharmacy must be given notice 14 days before an initial on-site audit is conducted;
2. an audit that involves clinical or professional judgment must be conducted by or in consultation with a licensed pharmacist; and
3. each pharmacy shall be audited under the same standards and parameters as other similarly situated pharmacies.

(b) Unless otherwise prohibited by federal requirements or regulations, for any entity conducting a pharmacy audit the following items apply:

1. the period covered by the audit may not exceed 24 months from the date that the claim was submitted to or adjudicated by the entity, unless a longer period is required under state or federal law;
2. if an entity uses random sampling as a method for selecting a set of claims for examination, the sample size must be appropriate for a statistically reliable sample. Notwithstanding section 192.12, the auditing entity shall provide the pharmacy a masked list that provides a prescription number or date range that the auditing entity is seeking to audit;
3. an on-site audit may not take place during the first five business days of the month unless consented to by the pharmacy;
4. auditors may not enter the pharmacy area unless escorted where patient-specific information is available and to the extent possible must be out of sight and hearing range of the pharmacy customers;
5. any recoupment will not be deducted against future remittances until after the appeals process and both parties have received the results of the final audit;
6. a pharmacy benefit manager may not require information to be written on a prescription unless the information is required to be written on the prescription by state or federal law. Recoupment may be assessed for items not written on the prescription if:
   i. additional information is required in the provider manual; or
   ii. the information is required by the Food and Drug Administration (FDA); or
   iii. the information is required by the drug manufacturer's product safety program; and
   iv. the information in item (i), (ii), or (iii) is not readily available for the auditor at the time of the audit; and
7. the auditing company or agent may not receive payment based on a percentage of the amount recovered. This section does not apply if the auditor has absolutely no reason to ever be within the confines of the pharmacy proper. I used to set up a table either in the break room or at least 20 feet away from the pharmacy and bring the auditor files that person needed to see. That should be standard discipline in MN.

Subd. 2. Requirement for recoupment or chargeback. For recoupment or chargeback, the following criteria apply:

1. audit parameters must consider consumer-oriented parameters based on manufacturer listings;
2. a pharmacy's usual and customary price for compounded medications is considered the reimbursable cost unless the pricing methodology is outlined in the pharmacy provider contract;
3. a finding of overpayment or underpayment must be based on the actual overpayment or underpayment and not a projection based on the number of patients served having a similar diagnosis or on the number of similar orders or refills for similar drugs;
4. the entity conducting the audit shall not use extrapolation in calculating the recoupment or penalties for audits unless required by state or federal law or regulations;
5. calculations of overpayments must not include dispensing fees unless a prescription was not actually dispensed, the prescriber denied authorization, the prescription dispensed was a medication error by the pharmacy, or the identified overpayment is solely based on an extra dispensing fee;
Subd. 3. Documentation. (a) To validate the pharmacy record and delivery, the pharmacy may use authentic and verifiable statements or records including medication administration records of a nursing home, assisted living facility, hospital, physician, or other authorized practitioner or additional audit documentation parameters located in the provider manual.

(b) Any legal prescription that meets the requirements in this chapter may be used to validate claims in connection with prescriptions, refills, or changes in prescriptions, including medication administration records, faxes, e-prescriptions, or documented telephone calls from the prescriber or the prescriber's agents.

Subd. 4. Appeals process. The entity conducting the audit must establish a written appeals process which must include appeals of preliminary reports and final reports.

Subd. 5. Audit information and reports. (a) A preliminary audit report must be delivered to the pharmacy within 60 days after the conclusion of the audit.

(b) A pharmacy must be allowed at least 45 days following receipt of the preliminary audit to provide documentation to address any discrepancy found in the audit.

(c) A final audit report must be delivered to the pharmacy within 120 days after receipt of the preliminary audit report or final appeal, whichever is later.

(d) An entity shall remit any money due to a pharmacy or pharmacist as a result of an underpayment of a claim within 45 days after the appeals process has been exhausted and the final audit report has been issued.

Subd. 6. Disclosure to plan sponsor. Where contractually required, an auditing entity must provide a copy to the plan sponsor of its claims that were included in the audit, and any recouped money shall be returned to the plan sponsor.

Subd. 7. Applicability of other laws and regulations. This section does not apply to any investigative audit that involves suspected fraud, willful misrepresentation, abuse, or any audit completed by Minnesota health care programs.

Subd. 8. Definitions. For purposes of this section, "entity" means a pharmacy benefit manager or any person or organization that represents a pharmacy benefit manager.

History: 20/A  c. 39 s 12

Commented [GB69]: This should be reworded to say no recoupments may be made unless there was harm to the patient or over billed cost to the plan sponsor. An honest error with no malicious intent is what PBMs look for and use that as an excuse to recoup funds from a pharmacy.

