



August 25, 2021

Legislative Reference Library
645 State Office Building
100 Rev. Dr. Martin Luther King Jr. Blvd.
St. Paul, Minnesota 55155

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, OAH docket number 21-9009-37561

Dear Librarian:

The Department of Commerce intends to adopt rules that clarify provisions of Minnesota Statutes, 62W related to licensure and regulation of pharmacy benefit managers.

We have published a Notice of Intent to Adopt Rules in the State Register on August 16, 2021 and have mailed the Notice under Minnesota Statutes Section 14.14.

As required by Minnesota Statutes, Section 14.116, the Commerce Department is sending you a copy of the notice and the Statement of Need and Reasonableness. For your information, we are also enclosing a copy of the proposed rules.

If you have any questions about these rules, you can sent an email at PBM.Licensing@state.mn.us or may contact Galen Benshoof at galen.g.benshoof@state.mn.us or Andrew Kleinendorst at andrew.kleinendorst@state.mn.us.

Sincerely,

A handwritten signature in blue ink, appearing to read 'Julia Dreier', written over a light blue horizontal line.

Julia Dreier
Deputy Commissioner

Enclosures: Notice of Intent to Adopt Rules
Statement of Need and Reasonableness
Proposed Rules

CC: Commissioner Grace Arnold

Minnesota Department of Commerce

Insurance Division

NOTICE OF HEARING

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

Overview. This notice is the Minnesota Department of Commerce's (Commerce) legal notice of its intent to adopt new rules following a hearing. The purpose of these rules is to provide industry and other stakeholders with clarity and predictability in the enforcement of the PBM law passed in 2019.

This notice provides you the opportunity to submit your comments on this rule to the Administrative Law Judge (ALJ) either orally at the hearing or in writing at any time before the close of the hearing record. The **Subject of Rules** section provides further description of these proposed rules. If the proposed rules affect you in any way, the Commerce encourages you to participate in the rulemaking process.

View the **Alternative Format/Accommodation** and **Commerce Contact Person** sections of this notice for information on requesting this document in an alternative format.

Public Hearing. The Department of Commerce intends to adopt rules after a public hearing following the procedures in the rules of the Office of Administrative Hearings, *Minnesota Rules*, parts 1400.2200 to 1400.2240, and the Administrative Procedure Act, *Minnesota Statutes*, sections 14.131 to 14.20. On Monday, September 20, 2021, starting at 9:00am CST and continuing until 5:00pm CST, the agency will hold a remote public hearing on the above-named rules, for video and audio connection to the virtual hearing, join through an internet connection, such as with a computer or tablet:

Enter: <https://minnesota.webex.com>

Meeting number: 146 559 7572

Meeting password: PyPHa54thb7

For audio connection only, join the hearing by phone:

Call: 1-415-655-0003

Access code: 146 559 7572

The agency will schedule additional days of hearing if necessary. All interested or affected persons will have an opportunity to participate by submitting either oral or written data, statements, or arguments. Statements may be submitted without appearing at the hearing.

Additional information regarding the hearings and the rules being proposed is provided at <http://mn.gov/commerce/policy-data-reports/rulemaking/index.jsp?id=17-412841>. Hearing exhibits will also be posted to this website before the hearing.

Administrative Law Judge. Administrative Law Judge Kimberly Middendorf will conduct the hearing. The rule hearing procedure is governed by *Minnesota Statutes*, sections 14.131 to 14.20, and by the rules of the Office of Administrative Hearings, *Minnesota Rules*, parts 1400.2000 to 1400.2240. You should direct questions about the rule hearing procedure to the administrative law judge. Judge Middendorf's Legal Assistant Michelle Severson can be reached at the Office of Administrative Hearings, 600 North Robert Street, P.O. Box 64620, Saint Paul, Minnesota 55164-0620, telephone 651-361-7900 and fax 651-539-0310 or denise.collins@state.mn.us.

Subject of Rules, Statutory Authority, and Agency Contact Person. The proposed rules would be a new chapter and are about the licensure and regulation of PBMs. The proposed rules are authorized by Section 20 of Minnesota Session Laws – 2019, Regular Session, Chapter 39 (codified in Minnesota Statutes, chapter 62W). The rules provide processes, forms and procedures for initial PBM licensure, license renewal, PBM data reporting, PBM business practices, as well as enforcement of the statute by Commerce.

A copy of the proposed rules is published in the *State Register* and attached to this notice as mailed and is available at the agency's website at <http://mn.gov/commerce/policy-data-reports/rulemaking/index.jsp?id=17-412841>. A print copy is available for the cost of reproduction by contacting the agency contact person named below.

A copy of Statement of Need and Reasonableness (SONAR) is available at the agency's website at <http://mn.gov/commerce/policy-data-reports/rulemaking/index.jsp?id=17-412841>. The SONAR summarizes the justification for the proposed rules, including a description of who will be affected by the proposed rules and an estimate of the probable cost of the proposed rules. A print copy is available for the cost of reproduction by contacting the agency contact person named below.

The agency contact person is: Andrew Kleinendorst (andrew.kleinendorst@state.mn.us), 651-539-1500; 85 7th Place East, Suite 280, Saint Paul, MN 55101.

If you wish to be placed on Commerce's rulemaking interested party mailing list, please contact the agency contact person.

Public Comment. You and all interested or affected persons, including representatives of associations and other interested groups, will have an opportunity to participate. The administrative law judge will accept your views either orally at the hearing or in writing at any time before the close of the hearing record. Please submit written comments **to the administrative law judge via the Office of Administrative Hearings Rulemaking eComments website** <https://minnesotaoah.granicusideas.com/discussions>. If it is not possible for you to use the eComments website, you may submit your written comments in person, by U.S. mail, or by fax to the judge using the contact information contained in the Administrative Law Judge section of this notice. Any comments or materials that you present or submit must relate to the proposed rules.

After the hearing, you may submit written comments to the administrative law judge using the eComments website (the preferred method) or by mail, fax, or personal delivery. These comments must be submitted within five working days after the hearing date. At the hearing, the administrative law judge may order this five-day comment period be extended for no more than 20 calendar days.

After the comment period ends, there is an additional five-working-day rebuttal period during which Commerce and any interested person may respond in writing to any new information submitted. No one may submit additional evidence during the five-day rebuttal period.

All comments and responses must be submitted no later than 4:30 p.m. on the due date. All comments or responses received are public and will be available for review at <https://minnesotaoah.granicusideas.com/discussions>.

You may learn more about the OAH Rulemaking eComments website, including step-by-step instructions and frequently asked questions at <https://mn.gov/oah/forms-and-filing/ecomments/>. Questions about submitting comments via the OAH Rulemaking eComments website should be directed to the OAH at 651-361-7900.

Please note that comments regarding the Commerce Department's proposal must be sent to the ALJ. Comments sent to Commerce alone will not be part of the rulemaking record. Comments submitted after the close of the comment period will not be accepted or considered part of the record.

Modifications. The agency may modify the proposed rules as a result of the rule hearing process. It must support modifications by data and views presented during the rule hearing process. The adopted rules may not be substantially different than these proposed rules, unless the agency follows the procedure under *Minnesota Rules*, part 1400.2110. If the proposed rules affect you in any way, the agency encourages you to participate.

Alternative Format/Accommodation. Upon request, this information can be made available in an alternative format, such as large print, braille, or audio. To make such a request or if you need an accommodation to make this hearing accessible, please contact the agency contact person at the address or telephone number listed above.

Adoption Procedure after the Hearing. After the close of the hearing record, the administrative law judge will issue a report on the proposed rules. You may ask to be notified of the date when the judge's report will become available and can make this request at the hearing or in writing to the administrative law judge. You may also ask to be notified of the date that the agency adopts the rules and files them with the Secretary of State or ask to register with the agency to receive notice of future rule proceedings. You may make these requests at the hearing or in writing to the agency contact person stated above.

Lobbyist Registration. *Minnesota Statutes*, chapter 10A, requires each lobbyist to register with the State Campaign Finance and Public Disclosure Board. You should direct questions regarding this requirement to the Campaign Finance and Public Disclosure Board at:

Suite #190, Centennial Building, 658 Cedar Street, St. Paul, Minnesota 55155, telephone (651) 539-1180 or 1-800-657-3889.

Order. I order that the rulemaking hearing be held at the date, time, and location listed above.

8/02/2021

Date



Grace Arnold, Commissioner
Minnesota Department of Commerce



**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: R-
04625.**

STATEMENT OF NEED AND REASONABLENESS

Insurance Division

July 2021

General information:

1) Availability: The State Register notice, this Statement of Need and Reasonableness (SONAR), and the proposed rule will be available during the public comment period on the Department's rulemaking website: <http://mn.gov/commerce/policy-data-reports/rulemaking/index.jsp?id=17-412841>.

2) View older rule records at: Minnesota Rule Statutes
<https://www.revisor.mn.gov/rules/status/>.

3) Department contact for information, documents, or alternative formats: Upon request, this Statement of Need and Reasonableness can be made available in an alternative format, such as large print, braille, or audio. To make a request, contact:

Andrew Kleinendorst
Department of Commerce
85 7th Place East
Suite 280
Saint Paul, MN 55101
Email: andrew.kleinendorst@state.mn.us
Telephone 651-539-1500.

CONTENTS

| | |
|---|-----------|
| Introduction and Scope | 1 |
| Introduction | 1 |
| Scope of the proposed rules | 2 |
| Public participation and stakeholder involvement | 2 |
| Statutory authority | 6 |
| Statement of General Need | 6 |
| Reasonableness of the Rules | 8 |
| General Reasonableness | 8 |
| Rule-by-Rule Analysis | 8 |
| 2737.0100 DEFINITIONS..... | 8 |
| 2737.0200 AUTHORITY, SCOPE, AND PURPOSE..... | 10 |
| 2737.0300 GOVERNMENT PROGRAMS..... | 10 |
| 2737.0400 BUSINESS LICENSE REQUIREMENTS (INITIAL APPLICATION)..... | 10 |
| 2737.0500 BUSINESS LICENSE REQUIREMENTS (RENEWAL APPLICATION) | 12 |
| 2737.0600 REVIEW BY COMMISSIONER | 13 |
| 2737.0700 ENFORCEMENT BY COMMISSIONER | 14 |
| 2737.0800 ADEQUATE NETWORK..... | 14 |
| 2737.0900 ACCESSIBLE NETWORK..... | 15 |
| 2737.1000 TRANSPARENCY REPORTS TO PLAN SPONSORS..... | 16 |
| 2737.1100 TRANSPARENCY REPORTS TO THE COMMISSIONER | 17 |
| 2737.1200 PHARMACY OWNERSHIP INTEREST | 18 |
| 2737.1300 SECTION 340B PARTICIPANTS | 19 |
| 2737.1400 OUT-OF-POCKET COST COMPARISONS | 19 |
| 2737.1500 MAXIMUM ALLOWABLE COST PRICING | 20 |
| 2737.1600 PHARMACY AUDITS..... | 21 |
| 2737.1700 ALLOWABLE CLAM AMOUNT..... | 21 |
| 2737.1800 RETROACTIVE ADJUSTMENTS | 21 |
| Regulatory analysis | 22 |
| Classes Affected | 22 |
| Agency Costs | 23 |
| Less Costly/Intrusive Methods | 23 |
| Alternatives Considered | 23 |
| Cost to Comply | 24 |
| Cost of Non-Adoption of Rules..... | 24 |
| Differences with Federal Regulations | 24 |
| <i>ERISA Preemption Generally</i> | 25 |
| <i>ERISA Preemption of PBM Regulations</i> | 26 |
| <i>Rutledge v. PCMA</i> | 29 |
| Cumulative Effect | 30 |
| Statutory Requirements | 30 |
| Notice Plan | 30 |
| Performance-based rules | 33 |
| Consult with MMB on local government impact | 33 |
| Impact on local government ordinances and rules..... | 33 |
| Costs of complying for small business or city..... | 33 |

| | |
|--|-----------|
| Authors, witnesses and SONAR exhibits | 34 |
| Witnesses and other staff | 34 |
| SONAR exhibits..... | 34 |
| Conclusion | 34 |

Acronyms

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

Statement of Need and Reasonableness (SONAR)

Introduction and Scope

Introduction

The Minnesota Department of Commerce (“Commerce” or the “Department”) proposes a new rule to provide guidance on Pharmacy Benefit Manager (PBM) licensing, regulation, and transparency reporting (hereinafter the “PBM Law” or the “Act”).

