

STATE OF MINNESOTA
OFFICE OF ADMINISTRATIVE HEARINGS

In the Matter of Proposed Adoption of New
Rules Governing Pharmacy Benefit
Manager (PBM) Licensure and Regulation

**REPORT OF THE
ADMINISTRATIVE LAW JUDGE**

This matter came before Administrative Law Judge Kimberly Middendorf for a rulemaking hearing on September 20, 2021. To safeguard public health due to the ongoing COVID-19 pandemic, the public hearing was held remotely through an interactive video conference on the WebEx platform.

As explained below, the Minnesota Department of Commerce (Department or Commerce) proposes to adopt new administrative rules to implement and enforce Minnesota Statutes chapter 62W, the Minnesota Pharmacy Benefit Manager Licensure and Regulation Act (PBM Law), which was enacted in 2019. The public hearing and this Report are part of a larger rulemaking process under the Minnesota Administrative Procedure Act.¹ The Minnesota Legislature designed this process to ensure that state agencies meet all requirements of law and rule in adopting and amending rules.

The public hearing was conducted to permit Department representatives and the Administrative Law Judge the opportunity to hear public comments regarding the impact of the proposed rules, and any changes that might be appropriate. Further, the hearing process provides the public an opportunity to review, discuss, and critique the proposed rules, and to ensure a fully developed rulemaking record. In addition to the comments received at the public hearings, the public was permitted to submit written comments into the record.

The Department and the Administrative Law Judge received written comments on the proposed rules prior to the hearing. At the hearing, the deadline for filing written comment was extended to October 8, 2021, to allow interested persons and the Department an opportunity to submit written comments. Following the initial comment period, the record remained open for an additional five business days to allow interested persons and the Department the opportunity to file a written response to the comments received during the initial period. A number of comments were received into

¹ See Minn. Stat. §§ 14.05-.20 (2020).

the record during the rulemaking process.² To aid the public in participating in this matter, comments were posted on the Office of Administrative Hearings' website as they were received. The hearing record closed for all purposes on October 15, 2021.³

As described more extensively below, the Department must establish that the proposed rules are needed and reasonable; the rules are within the agency's statutory authority; the agency has fulfilled all procedural requirements; and that any modifications to the rule made after the proposed rules were initially published in the *State Register* are within the scope of the matter that was originally announced.

SUMMARY OF CONCLUSIONS

The Department established it has the statutory authority to adopt the proposed rules, except as to Minn. R. 2737.0600, subp. 4; it complied with all procedural requirements of law and rule; and the proposed rules are needed and reasonable. Therefore, the Administrative Law Judge **APPROVES** the proposed rules and recommends they be adopted. Minn. R. 2737.0600, subp. 4, is **APPROVED** as modified herein.

Based upon the record, including the Department's exhibits, and the oral and written comments received, the Administrative Law Judge makes the following:

² See Exhibit (Ex.) I, containing written comments from Bentley Graves, on behalf of Minnesota Chamber of Commerce (Chamber Comment); Cory Brown, on behalf of Sanford Health (Sanford Comment), Alex Sommer, on behalf of Prime Therapeutics (Prime Comment), Michelle Mack, on behalf of Pharmaceutical Care Management Association (PCMA), Lucas Nesse, on behalf of Minnesota Council of Health Plans (MCHP Comment), Sarah Derr, Tamara Bezidcek, and Buck Humphrey, on behalf of Minnesota Pharmacy Alliance and Minnesota Society of Health-Systems Pharmacists (Pharmacists Comment); Andrew L. Askew, on behalf of Essentia Health (Essentia Comment); Joshua D. Keepes, on behalf of America's Health Insurance Plans (AHIP Comment); Matthew Magner, on behalf of National Community Pharmacists Association (NCPA Comment); Tony Collins-Kwong, on behalf of Allina Health (Allina Comment); Robert Beacher, on behalf of Fairview Health Services (Fairview Comment); Christene Jolowsky, for Hennepin Healthcare – HCMC (HCMC Comment); Mary Krinkie and Danny Ackert, on behalf of Minnesota Hospital Association (MHA Comment); Paul Krogh, for North Memorial Health (North Memorial Comment); Steven C. Anderson and Jill McCormack, for National Association of Chain Drug Stores (NACDS Comment); and Mark Whittier (Whittier Comment). Sarah Derr, Tamara Bezidcek, and Buck Humphrey submitted rebuttal comments on behalf of Minnesota Pharmacy Alliance and Minnesota Society of Health-Systems Pharmacists (Pharmacists Rebuttal) and Steven C. Anderson and Jill McCormack submitted rebuttal comments on behalf of National Association of Chain Drug Stores (NACDS Rebuttal). Ms. Derr, Ms. Mack, and Mr. Sommer also offered oral commentary at the hearing. See Transcript (Tr.). Gary Boehler, on behalf of Dakota Drug (Dakota), offered an extensive list of concerns about the PBM Law, many of which illuminate problematic PBM practices and were similar to those raised by other stakeholders throughout the rulemaking process. See Ex. I. Comments were offered by members of the public on the topics of wound care and CBD, which are not germane to the proposed rules.

³ Transcript (Tr.) at 11, 43; Ex. K (Hearing Presentation).

FINDINGS OF FACT

I. Background Regarding the Proposed Rules

1. The Department proposes new rules to provide guidance on Pharmacy Benefit Manager (PBM) licensing, regulation, and transparency reporting (hereinafter the “PBM Law” or the “Act”).⁴

2. PBMs manage the pharmacy benefits provided by health plans and plan sponsors. PBMs exist 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.⁵

3. A PBM is an entity that contracts directly or indirectly with pharmacies to provide prescription drugs to enrollees or other covered individuals; administers a prescription drug benefit; processes or pays pharmacy claims; creates or updates prescription drug formularies; makes or assists in making prior authorization determinations on prescription drugs; administers rebates on prescription drugs; or, establishes a pharmacy network.⁶

4. PBMs have existed for approximately 50 years but have only recently become subject to regulation. 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, 2020.⁷

5. According to PCMA, PBMs administer prescription drug plans for more than 266 million Americans with health coverage provided by large and small employers, health insurers, labor unions, and federal- and state-sponsored health programs.⁸

6. The Pharmacists describe the industry conditions leading to the passage of the PBM Law as follows:

At a time when Minnesota leads the nation in pharmacy closures and more than 30 percent of independent pharmacies have closed in Minnesota over the past decade, critical access to pharmacy healthcare services for . . . Minnesota patients is in jeopardy. Over the past several years, the Minnesota legislature heard from patients, pharmacy owners and pharmacists from across Minnesota about consistent below-cost payment reimbursement by PBMs, a tremendous increase in the use of retroactive fees, and PBM-owned pharmacy and mail order steering, as well as patient

⁴ Ex. D; Tr. at 6-7.

⁵ Ex. D.

⁶ Ex D; Tr. at 7.

⁷ Ex. D.

⁸ Tr. at 27.

prescription poaching and, in general, a fairly hostile payer/payee environment; all the while, PBMs are earning record profits.⁹

7. Prior to the enactment of the PBM Law, PBMs doing business in Minnesota did not require specific licensure. Many PBMs were licensed as “Third Party Administrators” (TPA) under Minnesota law. PBM licensure is separate and distinct from TPA licensure. The Department anticipates that most entities meeting the PBM definition will maintain dual licensure.¹⁰

8. Commerce is proposing adoption of these rules to address the following needs: first, create clarity for industry and Minnesotans of the meaning of key statutory provisions; second, increase predictability in the enforcement of the PBM Law; and third, provide greater detail to the processes required by statute, such as licensure and data reporting.¹¹

9. This rulemaking is informed by the Department’s experience of implementing the PBM Law since it went into effect in 2019.¹²

10. In addition, the Department sought input and comments from the general public, stakeholders, and individuals and entities directly impacted by the content of proposed rules.¹³