Commented [GB70]: Also to be included should be signature logs for patients during COVID-19 where deliveries were made or where curb side services were rendered for those patients. Pharmacies were told by PBMs to make that notation on the signature logs. We should not let them forget that or they will look for recoupments.

Commented [GB71]: How will this be regulated by Commerce?
62W.10 SYNCHRONIZATION.

(a) For purposes of this section, “synchronization” means the coordination of prescription drug refills for a patient taking two or more medications for one or more chronic conditions, to allow the patient’s medications to be refilled on the same schedule for a given period of time.

(b) A contract between a pharmacy benefit manager and a pharmacy must allow for synchronization of prescription drug refills for a patient on at least one occasion per year, if the following criteria are met:

1. The prescription drugs are covered under the patient’s health plan or have been approved by a formulary exceptions process;
2. The prescription drugs are maintenance medications as defined by the health plan and have one or more refills available at the time of synchronization;
3. The prescription drugs are not Schedule II, III, or IV controlled substances;
4. The patient meets all utilization management criteria relevant to the prescription drug at the time of synchronization;
5. The prescription drugs are of a formulation that can be safely split into short-fill periods to achieve synchronization; and
6. The prescription drugs do not have special handling or sourcing needs that require a single, designated pharmacy to fill or refill the prescription.

(c) When necessary to permit synchronization, the pharmacy benefit manager must apply a prorated, daily patient cost-sharing rate to any prescription drug dispensed by a pharmacy under this section. The dispensing fee must not be prorated, and all dispensing fees shall be based on the number of prescriptions filled or refilled.

(d) Synchronization may be requested by the patient or by the patient’s parent or legal guardian if the patient is under the age of 18 or is incapacitated as defined in section 544.5-02, or by the patient’s health care agent as defined in chapter 145C.

History: 2019 c 39 s 13
62W.11 GAG CLAUSE PROHIBITION.

(a) No contract between a pharmacy benefit manager or health carrier and a pharmacy or pharmacist shall prohibit, restrict, or penalize a pharmacy or pharmacist from disclosing to an enrollee any health care information that the pharmacy or pharmacist deems appropriate regarding the nature of treatment; the risks or alternatives; the availability of alternative therapies, consultations, or tests; the decision of utilization reviewers or similar persons to authorize or deny services; the process that is used to authorize or deny health care services or benefits; or information on financial incentives and structures used by the health carrier or pharmacy benefit manager.

(b) A pharmacy or pharmacist must provide to an enrollee information regarding the enrollee’s total cost for each prescription drug dispensed where part or all of the cost of the prescription is being paid or reimbursed by the employer-sponsored plan or by a health carrier or pharmacy benefit manager, in accordance with section 11.11, subdivision 1.

(c) A pharmacy benefit manager or health carrier must not prohibit a pharmacist or pharmacy from discussing information regarding the total cost for pharmacy services for a prescription drug, including the patient’s co-payment amount and the pharmacy’s own usual and customary price of the prescription.

(d) A pharmacy benefit manager or health carrier must not prohibit a pharmacist or pharmacy from discussing the availability of any therapeutically equivalent alternative prescription drugs or alternative methods for purchasing the prescription drug, including but not limited to paying out-of-pocket the pharmacy’s usual and customary price when that amount is less expensive to the enrollee than the amount the enrollee is required to pay for the prescription drug under the enrollee’s health plan.

History: 2019 c. 39 s 11

Commented [GB73]: The pharmacist may also show the patient where a cash plan may be more affordable for that patient v. the copay as adjudicated through the PBM.
62W.11 GAG CLAUSE PROHIBITION.

(a) No contract between a pharmacy benefit manager or health carrier and a pharmacy or pharmacist shall prohibit, restrict, or penalize a pharmacy or pharmacist from disclosing to an enrollee any health care information that the pharmacy or pharmacist deems appropriate regarding the nature of treatment; the risks or alternatives; the availability of alternative therapies, consultations, or tests; the decision of utilization reviewers or similar persons to authorize or deny services; the process that is used to authorize or deny health care services or benefits; or information on financial incentives and structures used by the health carrier or pharmacy benefit manager.

(b) A pharmacy or pharmacist must provide to an enrollee information regarding the enrollee's total cost for each prescription drug dispensed where part or all of the cost of the prescription is being paid or reimbursed by the employer-sponsored plan or by a health carrier or pharmacy benefit manager, in accordance with section 15214.

(c) A pharmacy benefit manager or health carrier must not prohibit a pharmacist or pharmacy from discussing information regarding the total cost for pharmacy services for a prescription drug, including the patient's co-payment amount and the pharmacy's own usual and customary price of the prescription.