PBMs have been around for roughly 50 years but have only recently found themselves the subject of regulation.¹ The PBM Law was passed during the 2019 Minnesota legislative session, adding Chapter 62W to Minnesota Statutes. The Act required all PBMs contracting with plan sponsors doing business in Minnesota to be licensed as of January 1, 2020. Prior to this law being enacted, PBMs doing business in Minnesota did not require specific licensure. Many PBMs, however, were licensed as Third Party Administrators (TPA) under Minnesota law. PBM licensure is separate and distinct from TPA licensure, and most entities meeting the PBM definition will maintain dual licensure.

The Minnesota law defines a PBM as an entity that performs any one of the following:

- Contracting directly or indirectly with pharmacies to provide prescription drugs to enrollees or other covered individuals;
- administering a prescription drug benefit;
- processing or paying pharmacy claims;
- creating or updating prescription drug formularies;
- making or assisting in making prior authorization determinations on prescription drugs;
- administering rebates on prescription drugs; or
- establishing a pharmacy network.

PBMs, as the name implies, manage the pharmacy benefits provided by health plans and plan sponsors. PBMs sit in the center of the system of prescription drug distribution in Minnesota, and the country. PBMs have contractual relationships with plan sponsors, drug manufacturers, and pharmacists. The PBM law regulates a number of those relationships:

¹ Peter Callaghan, How big an issue is the cost of prescription drugs? So big that the 2019 Minnesota Legislature actually managed to pass a bill addressing it, MINNPOST (May 17, 2019) <https://www.minnpost.com/state-government/2019/05/how-big-an-issue-is-the-cost-of-prescription-drugs-so-big-that-the-2019-minnesota-legislature-actually-managed-to-pass-a-bill-addressing-it/>.

PBM-Enrollee: The law requires that PBMs provide enrollees with quick and easy access to information about the cost of filling prescriptions at pharmacies that are both in and out of network (§§62W.076, 62W.077) and allowing greater choice by prohibiting self-dealing by PBMs in favoring pharmacies owned by the PBM over non-owned pharmacies (§62W.07).

PBM-Pharmacy: The PBM Law regulates the relationship between PBMs and pharmacies, by requiring, inter alia, that PBMs be transparent about pricing for multi-source drugs (i.e. those drugs where there is more than one brand of the same drug) (§62W.08), that PBMs adhere to specific procedures when auditing a pharmacy in its network (§62W.09), and prohibits PBMs from preventing pharmacists from disclosing certain cost information to enrollees (§62W.10).

PBM-Plan Sponsor: The Act includes provisions imposing a duty of good faith and fair dealing in the performance of PBMs' contracts with health carriers and plan sponsors (§62W.04) and requires PBMs to disclose to health carriers and plan sponsors certain information about its business practices (62W.06, subd. 1) (PBMs must make similar annual disclosures to Commerce (§62W.06, subd. 2)).

Additionally, the law places certain constraints on PBMs; namely, requiring a license to do business in Minnesota (§ 62W.03) and requiring adequate and accessible networks of pharmacies (62W.05). Commerce is required to license PBMs, and authorized specific enforcement powers for non-compliance. Initial requirements for licensure include the submission of an application to the Department of Commerce, accompanied by a non-refundable licensing fee of \$8,500. Applicants must provide general information about their business, including details about its structure, membership of boards or other governing bodies for the organization. The initial application requires the Department of Commerce to work with the Department of Health for the purposes of verifying network adequacy of the PBM applicant's pharmacy network. Requirements for network adequacy reporting are referenced by the Act as specified under Minnesota Statutes 2019, Section 62K.10.

Scope of the proposed rules

The proposed rules will establish a new chapter of Minnesota rules, chapter, 2737.

Public participation and stakeholder involvement

Consistent with the requirements of Minnesota Statutes, Chapter 14, and Minnesota Rules, Chapter 1400, Commerce sought out input and comments from the general public, stakeholders, and individuals directly impacted by the content of proposed rules. Consistent with The Minnesota Administrative Procedures Act (APA), Commerce published a request for comments in the Minnesota State Register, on Monday September 30, 2019. In order to increase accessibility and public feedback, Commerce maintained a website with information specifically for the PBM law's rulemaking process: <https://mn.gov/commerce/policy-data-reports/rulemaking/#/detail/appld/2/id/412841>.

During the rulemaking process, from September of 2019 through February of 2021, Commerce received fourteen communications from ten different sources. The authors included industry

organizations for PBMs, owners of small pharmacy chains, independent pharmacies, pharmacist consultants, practicing pharmacists, and community health systems. To interested parties that offered written feedback to department rulemaking staff, Commerce offered listening sessions so that such parties could more fully explain their comments and feedback. The feedback received during this initial comment period was considered and is reflected in the proposed rules.

Another way of reaching interested persons is through the formation of an advisory committee. Advisory committees are generally a collection of individuals with unique knowledge and skills that can be transferred to leadership in an organization or government to make informed decisions regarding a variety of topics. The purpose of an advisory committee is to have each member uniquely represent an area of expertise pertinent to the subject matter at hand.

Though not required to do so by law, Commerce chose to form an advisory opinion given the complex nature of the issues presented in the PBM Law, and the diverse set of constituencies that would be impacted by rulemaking. Moreover, Commerce determined that this step would increase the number of interested persons reached and aid the development of a reasonable set of proposed rules.

In early 2020, Commerce formed a rulemaking advisory committee to provide input and advice on the Pharmacy Benefit Manager (PBM) Licensure and Regulation Act. The committee was a limited duration standing committee commissioned by Commerce for the purposes of advising on rule development. The work of the Advisory Committee was limited to advising on matters directly concerning potential areas of rulemaking for PBM licensure and regulation established under Minnesota Statutes 2019, Chapter 62W. Committee members came from varied backgrounds, as detailed in Table 1.

Table 1. Advisory Committee Members

| Name | Organization | Title/Role | Industry Represented |
|-----------------------------|----------------------------------|--|----------------------|
| Andrew R Behm, PharmD, BCGP | Express Scripts | Vice President, Office of Clinical Evaluation and Policy | PBM |
| Michael Dewberry | Blue Cross Blue Shield Minnesota | Pharmacy & Drug Management, PBM Business Consultant | Insurance/PBM |

SONAR – INSURANCE DIVISION

| | | | |
|--|---|--|-------------------|
| Richard Bruzek, RPh, PharmD | | Independent Consultant | Pharmacy |
| Stacey Drentlaw, JD | Taft Stettinius & Hollister LLP | Attorney | Legal |
| Nathaniel Gansen | Medica | | Insurance |
| Margaret Kasting | SFM Mutual Insurance Company | Vice President Claims | Insurance |
| Amy J. Monahan, JD | University of Minnesota Law School | Melvin C. Steen Professor and Associate Dean for Research & Planning | Academic |
| Alyssa Poehls | ClearScript | Compliance and Licensing Manager | PBM |
| James Read, PhD | College of Saint Benedict/Saint John's University | Professor | Academic |
| Stephen W. Schondelmeyer, BS, PharmD, MA, PhD, FAPhA | University of Minnesota, College of Pharmacy | Professor of Pharmaceutical Management & Economics | Academic/Pharmacy |
| Laura Schwartzwald, RPh | GuidePoint Pharmacy | Pharmacist | Pharmacy |
| Steven Simenson, BPharm, FAPhA, FACA, FACVP, DPNAP | Goodrich Pharmacy | Pharmacist | Pharmacy |
| Jay A. Warmuth, JD | Faegre Drinker Biddle | Attorney | Legal |

| | | | |
|------------------------|--------------|----------|-------|
| | & Reath LLP | | |
| Stuart T. Williams, JD | Henson Efron | Attorney | Legal |

The committee held its first meeting in February of 2020, to discuss possible rules to support the new PBM Law. The schedule anticipated that the committee would meet about once a month to discuss specific areas of the statute for the next six months. After the committee's meeting in early March, the COVID-19 pandemic required changes to the format and schedule of the committee's work. The Committee held additional meetings in May, June and July using remote meeting software. Each of these meetings covered specific areas of the law, as described in Table 2.

Table 2. Advisory Committee Topics

| Date | Topics | Statutory Corollary |
|--------------------|---|---|
| February 12, 2020 | Introductions and Process | §62W.01, <i>et seq.</i> |
| March 5, 2020 | Transparency reporting | §62W.06 |
| May 13, 2020 | Transparency reporting ² | §62W.06 |
| June 11, 2020 | License to do business; business practices; network adequacy | §§62W.03, 62W.04, 62W.05 |
| July 9, 2020 | Pharmacy ownership; therapeutic alternatives; specialty pharmacy; preferred networks; MAC; audits, synchronization, gag clause, point of sale, retroactive adjustments, prompt filing | §§62W.07, 62W.075, 62W.076, 62W.077, 62W.08, 62W.09, 62W.10, 62W.11, 62W.12, 62W.13, 62W.14 |
| September 10, 2020 | definitions/wrap up | §62W.01, <i>et seq.</i> |

After reviewing the feedback from each meeting, as well as written comments, the committee held a final meeting in September 2020, to review the entirety of the statute with an eye

² Recognizing the difficulty with adjusting to new formats, as well as, the extensive and robust discussion on the topic, the Advisory Committee revisited the transparency reporting topic at its first virtual meeting.

towards areas that would benefit from rulemaking. Commerce made the decision to make every meeting, both those hosted in person and virtually, open to the public. Commerce made available the materials shared with committee to the public as well. Agendas were sent in advance of each meeting to the list of distribution list of interested parties maintained by Commerce. For those meetings hosted virtually via WebEx, Commerce sent the log-in information to the interested parties list as well. At the close of each meeting, any member of the public who wished to provide commentary or feedback was presented the opportunity to be heard.

Statutory authority

Section 20 of Minnesota Session Laws – 2019, Regular Session, Chapter 39 explicitly provides that the Commissioner of Commerce may adopt permanent rules for:

- license application and renewal requirements
- forms
- procedures
- network adequacy, and
- reporting procedures and compliance

Based on Section 20, if the commissioner does not adopt rules by January 1, 2022, rulemaking authority is repealed. Section 20 also states that the commissioner cannot adopt rules to implement Minnesota Statutes, chapter 62W under any other rulemaking authority. The rulemaking authority provided to the Department is explicitly not continuing authority to amend or repeal rules. Under section 20, the Department’s typical rulemaking authority, which is Minnesota Statutes, section 14.125, is not available for any additional rulemaking after this rule’s adoption. Future rulemaking would require future legislated authority.