11. Commerce maintained a website for the PBM Law’s rulemaking process: <https://mn.gov/commerce/policy-data-reports/rulemaking/#/detail/appld/2/id/412841>.¹⁴

12. In early 2020, Commerce formed a rulemaking advisory committee to provide input and advice on the Pharmacy Benefit Manager (PBM) Licensure and Regulation Act. Commerce commissioned the Advisory Committee to obtain advice and input from stakeholders on development of the rule. The work of the Advisory Committee was limited to advising on matters directly concerning potential areas of rulemaking for PBM licensure and regulation under Minn. Stat. ch. 62W.¹⁵

13. The Advisory Committee met on six occasions in 2020 to discuss various topics and issues related to the PBM Law and the proposed rule. These meetings were open to members of the public.¹⁶

⁹ Tr. at 17.

¹⁰ Ex. D.

¹¹ *Id.*; Tr. at 7, 12.

¹² Ex. D; Tr. at 14.

¹³ *Id.*; Tr. at 12-13.

¹⁴ Ex. D; Tr. at 12, 14-15.

¹⁵ Ex. D; Tr. at 13.

¹⁶ Ex. D at 5; Tr. at 13.

II. Rulemaking Authority

14. Commerce cites Minn. Laws. 2019 ch. 39, § 1 as its authority for the PBM rules.¹⁷

15. Minn. Laws. 2019 ch. 39, § 1 provides the Department's PBM rulemaking authority as follows:

The commissioner of commerce may adopt permanent rules for license application and renewal requirements, forms, procedures, network adequacy, and reporting procedures and compliance, for pharmacy benefit manager licensing under Minnesota Statutes, chapter 62W. The commissioner must not adopt rules to implement Minnesota Statutes, chapter 62W, under any other grant of rulemaking authority. If the commissioner of commerce does not adopt rules by January 1, 2022, rulemaking authority under this section is repealed. Rulemaking authority under this section is not continuing authority to amend or repeal rules. Notwithstanding Minnesota Statutes, section 14.125, any additional action on rules after adoption must be under specific statutory authority to take the additional action.¹⁸

16. Commenters supporting and opposing the proposed rules filed comments addressing the Department's authority to adopt the rules.¹⁹

17. Opponents of the rules suggest that the PBM Law is sufficiently specific on its face and does not require rulemaking to implement and enforce it except in very specific and narrow instances. They view this rulemaking as unnecessary and urge a narrow construction of the Department's rulemaking authority.²⁰

18. The legislature has established that "[t]he object of all interpretation and construction of laws is to ascertain and effectuate the intention of the legislature."²¹ Every law must be construed, if possible, to give effect to all of its provisions,²² and it is presumed that the legislature intends the entire statute to be effective and certain.²³

19. Under Minn. Laws. 2019 ch. 39, § 1, the legislature determined that the public interest required that Commerce establish rules to regulate PBMs, including the licensing, network adequacy, reporting, and compliance of PBMs, and granted Commerce authority to adopt rules and standards having the force of law to address these

¹⁷ Ex. D; *see also* Tr. at 11-12.

¹⁸ 2019 Minn. Laws ch. 39 § 1.

¹⁹ *See* Ex. I (Comments).

²⁰ *See* Ex. I; *see also* Tr. at 28.

²¹ Minn. Stat. § 645.16 (2020).

²² *Id.*

²³ Minn. Stat. § 645.17(2) (2020).

topics. Under the plain language of this law, the Department has the statutory authority to adopt the proposed rules.²⁴

III. Procedural Requirements of Minn. Stat. Ch. 14 and Minn. R. Ch. 1400

20. This rulemaking matter has proceeded according to statutes and rules governing the process for the adoption or amendment of rules following a public hearing. The process is intended to fulfill one of the purposes of the Minnesota Administrative Procedure Act, as identified by the legislature in Minn. Stat. § 14.001 (2020), which is to increase public participation in the formulation of administrative rules. A rulemaking proceeding that includes one or more public hearings, in addition to a period for submission of written comments, offers an opportunity for members of the public to participate in the rulemaking process.