(d) A pharmacy benefit manager or health carrier must not prohibit a pharmacist or pharmacy from discussing the availability of any therapeutically equivalent alternative prescription drugs or alternative methods for purchasing the prescription drug, including but not limited to paying out-of-pocket the pharmacy's usual and customary price when that amount is less expensive to the enrollee than the amount the enrollee is required to pay for the prescription drug under the enrollee's health plan.

History: 2019 c 39 s 1
No pharmacy benefit manager or health carrier shall require an enrollee to make a payment at the point of sale for a covered prescription drug in an amount greater than the lesser of:

1. the applicable co-payment for the prescription drug;
2. the allowable claim amount for the prescription drug; or
3. the amount an enrollee would pay for the prescription drug if the enrollee purchased the prescription drug without using a health plan or any other source of prescription drug benefits or discounts.

History: 2017 c 59 s 15

Commented [GB74]: Language needs to be written that also “overpays” a pharmacy for a claim. I have examples of where PBMs have grossly overpaid a pharmacy for an inexpensive claim (charged the patient a normal copay) but then later come back and take a huge recoupment back from the pharmacy. To me this is done by a PBM to show a plan sponsor of the costs for a particular plan, patient, or group of patients to be able to get a higher PMPM payment from the plan sponsor for an upcoming year. PBMs need to be asked WHY that occurs. I have specific examples I can share upon request.

Commented [GB75]:
62W.13 RETROACTIVE ADJUSTMENTS.
No pharmacy benefit manager shall retroactively adjust a claim for reimbursement submitted by a pharmacy for a prescription drug, unless the adjustment is a result of a:

(1) pharmacy audit conducted in accordance with section 62W.09; or
(2) technical billing error.

History: 2019 c 39 s/t

Commented [GB76]: This appears to include DIR fees which are most often taken retrospectively within 90 to 180 days after a claim has been adjudicated. That said, Prime Therapeutics began charging a “rebate” upfront at the point of a fill. Humana also does the same on some plans. Language needs to be written to avoid that as well.
62W.14 PROMPT FILLING FOR SPECIALTY DRUGS.

(a) A health carrier or pharmacy benefit manager that requires or provides financial incentives for enrollees to use a mail order pharmacy to fill a prescription for a specialty drug must ensure through contract and other means that the mail order pharmacy dispenses the prescription drug to the enrollee in a timely manner, such that the enrollee receives the filled prescription within seven business days of the date of transmittal to the mail order pharmacy. The health carrier or pharmacy benefit manager may grant to a mail order pharmacy an exemption from this requirement if the mail order pharmacy can document that the specialty drug was out of stock due to a delay in shipment by the specialty drug manufacturer or wholesaler. If an exemption is granted, the health carrier or pharmacy benefit manager must notify the enrollee within 24 hours of granting the exemption and, if medically necessary, must provide the enrollee with an emergency supply of the specialty drug.

(b) For purposes of this section, “health carrier” includes managed care plans and county-based purchasing plans participating in a public health care program under chapter 256B or 256L, and integrated health partnerships established under section 256B.071.

History: 1019 cJC 477

Commented [GB77]: How will this be enforced and tracked and what options are there for the patient in the event deliveries of these specialty drugs are late?

Commented [GB78]: Of key importance with specialty drugs is to get line by line detail from plan sponsors showing what the plan was charged for that specialty drug and then find out further from the pharmacy what that pharmacy was reimbursed by the PBM for that same prescription. Spread pricing runs rampant with specialty drugs administered by PBMs.
Spread pricing needs to be done on a line by line (script by script) basis so the state is able to gauge how much spread fees really are and how they differ between generic drugs, brand name drugs, and specialty drugs – something that will open up everyone’s eyes. It is not uncommon for spread pricing on specialty drugs to be in the thousands of dollars per prescription. I have one example from North Dakota Medicaid (before the state went 100% fee for service) where the PBM had spread pricing of about $160,000 on one single drug for a cancer patient for nine months (i.e., nearly $18K per month) and I have verified that with the Department of Human Services in Bismarck. I have all the details and the PBM involved and am happy to share. The Commerce Commissioner’s office needs to have full knowledge of how PBMs operate in the shadows and prefer it to stay that way. We have the opportunity with this language to shed some light on PBM transgressions!

Won’t PBMs then poo-poo the need for a report to plan sponsors and downplay those reports? It should be a requirement and no plan sponsor should be required to sign an NDA. It must become an expectation by the plan sponsor of the PBM to supply that information – part of being a “manager” of benefits!

To include any and all remunerations, whether prospective, retrospective, or as a payment in kind that is intended to reduce the PBMs’ cost of drugs; must also include any/all rebate aggregator rebates/expenses by supplying a full report from each aggregator.