Statement of General Need

The Minnesota APA requires Commerce to explain the facts establishing need for the proposed rulemaking. Commerce finds that adoption of rules is needed and reasonable, since certain sections of Minnesota Statutes, chapter 62W were written specifically with rulemaking in mind, recognizing Commerce’s expertise would allow for better implementation of the law.

Commerce has used the timeframe provided by the Legislature for rulemaking to engage many different industry stakeholders—including PBMs, pharmacists, plan sponsors—to develop enough expertise in the field to propose adequate and helpful rules. As noted above, over the course of 2020, Commerce solicited and considered extensive feedback from an advisory panel that included experts in pharmacology, health insurance, and law. After the expiry of the advisory committee, Commerce continued to hold listening sessions with interested parties. It was clear from these meetings was that rulemaking was needed to provide industry and other

stakeholders with clarity and predictability in the enforcement of the PBM Law. Moreover, Commerce has been enforcing the law since its effective date at the start of fiscal year 2020, and has undertaken the initial license process, license renewal, as well as collected and published transparency reports.

The need for rulemaking is particularly acute in the area of licensure, data reporting, and PBM business practices. As discussed more fully below, the sections of the statute covering licensure, while providing a general framework, lack the necessary detail to allow Commerce to carry out the purpose of its statutorily assigned duties. For example, the statute does not include the content and basis for the annual renewal of PBM licenses as well as specifics surrounding the level and application of penalties. Further, many PBMs, prior to the PBM law, were not acquainted with Minnesota's current TPA licensing and network adequacy standards and processes.

In preparing this document, the Department has consulted with leadership and network adequacy experts from the Minnesota Department of Health (MDH), as MDH has authority over the network adequacy requirements and processes under both past insurance laws as well as Minnesota Statutes, chapter 62W. In consultation with MDH, Commerce has proposed standards in this document, in order to promulgate network adequacy standards for PBMs that are more closely aligned with consumer interests and industry standards.

The Department would also like to ensure that the data transparency requirements placed upon PBMs will enable 1) standardized submission formats from PBMs, 2) the Department to have timely understanding of expected versus actual rebates through time, 3) clear understanding of the content of the public transparency report produced by the Department, and 4) data formats that promote the Department's ability to meet the 60-day reporting turnaround time.

Many of the components of Minnesota Statute, section 62W, pertain to business practices by PBMs. These sections often provide a general statement either prohibiting or requiring certain actions, but do not include sufficient detail for Commerce to adequately enforce the law.

Aside from the technical points summarized above, the Department believes that rulemaking has its own advantages, since the Department has benefited from PBM, insurer, employer, policymaker and public input provided through the formal rulemaking process. Based on past industry behavior, the threat of court action on the Department for desk draw rulemaking is very real, particularly on this new chapter of statute. Indeed, as the Department has implemented portions of the law already, it has become clear that often times the statutory text lacks the necessary technical detail to adequately carry out the purpose of the legislature.

Finally, Commerce believes rulemaking is needed, because while many other states are similarly focused on topics surrounding PBMs, Minnesota's law enactment precedes most other states by one to three years. Minnesota participates in the National Association of Insurance Commissioners (NAIC) subgroup that was created in 2018 to address standardized PBM laws, regulations and practices relating to licensing, transparency, and operational practices. It is

likely that other states would benefit from a formal, public rulemaking process in Minnesota, and vice versa. The rulemaking process will provide an opportunity to incorporate standardized regulatory content and processes into the topics which are governed by Minnesota Statutes, chapter 62W.

Reasonableness of the Rules

Minnesota Statute, section 14 requires Commerce to explain the facts establishing the need for and reasonableness of the rule as proposed. In this section, Commerce first provides an analysis for the general reasonableness of the rules proposed, and then presents a rule-by-rule analysis of the reasonableness of each rule proposed.

General Reasonableness

When considering the reasonableness of the proposed rules, it should be noted that the rules were developed over the course of a year. As noted above, Commerce established a large advisory committee with members representing the interests of key constituencies affected by the PBM law.

The rules proposed reflect an ongoing and serious discussion with those constituencies. Commerce has thoughtfully considered all feedback received from members of the public and weighed multiple factors and parties' interests. The proposed rules reflect this thoughtfulness, statutory requirements, and provide minimum standards that offer performance-based rules to the extent feasible while maintaining clarity and enforceability.

Rule-by-Rule Analysis

2737.0100 DEFINITIONS.

Subpart 1 is necessary to clarify the definitions in this part apply only to the Minnesota Pharmacy Benefit Manager Licensure and Regulation Act and these proposed rules. Clear, comprehensive, consistent definitions are required if the Department is to achieve the fundamental objective of program rules that clearly communicate standards, processes, and outcome expectations of the Minnesota Pharmacy Benefit Manager Licensure and Regulation Act. The pharmacy industry is replete with terms of art as well as more malleable terms. Each of the remaining subparts attempts to specify the meaning for those words or phrases with sufficient precision to allow regulated entities, as well as, persons and organizations affected by the statute and these rules to know what is and is not permitted.

Subpart 2 is necessary to define an oft used term that may potentially be susceptible to multiple meanings. The term Aggregate is used repeatedly in the statute, as well as in the rules, as a basis for the type of data sought in relation to the submission of transparency reports to both Plan Sponsors and the Commissioner.

Subpart 3 alleviates potential confusion over whom is subject to the statute's reporting requirements. The statute requires that a PBM report on behalf of any plan sponsor who does business in Minnesota. As the Department underwent the first round of the required reporting,

this question of which data should be reported was central. PBMs often provide services across a number of states and sought clarity as to whether they would be required to report under Minnesota Statutes, section 62W.06, subdivision 2. Moreover, this problem is particularly acute in Minnesota, with a number of populous border communities. It is not uncommon for residents of Minnesota to work in either Wisconsin or North Dakota, nor is it uncommon for North Dakota or Wisconsin residents to work in Minnesota.

The statute itself does not define what constitutes doing business in Minnesota. However, this phrase is defined elsewhere in Minnesota's Statutes and Rules, and explicitly defined in two locations:

Minn. Stat. § 5325, subd. 4(b):

A foreign corporation is considered to be doing business in Minnesota if it makes a contract with a resident of Minnesota to be performed in whole or in part by either party in Minnesota, or if it commits a tort in whole or in part in Minnesota against a resident of Minnesota.

Minn. Stat. § 626.18, subd. 1 (e):

A "foreign corporation" is considered to be doing business in Minnesota if it makes a contract or engages in a terms of service agreement with a resident of Minnesota to be performed in whole or in part by either party in Minnesota.

The Department proposes a definition that is consistent with each of these definitions and provides sufficient ground for a PBM to make a determination as to whether one of its plan sponsors is doing business in Minnesota. In approaching this term, the Department aimed to strike a middle ground between being overly broad, and overly constrictive. If on the one hand the Department chose to limit the phrase to only those companies that are domestic companies, then a large swath of Minnesotans would be excluded from the reporting requirements, thereby failing to effectuate the legislature's goals. On the other hand, an overly broad interpretation of the phrase may inundate Commerce with data from plans sponsors that is not relevant to the goals and aims of the reporting requirement. The Department believes the reliance on Minnesota statutes for guidance on this question is the best approach to ensure that the Department receives robust and relevant data under Minnesota Statutes, section 62W.06, subdivision 2.

Subpart 4 provides a concise definition, referring to federal statutes, of what constitutes machine readable format. The purpose of requiring machine readable formatted Maximum Allowable Cost (MAC) pricing lists will be discussed in detail in the portion of this SONAR covering Rule 2737.1500 below. As part of the Department's Advisory Committee process, and subsequent public commentary, it became clear that PBMs and pharmacies would benefit from a shared expectation about the format of any data. This definition provides a working definition (easily processed by a computer) while also providing a non-exclusive list of formats that meet the requirement.

Subpart 5 defines a key phrase used in both the statute and these rules. A key piece of the statute limits actions by PBMs with respect to pharmacies that either the PBM owns, or PBMs owned by a pharmacy company. Because of the often complex and overlapping structure of corporate groups, the definition provides clarity that ownership can be direct or indirect. The Department has chosen not to place a threshold on ownership percentage, because the statute’s purpose—to protect Minnesota citizens from potential self-dealing due to conflicts of interest—is best served with an absolute standard.

2737.0200 AUTHORITY, SCOPE, AND PURPOSE.

This part is needed to specify that the rules apply to applicants, prospective applicants, licensed or authorized PBMs doing business in Minnesota and subject to the provisions of the Minnesota Pharmacy Benefit Manager Licensure and Regulation Act.

2737.0300 GOVERNMENT PROGRAMS.

This part is designed to clarify when an entity may rely on the legislature’s exemption of DHS from the plan sponsor definition. This rule contains two interrelated subparts designed to provide clarity as to when an exemption as a plan sponsor applies and when it does not.

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. For example, the Minnesota Department of Administration operates an entity that provides cooperative purchasing contracts for eligible members, both in Minnesota and across the nation, through joint powers agreements with each state. This entity, MMCAP Infuse, also collects and evaluates transactional data on behalf of its members to ensure that the product and service pricing contractual agreements are met. Eligible MMCAP Infuse members are state agencies, counties, municipalities, and in certain other states, nonprofit organizations. MMCAP Infuse provides contracts used primarily by departments of corrections, public health agencies, mental health, and student health. The Department believes that these exemptions are consistent with the intent of the statute.

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. Allowing the PBMs for these MCOs/HMOs to rely on the exemption of DHS from the plan sponsor definition would frustrate the legislature’s intent.

2737.0400 BUSINESS LICENSE REQUIREMENTS (INITIAL APPLICATION)

The next three sections contain rules relating to the review and issuance of PBM licenses. In addition to having extended discussions with the advisory committee about this process, Commerce has now gone through an entire application and renewal cycle. These proposed rules reflect not only the insight of industry and Commerce staff from a theoretical perspective, but also from the lived experience of the first wave of initial applications in 2019/2020 and the

first wave of renewals at the end of 2020.

This part, dealing with initial applications, is designed to provide greater specificity as to the requirements for an application to be a licensed PBM in Minnesota.

Subpart 1 restates portions of the chapter 62W and makes clear that a PBM must seek approval no later than 90 days prior to the date it intends to begin providing PBM services in Minnesota. After January 1, 2020, the initial date set by the statute for existing PBMs to seek licensure, it is anticipated that the only reason a PBM would seek licensure is if it had already begun the process of lining up potential contracts with plan sponsors. The statute provides that Commerce has 90 days to review an initial license application. Subdivision 6, of section 62W.03, makes acting without a license punishable by a substantial fine. This rule thus aligns the time frame within which Commerce must review an initial application with the rule's required time frame to submit an application to ensure that a PBM would not be subject to a fine while its application is pending.