A. Request for Comments

21. Minn. Stat. § 14.101 requires that an agency solicit comments from the public on the subject matter of a proposed rulemaking at least 60 days prior to the publication of a notice of intent to adopt rules or a notice of hearing. Such notice must be published in the *State Register*.²⁵

22. Consistent with The Minnesota Administrative Procedures Act (APA), Commerce published a request for comments in the Minnesota State Register, on Monday, September 30, 2019.²⁶ The Department explained the purpose of the rulemaking as follows:

The Department is considering rules needed to establish explicit requirements for licensure and renewal of PBMs doing business with plan sponsors in the state. The [D]epartment is also considering rules needed to finalize requirements related to data collection, transparency reporting, enforcement standards, and other items needed as they come up to appropriately implement the Minnesota Pharmacy Benefit Manager Licensure and Regulation Act.²⁷

23. The Request for Comments was published at least 60 days prior to the publication of the Notice of Intent to Adopt Rules.

24. Commerce complied with the requirements established by Minn. Stat. § 14.101.

²⁴ Where comments were offered in challenge to Commerce's authority to adopt a specific provision of the rules, those comments are addressed in the rule-by-rule analysis below.

²⁵ Minn. Stat. § 14.101.

²⁶ Ex. A (Request for Comments).

²⁷ *Id.*

B. Publication of Notice of Intent to Adopt Rules

25. Minn. Stat. § 14.14, subd. 1a(a) (2020), and Minn. R. 1400.2080, subp. 6 (2021), require that an agency publish in the *State Register* a notice of intent to adopt rules at least 30 days prior to the date of hearing and at least 30 days prior to the end of the comment period.

26. The Department requested approval of its Additional Notice Plan and Notice of Intent to Adopt Rules with a Hearing (Notice of Hearing) on July 30, 2021. The Administrative Law Judge approved both by Order dated August 4, 2021.²⁸ A public hearing on the proposed rules was scheduled to take place on September 20, 2021.²⁹

27. The Department published its Notice of Hearing in the *State Register* issued on August 16, 2021 (46 SR 137).³⁰ The Notice of Hearing scheduled the hearing to take place by video conference on September 20, 2021. The Notice of Hearing provided information on how persons could submit comments on the proposed rules and how persons could join the hearing via the internet or telephone.³¹

28. The Notice of Hearing contained all the information required under Minn. R. 1400.2080 (2021) and was published more than 30 days before the hearing and the close of the comment period as required by Minn. Stat. § 14.14, subd. 1a(a).³²

C. Notice Requirements

1. Notice to Official Rulemaking List

29. Minn. Stat. § 14.14, subd. 1a (2020), requires that each agency maintain a list of all persons who have registered with the agency for the purpose of receiving notice of rule proceedings.

30. On August 17, 2021, Commerce emailed a copy of the Notice of Hearing to all persons and entities on its official rulemaking list.³³ The official rulemaking list included all persons and entities who requested to be placed on the Department's GovDelivery system for the purpose of receiving such notice.³⁴

31. The Notice of Hearing advised that the comment period would expire on a date to be determined by the Administrative Law Judge following the hearing on September 20, 2021.³⁵ The comment period was extended until October 8, 2021.³⁶

²⁸ See Order Approving Additional Notice Plan and Notice of Hearing (Aug. 4, 2021).

²⁹ Ex. F (Notice of Hearing).

³⁰ *Id.*

³¹ *Id.*

³² See *id.*

³³ Ex. G-1 (Certificate of Mailing Notice of Hearing).

³⁴ *Id.*

³⁵ Ex. F.

³⁶ Tr. at 11.

32. Minn. Stat. § 14.14, subd. 1a, requires that an agency give notice of its intent to adopt rules by U.S. mail or electronic mail to all persons on its official rulemaking list at least 30 days before the date of the hearing.