Subpart 2 provides additional detail with respect to the contents of an application for PBM Licensure. This part mirrors the process and content of applications Commerce uses to license TPAs, which operate similarly to PBMs. Item D in particular spells out the categories of information that Commerce believes is necessary to make an informed review of PBM license applications. In order to determine whether a PBM should be licensed in Minnesota, Commerce believes it is imperative to determine if an applicant, or a key employee of the applicant has engaged in fraudulent or criminal behavior or behavior that other regulatory agencies and divisions have thought warranted discipline.

Earlier iterations of this subpart contained far greater categories of data, as well as a broader slice of persons at a PBM required to be included in the application. During the course of the advisory committee's review of this section, it became clear that Commerce could better scope both the categories of persons and the categories of data it sought in the initial application.

Subpart 3 deals with a PBM applicant's duty to properly time its request from MDH for review of the PBM's proposed pharmacy network. An application for an initial license is not complete without a Network Adequacy Report approved by MDH. MDH, however, is not subject to the same time constraints that Commerce is, under the text of the statute. This subpart thus makes clear that the onus is on the entity seeking licensure as a PBM to first have the network reviewed by MDH, and upon receipt of an approval or limited network report from MDH, submit its application for a PBM license.

Subpart 4 provides clarification that in order to effectuate an efficient and effective experience in application submission, that a small fee, in addition to the statutorily mandated fee may be applicable in order to cover the cost associated with the use of such a service provider and its software.

Subpart 5 requires that PBMs alert Commerce if any of the information provided in its application changes. As this requirement could become onerous were it to apply to the entirety

of the application, Commerce has proposed a rule that is limited to the information that is unlikely to change frequently, and to information that may lead the agency to reconsider a license had the information been disclosed at the time of the application. This requirement is consistent with the text of the statute, notably section 62W.03, subdivision 4, which provides the Commissioner with substantial oversight authority. Specifically, the statute allows the Commissioner to “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[.]” In placing a requirement for ongoing reporting, in the event of changes to key facts forming the basis of the application’s approval, Commerce is able to efficiently effectuate the intent of the legislature in passing the PBM Law.

This subpart also requires that a PBM report to MDH any changes in the make-up of the pharmacy network(s) it submitted with its application. Section 62W.05 requires that a PBM’s network of pharmacies meet certain guidelines. Where it fails to meet such guidelines, MDH may place restrictions on the network’s geographic reach. Those restrictions then become part of the PBM license issued, such that the PBM may only offer the network in the areas approved by MDH. The loss of one or more pharmacies from a network could potentially cause a network to no longer meet the requirements of the PBM Law. This rule ensures that in cases where a PBM’s network(s) undergo change mid-plan-year, both MDH and Commerce are aware and can take remedial steps as necessary.

Even though the PBM license is only valid for a single year, the requirement to report changes to an application required under this part of the rules, is necessary to effectuate the purpose of the PBM law.

2737.0500 BUSINESS LICENSE REQUIREMENTS (RENEWAL APPLICATION)

This part of the rules is substantially similar to the previous, with the exception that it governs the renewal application process rather than the initial license application process. The primary goal of this part is to make clearer the timeline and process for seeking approval of a renewal application. Unlike the section of the statute covering initial applications, the sections covering renewal are less prescriptive. While both sections provide that an application must be on forms prescribed by the Commissioner of Commerce, require a network adequacy report approved by MDH and a fee of \$8500, only the initial application section imposes specific time constraints (30 days for Commerce to seek additional information, and 90 days to make a determination).

Subpart 1 lays out the relevant portions of the PBM Law and these rules which will be used to determine whether a renewal application is approved. This is intended to effectuate the provisions of Minnesota Statutes, section 62W.03, subdivision 3, paragraph c, clause 1.

Subpart 2 advises PBM applicants of necessary steps and the order in which to take them to submit a renewal application. As with chapter 2737, part 0400, subpart 3, this subpart makes clear to applicants that it must first seek approval of its proposed networks from MDH, prior to submitting a renewal application.

Subpart 3 and subpart 4 impose the same requirements on renewal applications as Commerce proposes to place on initial applicants. The reasonableness for these subparts the same as the basis contained in chapter 2737, part 0400, subparts 4 and 5.

2737.0600 REVIEW BY COMMISSIONER

Commerce's proposed rules covering renewal applications intend to harmonize the process and timelines with the initial application process. To that end, this subpart creates rules that would govern both the initial and renewal application process.

Subpart 1 this subpart clarifies that the Commissioner's ability to seek additional information from an applicant must be made within 30 days of the receipt of a completed application. This rule is intended to ensure that applications are reviewed in a prompt fashion and that applicants are alerted as early as practicable to potential issues requiring additional information. It also clarifies that the time period begins to run only once a PBM has submitted its completed application.

Subpart 2 mirrors the 90-day period provided to Commerce to make a determination on an application in Minnesota Statutes, section 62W.03, subdivision 2. It also provides applicants with clear outcomes of an application. Subitem C requires Commerce to articulate the basis for rejection. The rule provides for applicants to remedy the basis for denial of a renewal application, without encumbering an additional application fee. This subpart is proposed to ensure that both Commerce and the applicant work in a timely manner toward resolution. It also eliminates potential ambiguity around recourse for an application denial by providing a clear and immediate process by which an applicant can contest a denial.

Subpart 3 makes clear that any geographical or other restrictions placed on a PBM's network by MDH are part of the license issued by Commerce. Moreover, this section, mirroring the duty imposed on PBMs to disclose new information, allows for a PBM to seek removal of the limitation or restriction where it can show the conditions giving rise to the limitation or restriction have been eliminated.

Subpart 4 creates a process for PBMs to seek immediate review of the decision by the Commissioner. This process provides a cost effective and predictable method for reviewing the determinations made by the licensing team within the insurance division in Commerce. It provides a specific steps and concrete timelines. The process, recognizing the time-sensitive nature of the issues, is designed to adjudicate the issues quickly. Finally, this proposed rule removes any ambiguity over what would constitute a final agency determination for a party aggrieved wishing to seek judicial review.

Subpart 5 is designed to ensure that delays in process do not prevent a PBM from continuing its work. The requirement of an annual renewal necessitates tight timelines. Minnesota, as with many other states, uses a third-party platform to manage and track insurance filings, including license applications and renewals. Minnesota's platform provider is SIRCON, whose system only allows that the window for renewal applications can only open 90 days prior to the expiration

of the current license. Recognizing the extensive use of the SIRCON platform by Commerce and its licensees, this rule creates a workable time frame consistent with the statute, without imposing additional costs or diverting the resources of Commerce and its licensees.

While it is anticipated that both Commerce and PBMs will meet each benchmark created in the rules, there remains a possibility that a PBM could find itself in the renewal process after the expiry of its prior year license. This potential situation was raised by various members of the advisory committee, and Commerce has endeavored to make sure that the renewal process is structured in a manner to avoid that outcome. That said, this proposed rule is designed to account for the possibility and provide relief should a PBM have made a timely application, but not yet have a determination as to the renewal license at the time its previous license would expire.

This subpart is consistent with the authority vested in the Commissioner to issue a limited or restricted license—here the limitation or restrictions would be that the prior year’s license is automatically extended, pending review of the current renewal application.

2737.0700 ENFORCEMENT BY COMMISSIONER

Minnesota Statutes, section 62W.03, subdivision 4, provides the Commissioner with substantial oversight authority. The breadth of that grant of power is not joined with commensurately broad list of what activities may engender the Commissioner’s execution of such authority. The statutory text is as follows:

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;

Initially, Commerce considered using the list in subpart 2 of this part as a part of the initial and renewal application process. During the advisory committee process, it became clear that this level of detail in the application process would be onerous. However, it was also clear that this level of detail as to the areas of Federal and State law Commerce viewed as sufficiently connected to the administration of pharmacy benefits to impact licensure was beneficial. To that end, Commerce proposes this rule, which provides a nonexclusive, but highly specific, list of the areas of law which could result in the suspension, revocation, or a probation of a PBM License.

2737.0800 ADEQUATE NETWORK

The next two portions of the rules concern the PBM Law’s network adequacy requirements. The text of Minnesota Statutes, section 62W.05, subdivision 1, requires that each PBM provide

“an adequate and accessible pharmacy network.” Neither of these terms is defined in the statute. To create greater transparency on the network adequacy review process, Commerce proposes two rules, the first clarifying what constitutes an adequate network and the second clarifying what constitutes an accessible network. Given the role that MDH plays, Commerce worked with MDH to ensure that the proposed rules were consistent with its policies and procedures.

Subpart 1 recognizes that the pharmacy industry contains far more than the typical retail pharmacy. In order for a network to adequately meet the needs of enrollees, it must be able to provide enrollees with access to all types of drugs, and across multiple settings. Each of these types of pharmacies is commonly found in the networks submitted to MDH for review. The requirement to include each is reasonable and serves to the legislature’s intent of ensuring that enrollees have adequate networks.

Subpart 2 provides a mechanism for PBMs to seek relief from subpart 1, where there are extenuating circumstances that necessitate that one or more pharmacy type is not included in network. This subpart is consistent with MDH’s authority under Minnesota Statutes, section 62W.05, subdivision 2, which grants MDH the authority to issue waivers to the network adequacy requirement.

2737.0900 ACCESSIBLE NETWORK

As seen above, the network adequacy portion of the statute is not very robust. The task of determining whether a network is accessible is assigned to the Department of Health, and the method of determination of accessibility to conveyed via reference to the ‘relevant’ portions of another statute— Minnesota Statutes, section 62K.10—that is used by Health for determinations about health carrier networks. The proposed rule merely clarifies what portion of Minnesota Statutes, section 62K.10 is relevant for the purposes of making a determination as to the accessibility of a pharmacy network.

Nothing in Minnesota Statutes, section 62K.10 deals with the provision of pharmacy benefits. The statute contains two separate mileage/distance requirements:

Subd. 2. Primary care; mental health services; general hospital services. The maximum travel distance or time shall be the lesser of 30 miles or 30 minutes to the nearest provider of each of the following services: primary care services, mental health services, and general hospital services.

Subd. 3. Other health services. The maximum travel distance or time shall be the lesser of 60 miles or 60 minutes to the nearest provider of specialty physician services, ancillary services, specialized hospital services, and all other health services not listed in subdivision 2.

From the text of the statute is not clear where one would place pharmacy services. Do they constitute primary services, are they part and parcel of general hospital services, or do they fall under other services? In consultation with MDH, Commerce believes the relevant section would

be subdivision 2, and the 30 mile/minutes limitation.³ Pharmacy services are certainly on par with primary care, mental health and hospital services.

This proposed rule would likely require PBMs to include more rural pharmacies in network in order to meet the tighter geographical constraints, vis-à-vis the 60/60 requirement contained in Minnesota Statutes, section 62K.10, subdivision 3. The use of the 30/30 requirement is reasonable inasmuch as it furthers the legislative aim of making sure Minnesotans have access to prescription drugs.

2737.1000 TRANSPARENCY REPORTS TO PLAN SPONSORS

The PBM Law requires that PBMs share certain categories of data with both the plan sponsors for whom they work and Commerce. This proposed rule governs the reporting to plan sponsors. This section reflects substantial feedback from the advisory committee as well as other industry participants, which suggested that the nature of the PBM-Plan Sponsor relationship, was not directly benefited by Commerce taking an active role in mediating disputes. These proposed rules reflect that sentiment, while attempting to provide clarity of process for plan sponsors seeking to enforce their rights under section 62W.06, subdivision 1.

Subpart 1 proposes that Commerce will create a standardized form for plan sponsors to use to request the data made available to it under section 62W.06, subdivision 1. Based on the comments from industry and the advisory committee, Commerce does not believe it is necessary to make use of this form. That said, while some plan sponsors may not make use of the form, the provision of the form should benefit those, potentially smaller, plan sponsors with limited resources. The use of the published form may also alleviate concerns raised by some PBMs, that they may find themselves inadvertently subject to enforcement where a relatively low-level staffer at the plan sponsor sought a type of data referenced in the PBM law from a corollary staff member of the PBM.

Subpart 2 and subpart 3 are necessary to effectuate the enforcement provision contained in section 62W.06, subdivision 3. That subdivision of the section allows that the commissioner may impose a penalty of up to a thousand dollars a day for violations of the section. That section contains requirements to submit reports to Commerce annually, as well as to plan sponsors on request. The penalty accrues for each day a PBM is in violation. Subpart 2 of this rule thus fixes a timeline for submission of transparency reports to plan sponsors. Absent this rule, Commerce would be in the position of determining how long a PBM had been in violation of the statute on an ad hoc basis. This rule helps fix predictable and consistent rules. Similarly, subitems A and B, provide clarity on when a request has actually been made for the data contained in section 62W.06, subdivision 1. In the advisory committee process, it became clear that certain portions of the data contained in the PBM law routinely passed between PBMs and plan sponsors, and many PBMs expressed the concern noted above that relatively low-level

³ This is consistent with other states that have mileage requirements: New Hampshire requires 15 miles or 45 minutes, Montana requires 30 miles, and Kentucky uses a 30 miles/minutes range as well.

staff may trigger portions of the PBM Law.

2737.1100 TRANSPARENCY REPORTS TO THE COMMISSIONER

This part of the rules provides guidance and clarity on the annual data reporting requirements in section 62W.06, subdivision 2. While the statute is fairly clear on the type of data to be reported, it is less clear on the manner in which that data should be reported, and how the public facing portion of the data should be shared. This part of the rule clarifies those issues.

As with licensing, Commerce has relied on the advisory committee and input received in public comments, but also relied on the experience it has gained by overseeing the collection of the first transparency reports in 2020. In the process of collecting transparency reports for 2020, the department held a number of meetings with PBMs to discuss process, at which the department solicited feedback. That feedback is reflected in these rules.

Subpart 1 proposes a rule requiring Commerce to publish three templates for PBMs to use to report data. The first template covers the data required by section 62W.06 subdivision 2 paragraph a items 1-6. The second covers the data required by section 62W.06 subdivision 2 paragraph a item 7, and the final template covers the date that must be publicly reported by the Commissioner pursuant to section 62W.02 subdivision b.

Subpart 2 requires that all PBMs use the same forms provided by Commerce, unless there is a reasonable basis for not doing so. Given the volume of data collected, it is reasonable for Commerce to seek to ensure that the data arrives in the same format. Using standardized templates makes determinations of compliance easier. As will be discussed below, any burden placed on PBMs in compliance will be minimal.

Subpart 3 is a proposed rule born out of Commerce's first year administering the transparency reporting process. The definition of a PBM in the PBM Law includes seven distinct activities, and the performance of any one will necessitate that an entity be licensed as a PBM. While most of these activities would result in collection of the data required to be reported to Commerce under the PBM Law, there remain certain categories which would not, e.g., establishing a pharmacy network. In these cases, a PBM would not have anything to report. In 2020, there were 13 PBMs that did not submit a report. Follow-up letters were sent to determine the basis for those PBMs not submitting any reports. In conversation with stakeholders about the public reports posted by Commerce, the number of non-reporting PBMs came up repeatedly. Commerce believes that many of these PBMs did not report because they chose not to comply with the law, but rather because they either had no data, or the data they did have was duplicative of another PBM (see discussion of subpart 6). Commerce views this rule, requiring a statement at the time reports are due by all PBMs as a better approach. This rule will allow Commerce and interested parties accessing the public reports to have a better understanding of the PBM marketplace. The rule is also more efficient, as it requires action by all PBMs on the reporting date and minimizes the amount of work by Commerce and PBMs in subsequent communication.

Subpart 4 is needed and reasonable to allow the data collected by Commerce to be consistent and usable. Section 62W.06, subdivision 2, paragraph a requires that data be presented by therapeutic category. Within the pharmacy industry there are myriad different therapeutic classification systems. Absent a uniform system, the data collected would mean very little when looking across PBMs. In order for the data to hold value, it must be roughly similar across reports. To that end, Commerce proposes a rule that requires Commerce to select a preexisting, accessible classification system. In early internal discussions, Commerce proposed to create its own classification systems. Feedback from industry participants and key stakeholders revealed that to be a poor option. This rule provides Commerce flexibility in choosing the system, recognizing the efficacy of one system versus another may change over time, but the requirement that it be preexisting and commonly used, ensures that the system selected will not create a compliance burden on industry.

Subpart 5 proposes a rule to allow Commerce to engage persons external to the department to achieve the aims of the statute's requirements. While the staff at Commerce are knowledgeable and dedicated public servants, transparency reporting benefits from industry expertise. The rule is necessary to ensure that Commerce is able to understand current industry jargon, and adopt, for instance, the best therapeutic classification system.

Subpart 6 is needed to prevent duplicative data from being submitted to Commerce in the annual transparency reports. As noted above, the PBM statute covers multiple duties, and there is a certain amount of fragmentation and division of labor within the industry, such that it is not uncommon that two or more PBMs may provide services for the same plan sponsor, and in doing so may have all or part of data connected to the same enrollees. It is Commerce's understanding that the legislature's intent in creating the transparency reporting requirement was to obtain and shed light on the actual data concerning prescription benefits in Minnesota. That aim would not be served by having multiple submissions of the same data.

Based on feedback from the advisory committee and other industry participants, it is the understanding of Commerce that PBMs working together will often cover, in contract, which party is responsible for reporting. In the absence of such an agreement, this subpart creates default rule, that the party in charge of processing the claims at issue is responsible for reporting the data.

Subpart 7 is necessary to create clarity as to when a PBM would be subject to the penalties contemplated in section 62W.06, subdivision 3.

2737.1200 PHARMACY OWNERSHIP INTEREST

Commerce proposes this rule to clarify a number of ambiguous portions of section 62W.07.

Subpart 1 is necessary to clarify what that it means to require an enrollee to use a pharmacy as described in section 62W.07 paragraph a. This subpart is necessary and needed to make plain that a network which includes only owned pharmacies, as defined in chapter 2737, part 0100, subpart 5, constitutes a requirement that the enrollee use a pharmacy owned by the PBM.

Subpart 2 is necessary to effectuate the aims of the legislature to minimize the ability of PBMs to steer business towards its own corporate group through special incentives and discounts. Commerce views this statute as requiring a like for like pharmacy. That is, in order to offer an incentive at an owned retail pharmacy the PBM must make available that same incentive at at least one non-owned pharmacy. The hallmark of this section of the PBM law is to allow enrollees greater choice and flexibility in the pharmacy at which they choose to fill their prescriptions. This subpart is needed to prevent frustration of that aim. Without this rule, a PBM could, for instance, offer a very small incentive (\$1.00 discount off a copay) at an owned retail pharmacy and match that small incentive (\$1.00 off of a copay) at a non-owned pharmacy, while offering a massive deal (\$25.00 off of a copay) at an owned *mail order* pharmacy. This rule’s requirement that the incentives (or disincentives) be made available at the same type of pharmacy is the only way to achieve the legislative aim of the law.

Subpart 3, like subpart 2, attempts to clarify the statutory language, and achieve the legislature’s aims, by making clear that the imposition of a quantity or refill limit is only permissible if the PBM has set those same limits at owned an non-owned pharmacies of the same type.

Subpart 4 is necessary to make clear that the combined effects of section 62W.07, paragraphs b, d and e, is that a PBM cannot rely on paragraph e in isolation to establish a network with only a mail order pharmacy that it owns, and at which it provides incentives to enrollees to use the owned mail order pharmacy—including different refill and quantity limits. Subpart 4 makes clear that such an arrangement is incompatible with the text of section 62W.07. This subpart is likewise reasonable in that it forecloses a potential end-run around the aims of the legislature.

2737.1300 SECTION 340B PARTICIPANTS

This proposed rule is reasonable and needed clarify the language of section 62W.07 paragraph e. The statutory language contains a sort of double negative—must not prohibit—which can lead two competing interpretations of the statute. This subpart clarifies that the paragraph e does not require entry of one or all pharmacies in the 340B program into a PBM network, but rather prohibits a PBM from adopting a categorical prohibition on the inclusion of pharmacies that are participants. Interpretation issues related to this statute have already arisen, and Commerce believes adoption of this rule will promote clarity in the industry and prevent future confusion.

2737.1400 OUT-OF-POCKET COST COMPARISONS

This part of the rules covers two similar statutory requirements—contained in sections 62W.076 and 62W.077. These sections provide enrollees with the right to request from their PBM a comparison of the out-of-pocket cost for the enrollee for a specific drug at different pharmacies. Section 62W.076 entitles an enrollee to a comparison between the price of a prescription drug at a specialty pharmacy and an in-network retail pharmacy. Similarly, section 62W.077 requires a PBM that maintains a preferred network to provide out-of-pocket costs comparisons for a prescription drug at a preferred pharmacy and an in-network pharmacy.

Subpart 1 is needed to ensure that access to the information provided for by statute is easily available to enrollees. Requiring that any dedicate form, rules or guidelines developed by the PBM to handle these requests is a reasonable manner to effectuate the legislative intent of these sections.

Subpart 2 creates rules for the manner in which a PBM provides a response to an enrollee. The rule is reasonable insomuch as, it requires PBMs, where they have not established any system, to respond in a manner consistent with the manner in which the enrollee made the request. Likewise, the rule is reasonable in that it allows for PBMs to establish their own system, so long as they communicate to the enrollee, as part of the system, the manner in which the enrollee will receive the response. Finally, similar, to the requirements imposed on state agencies, the rule requires that any response use plain language that is easily understood by the enrollee making the request.

Subpart 3 establishes a time frame within which the PBM must respond to the request of the enrollee. Given the likely time sensitive nature of the decision facing an enrollee on where to fill the prescription at issue, Commerce believes the rules proposed in this part are needed to effectuate the legislative goal of empowering enrollees to make an informed decision.

Subpart 4 was added by Commerce after communication from PBMs and industry participants. Many PBMs commented that they already maintain an online system that provides this information. In order to make this rule as reasonable as possible, Commerce proposes that where a PBM provides such an online resource, the PBM has complied with the rules so long as they communicate to the enrollee how to access the system.

2737.1500 MAXIMUM ALLOWABLE COST PRICING

Minnesota’s Maximum Allowable Cost (MAC) pricing regulations, contained in section 62W.08, are fairly robust. After raising the issue with the advisory committee and industry participants, it was clear that the area of this portion of the PBM Law that would benefit from rulemaking was the technical process of delivering the MAC lists to pharmacists.

Subpart 1 establishes specific requirements for a PBM’s MAC list. Given the sheer volume of multi-source drugs⁴, an easily accessible and searchable format for these lists is imperative. The rule is reasonable, in that it places no additional burdens on PBMs, since it is impossible to believe that any PBM would not currently maintain a MAC list in an electronic format. Moreover, the requirement that the list be in a machine-readable format is eminently reasonable. This requirement will allow pharmacists to be able to easily and quickly download the MAC list into a format consistent with the operating software in their practice and search out the specific drug at issue.