33. Minn. R. 1400.2080, subp. 6, provides that a notice of hearing or notice of intent to adopt rules must be mailed at least 33 days before the end of the comment period or the date of the hearing.

34. The Department fulfilled the notice requirements established in Minn. Stat. § 14.14 and Minn. R. 1400.2080, subp. 6.

2. Additional Notice

35. Minn. Stat. § 14.14, subd. 1a(a), requires that an agency make reasonable efforts to notify persons or classes of persons who may be significantly affected by the rule being proposed by giving notice of its intent to adopt rules. Such notice may be made in newsletters, newspapers, or other publications, or through other means of communication.³⁷ This notice is referred to as “additional notice” and is detailed by an agency in its additional notice plan.

36. Minn. Stat. § 14.131 (2020) requires that an agency include in its Statement of Need and Reasonableness (SONAR) a description of its efforts to provide additional notice. Alternatively, the agency must detail why additional notification efforts were not made.³⁸

37. An agency may request approval of its additional notice plan by an administrative law judge prior to service.³⁹

38. Commerce requested approval of its Additional Notice Plan, which was granted on August 4, 2021.⁴⁰

39. The Department provided notice, as follows:⁴¹

- (a) It published Notice of Hearing on Commerce’s PBM Rule webpage at <https://mn.gov/commerce/policy-data-reports/rulemaking/#/detail/appld/2/id/412841>;
- (b) On August 17, 2021 at Saint Paul, Ramsey County, Minnesota, the Department mailed the Notice of Hearing to persons on the Department’s rulemaking mailing list established by Minnesota Statutes, section 14.14, subdivision 1a;

³⁷ Minn. Stat. § 14.14, subd. 1a(a).

³⁸ Minn. Stat. § 14.131.

³⁹ Minn. R. 1400.2060 (2021).

⁴⁰ Order Approving Additional Notice Plan and Notice of Hearing (Aug. 4, 2021).

⁴¹ Ex. H (Certificate of Additional Notice).

- (c) The Department provided an extended comment period by scheduling the rulemaking hearing more than 30 days after the Notice of Hearing was published;
- (d) The Department provided specific notice to health insurers, health care organizations, health care unions, other health care industry organizations, and members of the public, as described in the Additional Notice Plan;
- (e) The Department posted relevant rulemaking updates and associated documents including the Notice of Hearing, SONAR, and proposed rule on the PBM rulemaking webpage at <https://mn.gov/commerce/policy-data-reports/rulemaking/#/detail/appld/2/id/412841>.

40. The Department complied with its Additional Notice Plan and fulfilled the additional notice requirements provided in Minn. Stat. §§ 14.14, subd. 1a(a), .131.

3. Notice to Legislators

41. Under Minn. Stat. § 14.116 (2020), an agency is required to send a copy of the Notice of Intent to Adopt and the SONAR to certain legislators at the time it mails its Notice of Intent to Adopt to persons on its rulemaking list and pursuant to its additional notice plan.

42. On August 20, 2021, Commerce emailed a copy of the Notice of Hearing, SONAR, and proposed rules to the chairs and ranking minority party members of the legislative policy and budget committees with jurisdiction over the proposed rules, and to the Legislative Coordinating Commission.⁴²

43. Commerce fulfilled its notification responsibilities under Minn. Stat. § 14.116.

4. Notice to the Legislative Reference Library

44. Minn. Stat. § 14.131 and Minn. R. 1400.2070, subp. 3 (2021), require the agency to send a copy of the SONAR to the Legislative Reference Library when the Notice of Intent to Adopt is mailed.

45. On August 25, 2020, the Department emailed a copy of the SONAR to the Legislative Reference Library.⁴³

46. The Department complied with Minn. Stat. § 14.131 and Minn. R. 1400.2070, subp. 3.

⁴² Ex. G3 (Certificate of Sending Notice and SONAR to Legislators and Legislative Coordinating Commission).

⁴³ Ex. E.