Subpart 2 prohibits a PBM from conditioning network inclusion on either waiving or

⁴ Multi-source refers to a drug that is manufactured by more than one company or source, available as both a brand name drug and a generic. Only multi-source drugs are subject to the MAC pricing regulations.

dimensioning the rights given to pharmacists under this section. In particular, this rule prohibits the use of a private contract to negotiate around the mandated appeals process. Contracts between PBMs and pharmacies often contain provisions related to the process to appeal disputes over MAC pricing, however, section 62W.08 sets a floor for those contracts in Minnesota, and it is reasonable to establish a rule that those minimum standards may not be waived.

2737.1600 PHARMACY AUDITS

As with the prior section, the section of the PBM law addressing the conducting and reporting of a pharmacy audit by a PBM is fairly robust and prescriptive. That said, one piece of feedback that Commerce received from multiple parties was a sense that the law could not be fully effectuated unless the pharmacy under audit was aware of the standard by which the audit would be conducted.

Subpart 1 is designed to alleviate that concern. This subpart requires that a PBM conducting an audit must provide the pharmacy with both the standards under which the audit will be conducted, as well as with the process by which a pharmacy may appeal any determination made in the audit. These rules are both needed and reasonable. The rules are needed to ensure that pharmacists have full understanding of how they will be reviewed, and how they may appeal any perceived inequities. This rule is reasonable, insomuch as it merely requires disclosure of information. It does not place any burden additional on PBMs that is not already contained in the statute—the statute requires that the standards used be the same for similarly situated pharmacies, and the establishment of a written appeals process.

Subpart 2, as with the similar rule in chapter 2737, part 0900, subpart 2, prohibits a PBM and pharmacy from agreeing to a contract that waves portions of this section of the PBM Law. This rule is needed and reasonable to effectuate the over aims of the PBM law. Allowing PBMs to contract around these provisions would obviously frustrate the law.

2737.1700 ALLOWABLE CLAM AMOUNT

This part of the rules provides a standardized method for calculating “allowable claim amount” as used in Minnesota Statutes, section 62W.12, paragraph 2. That section creates a ceiling for the amount an enrollee may be charged to purchase a prescription drug at a pharmacy. The statute includes three possible dollar amounts that may be used, but only two of those are sufficiently clear to not be subjected to more than one interpretation. The third, allowable claims amount, has the potential to be calculated differently by different actors. In order to create uniformity in the marketplace, and allow enrollees, pharmacists and PBMs to operate with predictable results, this subpart sets forth a precise method that allows anyone to easily determine what the allowable claim amount would be.

2737.1800 RETROACTIVE ADJUSTMENTS

This part of the rules proposed rules related to Minnesota Statutes section 62W.13, which prohibits a PBM from retroactively adjusting a claim, except where such an adjustment is tied

to either a pharmacy audit under section 62W.09, or a technical billing error. For same reasons stated above Commerce proposes subpart 1 to prohibit a PBM and pharmacy from contracting around this requirement.

As written the statute establishes a general prohibition on retroactive adjustments, subpart 2 adheres that predisposition by requiring that any claim of a technical error be accompanied by proof. This rule is necessary to make the administration of the statute smoother, as well as an intuitive rule. The rule does not impose an additional burden on any party, because a PBM would necessarily have to have found some piece of evidence in order to believe an error had occurred. This subpart merely requires that in order to invoke this exception to the general prohibition on retroactive adjustments the PBM provide that evidence to the pharmacy.

Finally, subpart three proposes a rule that would prevent a PBM from using retroactive adjustments to achieve what would not be achievable under the audit provisions. Fees that are paid separate and apart from the reimbursement of drug prices.

Regulatory analysis

Minnesota Statutes, section 14.131, sets out eight factors for a regulatory analysis that must be included in the SONAR. Paragraphs (1) through (8) below quote these factors and then give the Department's response.

Classes Affected

The classes of persons most affected by the rule includes PBMs, Pharmacists and Pharmacy owners, enrollees, plan sponsors, Commerce, and MDH. Each of these parties bear costs, though the costs predominantly fall on PBMs, and the two state agencies.

PBMs, which have heretofore been licensed as TPAs, will absorb direct costs in the form of annual licensing fees, which will be deposited into the state's general fund and thus not available to the Department. Many TPAs and all PBMs doing business with Minnesota plan sponsors will also absorb indirect staffing costs, particularly in the legal and account reporting departments. The PBM law, itself and, not this rule, however, is the driver of those costs.

This rule will likely reduce indirect costs of the Department, PBMs and many TPAs through clarifying and standardizing this new chapter of law for all stakeholders and avoiding legal challenges to the Department's implementation of Minnesota Statutes, chapter 62W.

Ultimately, the cost of this proposed rule itself will likely be minimal to PBMs, since most of the direct and indirect cost is dictated by the governing statute. One purpose of this rulemaking process is to ensure that the cost incurred by PBMs and the Department is reasonable, while the data transmitted to the Department will be in a format that allows the Department to meet the intent of the governing statute.

In addition to affecting multiple classes of persons, the rule will benefit multiple classes of persons. First, the rule will benefit Minnesotans with insurance that provides prescription

benefits via PBMs. Enrollees will have greater clarity on the rules governing PBMs, as well as define processes for vindicating rights provided to them in Minnesota Statute, chapter 62W. Plan sponsors doing business in Minnesota and offering drug benefits to their employees will benefit the most from the new statute and this associated rule, as plan sponsors will have access to their own PBM data through the statute and rule. Transparency enables interested plan sponsors to better budget costs, better make informed pharmacy coverage and operational decisions, and better select PBM partners. Researchers and policymakers will also benefit from the transparency report that the Department will release annually—beginning in November of 2020.⁵

Agency Costs

Commerce does not anticipate that these rules will increase agency cost. Rather, any cost incurred would be as a result of the statute, which included specific appropriations. Moreover, there is the possibility that state revenues would increase due to these rules, as this rule attempts to provide more clarity on penalty enforcement that would enable the Department to more readily assess whether a penalty should or should not be assessed, and if so, how much a penalty should be for certain transgressions.

Less Costly/Intrusive Methods

The purpose of the rules is to comply with the legislature’s mandate that the department adopt 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 legislature provided a non-exhaustive list of subjects that these rules must address and generally laid out prescriptive requirements related to these subjects throughout chapter 62W. Commerce relied on industry participants to guide its rulemaking process to ensure that rules were as narrow in scope as possible to accomplish the goals of the legislative intent of chapter 62W, without being unduly costly. The department knows no less costly or intrusive method for regulating and licensing PBMs in compliance with this mandate other than the proposed rules.

Alternatives Considered

Commerce has a number of regulatory arrows in its quiver, each with advantages and drawbacks. Commerce has, on occasion, used bulletins and legislative updates to provide guidance to industry. Issuing a bulletin covering areas of 62W identified above as in need of further clarification or refinement, would certainly be less time consuming, and potentially incur less cost. However, the number of issues arising from Minnesota Statutes, chapter 62W, would likely be inappropriate for a bulletin to address. Moreover, the rulemaking process, vis-à-vis the process of issuing a bulletin, allows for members of effected industries to participate in the process and shape the outcome. The Department would like to be as transparent as

⁵ The PBM law sets the date for transparency reporting annually in June, however, the COVID-19 pandemic delayed reporting in 2020.

possible, and the rulemaking process provides the best venue to achieve that goal.

Finally, Federal regulators are also currently focused on the PBM topics covered by Minnesota Statutes, chapter 62W, and federal regulators place more reliance on state statutes and rules than they place on bulletins and guidance.⁶ State regulators often make similar assertions to federal regulators when there are concerns over the enforceability of federal guidance that has not undergone the formal, public rulemaking process. In this case, Commerce believes the formal rulemaking process is the best mechanism for achieving the goals of the rule.

Cost to Comply

As noted above, in the sections on classes affected and agency costs, the probable costs of complying with the proposed rule, including the portion of the total costs that will be borne by identifiable categories of affected parties, such as separate classes of governmental units, businesses, or individuals, the vast majority of compliance costs associated with the rule originate in Minnesota Statutes, chapter 622W, not in the proposed rules. The proposed rules only clarify the requirements already imposed on PBMs, Plan Sponsor, and Pharmacies by statute by adding detail where it is lacking in chapter 62W. By clarifying these entities legal obligations, these rules should reduce administrative costs borne by those entities.

Cost of Non-Adoption of Rules

Failure to adopt the Rule would have substantial consequences with respect to both regulated entities and agencies. The rule is proposed to help clarify the regulatory environment and allow entities to act with clear knowledge of the processes by which Commerce will enforce chapter 62W. Absent the rule, PBMs, Plan Sponsors and other regulated entities may face increased costs to review, analyze and parse the Law.

Failure to adopt the rule would leave Commerce to face a public that is confused about the regulation of PBMs under chapter 62W. The clarity provided by the rules should limit these burdens and costs placed on the department, and potentially create a greater likelihood of litigation over enforcement of the Law. In addition, not adopting these rules would result in a failure to satisfy the legislative mandate requiring the department to issue the proposed rules.

Differences with Federal Regulations

The primary point of divergence with Federal Regulation is not a question of what the regulations say, but to whom they apply. The medical insurance industry is bifurcated in regulatory authority, with certain Federal regulations, rules and laws preempting state laws. As a general proposition, health insurance is regulated by the states; however, the federal government has in specific areas waded into health insurance regulation. Where the federal

⁶ In recent interactions with federal regulators, such as in the case of implementation of the Medicare Access and CHIP Reauthorization Act of 2015 (MACRA) which required that Medicare Supplement plans no longer cover the Medicare Part B deductible, federal regulators communicated to all states that bulletins would be an unacceptable means of demonstrating compliance with federal law. Only statute and rules were found to be acceptable to federal regulators.

government has chosen to act, its laws are generally understood to preempt state laws. In the area of health insurance these issues typically arise with respect to the Medicare Act⁷ and the Employee Retirement Income Security Act of 1974 (ERISA). Commerce must regularly assess whether it has the jurisdictional authority to act with respect to certain actors. In the context of the PBM Law, the question of whether the Employee Retirement Income Security Act of 1974 (ERISA) preempts the law is pertinent and been the subject of substantial litigation.

ERISA Preemption Generally

ERISA was passed to create a uniform regulatory environment for retirement and health plans established by private industry. The statutory text of ERISA explicitly preempts any state regulation that ‘relate to’ an employer sponsored plan:

Except as provided in subsection (b) of this section, the provisions of this title and title IV shall supersede any and all State laws insofar as they may now or hereafter relate to any employee benefit plan described in section 1003(a) of this title and not exempt under 1003(b) of this title.⁸

The savings clause referenced in that section provides that: “Except as provided in subparagraph (B), nothing in this title shall be construed to exempt or relieve any person from any law of any State which regulates insurance, banking or securities.”⁹ The central question for cases dealing with whether ERISA preempts a state law is whether that law is related to an employee benefit plan. In working towards a test of whether a statute is related to an employee benefit plan, the Supreme Court has divided preempted state laws into two categories:

First, ERISA pre-empts a state law if it has a reference to ERISA plans. To be more precise, where a State’s law acts immediately and exclusively upon ERISA plans or where the existence of ERISA plans is essential to the law’s operation, that reference will result in pre-emption. Second, ERISA pre-empts a state law that has an impermissible connection with ERISA plans, meaning a state law that governs a central matter of plan administration or interferes with nationally uniform plan administration. A state law also might have an impermissible connection with ERISA plans if acute, albeit indirect, economic

⁷ The Medicare Act expressly preempts state provisions “when (1) Congress or the Centers for Medicare and Medicaid Services (CMS) has established ‘standards’ in the area regulated by the state law; and (2) the state law acts ‘with respect to’ those standards.” *Pharm. Care Mgmt. Ass’n v. Rutledge*, 891 F.3d 1109, 1113 (8th Cir. 2018), *rev’d and remanded*, 141 S. Ct. 474 (2020) (citing 42 U.S.C. § 1395w–26(b)(3)).

⁸ 29 U.S.C. § 1144(a).

⁹ 29 U.S.C. § 1144(b)(2)(A).

effects of the state law force an ERISA plan to adopt a certain scheme of substantive coverage or effectively restrict its choice of insurers.¹⁰

With respect to the second category—which would be the category that regulations of PBMs would likely fall into—the Supreme Court “has considered the objectives of the ERISA statute as a guide to the scope of the state law that Congress understood would survive [preemption] and the nature of the effect of the state law on ERISA plans.”¹¹ The primary inquiry is determining whether the state law at issue would create “a multiplicity of regulation” which would frustrate “the nationally uniform administration of employee benefit plans.”¹² That is, the Court “must determine [] whether the [state law] . . . precludes the ability of plan administrators to administer their plans in a uniform fashion.”¹³

In general, state laws over insurer/TPA licensing, solvency and general business practices are not protected by the ERISA preemption and may be enforced by the state.¹⁴

ERISA Preemption of PBM Regulations

At present approximately thirty-eight states have passed some form of PBM regulations. To date, the Pharmaceutical Care Management Association (PMCA), a national trade association representing PBMs, has aggressively challenged states’ attempts to regulate PBMs. This area of law is relatively new, and the recent decision by the Supreme Court in *Rutledge v. PCMA*¹⁵ suggests that in the context of PBM regulations, the Supreme Court may be inclined to give greater deference to state regulations.

The first circuit court to weigh in on the question of whether PBM regulations by states are preempted by ERISA was the First Circuit. In *PMCA v. Rowe* the First Circuit held that Maine’s Unfair Prescription Drug Practices Act (Maine Rev. Stats., Title 22 § 2699), did not have an impermissible connection with ERISA, because, “[t]he plan administrators here have a free

¹⁰ *Gobeille v. Liberty Mut. Ins. Co.*, 136 S. Ct. 936, 943 (2016) (internal punctuation and citations omitted).

¹¹ *Id.* (internal punctuation and citations omitted).

¹² *New York State Conference of Blue Cross & Blue Shield Plans v. Travelers Ins. Co.*, 514 U.S. 645, 657 (1995).

¹³ *Pharm. Care Mgmt. Ass’n v. Rowe*, 429 F.3d 294, 302 (1st Cir. 2005).

¹⁴ See e.g., *Gobeille v. Liberty Mutual Ins. Co.*, 577 U.S.136 S.Ct. 936 (2016), *De Buono v. NYSA-ILA Medical and Clinical Services Fund*, 520 U.S. 806 (1997), *New York State Conference of Blue Cross & Blue Shield Plans v. Travelers Ins. Co.*, 514 U.S. 645 (1995), *District of Columbia v. Greater Washington Board of Trade*, 506 U.S. 125 (1992), *FMC Corp. v. Holliday*, 498 U.S. 52 (1990), *Firestone Tire & Rubber Co. v. Bruch*, 489 U.S. 101 (1989), *Pilot Life Ins. Co. v. Dedeaux*, 481 U.S. 41 (1987), *Metropolitan Life Ins. Co. v. Massachusetts*, 471 U.S. 724 (1985), *Shaw v. Delta Air Lines*, 463 U.S. 85 (1983).

¹⁵ 592 U.S. ____ (2020).

hand to structure the plans as they wish in Maine.”¹⁶ The *Rowe* Court went on to hold that:

ERISA, however, does not preempt state laws that touch upon enforcement but have no real bearing on the intricate web of relationships among the principal players in the ERISA scenario (e.g., the plan, the administrators, the fiduciaries, the beneficiaries, and the employer). Here, the UPDPA targets the PBMs, which, as stated above, are not ERISA fiduciaries. As such, they are outside of the intricate web of relationships among the principal players in the ERISA scenario.¹⁷

The *Rowe* court reasoned that this made sense, given that many of the provisions in the Maine law were ‘purely ministerial.’¹⁸

When the D.C. Circuit addressed the question of ERISA preemption of PBM legislation, it held that functionally the same set of regulations engendered ERISA preemption, because “ERISA [preemption] includes plan administrative functions performed by a third party on behalf of an [Employee Benefit Program].”¹⁹ The D.C. Circuit specifically held that the D.C. regulation “constrains an [Employee Benefit Plan] by forcing it to decide between administering its pharmaceutical benefits internally upon its own terms or contracting with a PBM to administer those benefits upon the terms laid down in [the law].”²⁰

The next wave of litigation occurred in the Eighth Circuit.²¹ Both the Arkansas and Iowa laws dealt primarily with MAC pricing.

The Iowa law, “§ 510B.8 regulate[s] the manner by which PBMs manage and administer prescription drug benefits by overseeing their MAC pricing methodologies, limiting the drugs subject to MAC pricing, and dictating the manner by which PBMs contract with pharmacies

¹⁶ 429 F.3d 294, 303 (1st Cir. 2005).

¹⁷ *Id.* at 305 (internal punctuation and citations omitted).

¹⁸ *Id.* at 301. The *Rowe* court entertained a sort of preliminary question: are PBMs fiduciaries under ERISA? That is do they “exercise discretionary authority or control in the management and administration of an ERISA plan.” *Rowe*, 429 F.3d at 300 (citing 29 U.S.C. § 1002(21)(A)). The First Circuit found that they were not, even though, the statute at issue imposed certain fiduciary duties on PBMs. *Id.* at 300-301.

¹⁹ *Pharm. Care Mgmt. Ass’n v. D.C.*, 613 F.3d 179, 190 n.* (D.C. Cir. 2010).

²⁰ *Id.* at 188. Certain provisions of the DC regulations contained ‘opt-in’ provisions, which the DC Circuit held removed them from preemption, because they did not bind an Employee Benefit Plan to any particular choice. 613 F.3d at 188.

²¹ See *Pharmaceutical Care Management Association v. Rutledge*, 891 F.3d 1109 (8th Cir. 2018) (challenging Arkansas’ PBM law) and *Pharmaceutical Care Management Association v. Gerhart*, 852 F.3d 722 (8th Cir. 2017) (challenging Iowa’ PBM Law). Minnesota, along with North Dakota, South Dakota, Nebraska, Iowa, Missouri, and Arkansas, sits in the Eighth Circuit.

regarding MAC pricing.”²² The *Gerhart* court held that the requirements of the statute at issues—reporting, disclosure, and recordkeeping—are central to the uniformity of ERISA, and as such “ERISA’s express preemption clause requires invalidation of the statute as applied to PBMs in their administration and management of prescription drug benefits for ERISA plans.”²³ *Rutledge* relied entirely on the *Gerhart* holding to find the Arkansas law preempted by ERISA.²⁴

After the success in Iowa and Arkansas, PCMA next challenged another PBM regulation in the Eighth Circuit: North Dakota’s PBM law.²⁵ The North Dakota statute contained “provisions concerning (1) the practice of pharmacy; (2) pharmacy accreditation and credentialing; and (3) perceived self-dealing and abusive practices on the part of PBMs.”²⁶ The *Tufte* court reviewed and rejected PCMA’s argument—rooted in *Gerhart* and *Rutledge*—that any statute which could conceivably reach an ERISA plan triggers ERISA preemption under the reference to test.²⁷

The *Tufte* court then went on to analyze the North Dakota statute under the ‘connection with’ test. The *Tufte* court found that the statute at issue, which “largely regulates pharmacy services, certain fees, and communication between pharmacies, their customers, and PBMs” was not central to ERISA plan administration.²⁸ Likewise, the court held that the statute did not trigger ERISA preemption by impermissibly interfering with ERISA’s stated goal of a uniform national plan administration.²⁹ The Eighth Circuit reversed that decision relying on its prior

²² *Gerhart*, 852 F.3d at 728.

²³ *Id.* at 730-731. *Gerhart* expressly classifies PBMs as Third-Party Administrators. *Id.* at 731. *Gerhart*, however, was on the whole a very poorly decided case. The Iowa statute expressly exempted from its reach ERISA plans. The *Gerhart* court found that this exclusion was an impermissible reference to ERISA and held that as grounds to invalidate the law. It also reasoned, counterintuitively, that the law “applies to only those PBMs who administer prescription drug benefits for plans subject to ERISA regulation . . .” *Id.* at 730.

²⁴ *Rutledge*, 891 F.3d at 1113.

²⁵ *Pharm. Care Mgmt. Ass’n v. Tufte*, 326 F. Supp. 3d 873 (D.N.D. 2018).

²⁶ *Id.* at 879.

²⁷ *Id.* at 882-86.

²⁸ *Id.* at 887.

²⁹ *Id.* at 887-88 (“A state law interferes with nationally uniform plan administration when it subjects plans to different requirements in different states. North Dakota’s law does not impose any requirements on ERISA plans. Consequently, the Court finds the legislation does not interfere with nationally uniform plan administration.” (Citations omitted)). The *Tufte* court did find that portions of the bill dealing with the reporting of spread pricing practices was preempted by Medicare Part D. the Court limited the application of those provisions to PBMs that did not serve Medicare Part D plans. *Tufte*, 326 F. Supp. 873, 896.

decisions in *Gerhart and Rutledge*.³⁰

Rutledge v. PCMA

The first PBM case to reach the Supreme Court on ERISA preemption grounds was the Arkansas case, *Rutledge v. PCMA*. The Court’s decision in *Rutledge* revisits the central tenets of ERISA preemption jurisprudence which has two independent inquiries to determine whether a state law is preempted, and inapplicable to ERISA plans.³¹ The first inquiry is whether the state law in question makes reference to ERISA, and the second is whether the state law has an impermissible connection with ERISA. The Supreme Court reviewed both determinations made by the Eighth Circuit and found that lower court’s analysis incorrect.

To determine if a plan makes reference to ERISA, a court must determine if the law at issue “acts immediately and exclusively upon ERISA plans or where the existence of ERISA plans is essential to the law’s operation.”³² Here the Supreme Court’s decision provides a clear workable framework. The Supreme Court held that the Arkansas law did not act immediately and exclusively on ERISA plans, because it applies to all PBMs irrespective of plan sponsor, and importantly noted that the law does not actually regulate any benefits plans at all. The brevity of the section delivering the Court’s opinion on this question makes clear that ERISA preemption does not arise simply because a state law attempts to regulate an area that falls within ERISA’s coverage.

In analyzing whether a state regulation has an impermissible connection to ERISA, the Supreme Court has instructed lower courts to consider the goals and objectives of Congress in passing ERISA—to allow plan sponsors uniformity in regulation across multiple states. In its decision, the Court stated it this way:

ERISA is therefore primarily concerned with pre-empting 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. . . . As a shorthand for these considerations,

³⁰ *Pharm. Care Mgmt. Ass’n v. Tufte*, 968 F.3d 901, 906 (8th Cir. 2020). The decision of the Eighth Circuit was appealed to the Supreme Court. Prior to fully briefing whether the Supreme Court should review the case (i.e. grant North Dakota’s petition for certiorari), the Supreme Court issued the decision in *Rutledge*. Both the State of North Dakota and PCMA, in their briefs on whether the Supreme Court should grant certiorari, have argued that the most prudent outcome would be for the Supreme Court to deny certiorari and return the case to the Eighth Circuit for a new hearing in light of the decision in *Rutledge*.

³¹ Justice Thomas’s concurrence argues that the two inquiries are unnecessary as the text of ERISA provides a sufficient method for determining if Congress intended the law at issue to be preempted.

³² *Rutledge v. PCMA*, 592 U.S. ___, at 6 (2020) (citations and punctuation omitted).

this Court asks whether a state law governs a central matter of plan administration or interferes with nationally uniform plan administration.³³

In analyzing the Arkansas law, the Supreme Court found that the law was a form of cost regulation and did not “forc[e] plans to adopt any particular scheme of substantive coverage.”³⁴ The Court’s analysis then focused on the manner in which the regulation worked, and importantly, on what entity the regulation was focused:

[The Arkansas Law] is merely a form of cost regulation [because it] requires PBMs to reimburse pharmacies for prescription drugs at a rate equal to or higher than the pharmacy’s acquisition cost. PBMs may well pass those increased costs on to plans, meaning that ERISA plans may pay more for prescription-drug benefits in Arkansas than in, say, Arizona. But cost uniformity was almost certainly not an object of pre-emption.³⁵

While the Court’s holding in this case relied on the idea that the Arkansas law was a cost regulation, the holding is broader: “ERISA does not pre-empt state rate regulations that merely increase costs or alter incentives for ERISA plans without forcing plans to adopt any particular scheme of substantive coverage.”³⁶ That second part of the holding is key to determining when and where ERISA preemption exists: does the statute at issue force plans to adopt a particular scheme or coverage, or, does the regulation increase costs for a PBM—that may or may not be borne by the plan sponsor—or incentivize a particular outcome?

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.

Cumulative Effect

As has been noted, the health insurance space is a thicket of overlapping regulation. The cumulative effect of the proposed rule is to have clear processes and requirements, which are neither duplicative of federal regulation nor in tension with federal regulation. Commerce, in enforcement of all the laws under its purview is mindful of established precedent which curtails its regulatory jurisdiction, e.g. Medicare Part D preemption.

Statutory Requirements

Notice Plan

In addition to the statutory requirements to publish notice in the State Register and to notify

³³ 592 U.S. ___, at 4-5 (2020) (citation omitted).

³⁴ 592 U.S. ___, at 6 (2020).

³⁵ 592 U.S. ___, at 6 (2020).

³⁶ 592 U.S. ___, at 6 (2020)

interested parties on the Department of Commerce rulemaking list, the Department will place a summary of the notice of rulemaking on the Department’s webpage at www.commerce.state.mn.us. The Department will also send an electronic notice with a hyperlink to electronic copies of the notice, SONAR and the proposed rules to each of the 41 PBMs that applied for a new or renewal license in 2020.

The Department will also send an electronic notice with a hyperlink to electronic copies of the notice, SONAR and the proposed rules to the following persons or classes of persons who may be affected by the proposed rule:

Table 3. Additional Notice Recipients.

| Health Insurers and Health Care Organizations | | |
|---|--|---|
| Nichole Melton Mitchell | Chief Operations Officer, Allina Health Aetna | 2925 Chicago Ave, Minneapolis, MN 55407 |
| Scott Lynch | Senior Vice President, Chief Legal Officer, Blue Cross Blue Shield of Minnesota | 3535 Blue Cross Road, Eagan, MN 55122 |
| Barbara Cox | Senior Director of Government Relations, HealthPartners | 8170 33rd Ave S, Bloomington, MN 55425 |
| Jim Jacobson | Senior Vice President and General Counsel, Medica | 401 Carlson Pkwy, Hopkins, MN 55305 |
| Kirsten Gorsuch | Chief Communications Officer, UnitedHealthcare | 9900 Bren Rd E, Hopkins, MN 55343 |
| Lucas Nesse | President and CEO, Minnesota Council of Health Plans | 2550 University Avenue West, Suite 255 South, St. Paul, MN 55114-1904 |
| Industry Organizations | | |
| Sarah Derr | Executive Director Minnesota Pharmacists Association | Westgate Drive, Suite 252, St. Paul, MN 55114 |
| Michelle D. Mack | Director, State Affairs, Pharmaceutical Care Management Association | 325 7th Street NW, 9th Floor, Washington, DC 20004 |

SONAR – INSURANCE DIVISION

| | | |
|-----------------------|--|--|
| Robyn Rowen | Executive Director, Minnesota Insurance and Financial Services Council | 407 River St, Minneapolis, MN 55401 |
| Matthew Magner | Director, State Government Affairs, National Community Pharmacists Association | 100 Dangerfield Rd., Alexandrian, VA 22314 |
| James Paist | Executive Director, Hemophilia Foundation of Minnesota and the Dakotas | 750 South Plaza Drive, Suite 207, Mendota Heights, MN 55120 |
| Leah Solo, Mike Asmus | Interim Executive Directors, Minnesota Association of Professional Employees (MAPE) | 3460 Lexington Ave N, Suite 300, Shoreview, MN 55126 |
| Annette Meeks | CEO, Freedom Foundation of MN | Medical Arts Building, 825 Nicollet Mall, Suite 815, Minneapolis, MN 55402 |
| Sue Grafstrom | Board President, Minnesota Rural Health Association | P.O. Box 62, Warren, MN, USA, 56762 |
| Brent Jeffers | President, Inter-Faculty Organization | 490 Concordia Ave, Suite 125, St. Paul, MN, 55103 |

Additionally, since the outset of the rulemaking process, the Department has maintained an email list of interested person and organizations. Commerce will provide each such person and organization an electronic notice with a hyperlink to electronic copies of the Notice, SONAR and the proposed rule amendments. The department will issue a press release announcing the Notice of Hearing and invite people to review and comment on the proposed rules. We will ask and encourage other organizations to publicize the public hearing on their websites and in their print newsletters. Commerce will give notice to the Legislature per Minnesota Statutes, section 14.116. This Notice Plan does not include notifying the Commissioner of Agriculture because the rules do not affect farming operations.

Under Minnesota Statutes, section 14.14, subdivision 1a, Commerce believes its regular means of notice, including publication in the *State Register* will adequately provide notice of this rulemaking to persons interested in or regulated by these rules.

Performance-based rules

Minnesota Statutes, section 14.002, requires state agencies, whenever feasible, to develop rules that are not overly prescriptive and inflexible, and rules that emphasize achievement of the agency’s regulatory objectives while allowing maximum flexibility to regulated parties and to the agency in meeting those objectives.

Commerce, in designing this rule, has kept in mind the directive to maintain flexibility. As noted above in the rule by rule analysis, Commerce has made specific choices that retain flexibility so as not to box Commerce or regulated entities into current technology or processes which may later prove inefficient. Throughout the development of the proposed rules and this SONAR, Commerce made every attempt to develop rules that will be understandable for Plan Sponsors, PBMs, Pharmacists, and enrollees to ensure efficient and effective enforcement of the PBM Law. Further, the Department proposes these amendments to make the rules clear in purpose and intent, flexible, and not overly prescriptive while allowing the state to fulfill its obligation of ensuring chapter 62W is carried out consistent with the intent of the legislature.

Consult with MMB on local government impact

As required by Minnesota Statutes, section 14.131, the Department will consult with Minnesota Management and Budget (MMB). Commerce will do this by sending MMB copies of the documents that we send to the Governor’s Office for review and approval on the same day we send them to the Governor’s office. We will do this before the Department’s publishing the Notice of Intent to Adopt. The documents will include: The Governor’s Office Proposed Rule and SONAR Form; the proposed rules; and the SONAR. The Department will submit a copy of the cover correspondence and any response received from Minnesota Management and Budget to OAH at the hearing or with the documents it submits for ALJ review.

Impact on local government ordinances and rules

Minnesota Statutes, section 14.128, subdivision 1, requires an agency to make a determination of whether a proposed rule will require a local government to adopt or amend any ordinances or other regulation in order to comply with the rule. Commerce has determined that the proposed rule will not have any effect on local ordinances or regulations.

Costs of complying for small business or city

Minnesota Statutes, section 14.127, subdivisions 1 and 2, require an agency to “determine if the cost of complying with a proposed rule in the first year after the rule takes effect will exceed \$25,000 for any one business that has less than 50 full-time employees, or any one statutory or home rule charter city that has less than ten full-time employees.” As the rules place no requirements on local government, there will be no cost to any statutory or home rule charter city that has less than ten full-time employees. With respect to any potential cost to small business with less than 50 full-time employees, as noted above, the vast majority of compliance costs associated with the rule originate in Minnesota Statutes, chapter 622W, not in the proposed rules.

Authors, witnesses and SONAR exhibits

Witnesses and other staff

Commerce does not anticipate calling any non-department witnesses. The only witnesses would be Commerce staff who are involved in rulemaking for these proposed rules, including:

- 1) Galen Benshoof (he/him/his), Minnesota Department of Commerce, Director of Regulation and Policy Strategy, will testify about the proposed rule language.
- 2) Andy Kleinendorst, (he/him/his), Minnesota Department of Commerce, Grant Program Manager, will testify about the proposed rule language
- 3) Julia Lyng (she/her/hers), Minnesota Department of Commerce, Chief Health Actuary, will testify about the proposed rule language.
- 4) Philip B. Moosbrugger (he/him/his), Minnesota Department of Commerce, Manager of WC Self-Insurance and MWCARP, will testify about the proposed rule language.
- 5) Eric Taubel (he/him/his), Minnesota Department of Commerce, Attorney, will testify about the proposed rule language, any Minnesota Administrative Procedures Act process questions, and introduce any required jurisdictional documents into the record.

SONAR exhibits

In support of the need for and reasonableness of the proposed rules, the Department anticipates that it will enter the following exhibits into the hearing record:

- 1) Advisory Committee Manual
- 2) Advisory Committee Meeting Agenda for February 12, 2020.
- 3) Advisory Committee Meeting Agenda for March 5, 2020.
- 4) Advisory Committee Meeting Agenda for May 13, 2020.
- 5) Advisory Committee Meeting Agenda for June 11, 2020.
- 6) Advisory Committee Meeting Agenda for July 9, 2020.
- 7) Advisory Committee Meeting Agenda for September 10, 2020.

Conclusion

The department's proposed rule amendments comply with the legislative directive given during the 2019 legislative session. The agency has provided the necessary notice and, in this SONAR, documented its compliance with all applicable administrative rulemaking requirements of Minnesota statute and rules. Based on the forgoing, the proposed amendments are both needed and reasonable.



Grace Arnold, Commissioner
Minnesota Department of Commerce

August 2, 2021

Date