5. Notice to Commissioner of Agriculture

47. Minn. Stat. § 14.111 (2020) imposes additional notice requirements when the proposed rules affect farming operations. The statute requires that an agency provide a copy of any such changes to the Commissioner of Agriculture at least 30 days prior to publishing the proposed rules in the *State Register*.⁴⁴

48. The Department's proposed PBM rule does not impose restrictions or have an impact on farming operations. As a result, Commerce was not required to notify the Commissioner of Agriculture.⁴⁵

D. Rule Hearing and Submission of Written Comments.

49. The Administrative Law Judge conducted a public rulemaking hearing on September 20, 2021.⁴⁶ Julia Dreier, Deputy Commissioner for Commerce's Insurance Division, and Galen Benshoof, Director of Regulation and Policy Strategy, presented information about the rule and were available for questions during the hearing.⁴⁷ Department Counsel Eric Taubel was also in attendance and available for questions.⁴⁸

50. In support of the Department's request for approval to adopt the proposed rules, the following documents were received into the record as exhibits, as required by Minn. Stat. § 14.14, subd. 2a, and Minn. R. 1400.2220 (2021):

Ex. A: Commerce's Request for Comments as published in the *State Register* on September 30, 2019;

Ex. C: Proposed rules dated July 27, 2021 (C1), including the Revisor's approval (C2);

Ex. D: Commerce's SONAR, dated August 3, 2021;

Ex. E: Copy of transmittal letter mailing the SONAR to the Legislative Reference Library on August 25, 2021;

Ex. F: Notice of Hearing as published in the *State Register* on August 16, 2021;

Ex. G: Certificate of Mailing the Notice of Hearing to the Agency's rulemaking mailing list on August 17, 2021 (G1); Certificate of Accuracy of Mailing List (G2); and Certificate of Sending Notice of Hearing and SONAR to Legislators and Legislative Coordinating Commission (LCC) on August 20, 2021 (G3);

⁴⁴ Minn. Stat. § 14.111.

⁴⁵ See Ex. D at 96.

⁴⁶ See Tr.

⁴⁷ Tr. at 6-7, 11-15.

⁴⁸ Tr. at 2.

Ex. H: Certificate of Giving Additional Notice Under the Additional Notice Plan on August 17, 2021;

Ex. I: Written comments on the proposed rules that the Department received during the comment period that followed the Notice of Hearing (I1), and during the post-hearing comment period (I2); and,

Ex. K: Additional documents, including Advisory Committee materials, the memorandum from Minnesota Management and Budget (MMB) regarding MMB's review under Minn. Stat. § 14.131, and the Department's slide presentation from the hearing.

51. Mr. Benshoof addressed the procedural requirements for rulemaking.⁴⁹ Deputy Commissioner Dreier and Mr. Benshoof presented Commerce's positions as to the need for and reasonableness of the rule.⁵⁰

52. Approximately 40 people attended the hearing on September 20, 2021. The hearing continued until all interested persons, groups, or associations had an opportunity to be heard concerning the proposed rules. Three members of the public made statements during the hearing.⁵¹

53. The Administrative Law Judge extended the time period for submission of public comments to October 8, 2021, to permit interested persons and the Department additional time to submit written comments.⁵²

54. Following the comment period, the hearing record remained open an additional five business days to permit interested persons and the Department to reply to the earlier-submitted comments. The rebuttal comment period closed on October 15, 2021, and the hearing record closed on that date.⁵³

V. Statutory Requirements

A. Regulatory Factors

55. The Administrative Procedure Act requires an agency adopting rules to address eight factors in its SONAR.⁵⁴ Those factors are:

- (1) a description of the classes of persons who probably will be affected by the proposed rule, including classes that will bear the costs of the proposed rule and classes that will benefit from the proposed rule;

⁴⁹ Tr. at 11-13.

⁵⁰ Tr. at 6-7; 11-15.

⁵¹ See Tr.

⁵² See Minn. Stat. § 14.15, subd. 1.

⁵³ See Tr. at 11; Ex. K.

⁵⁴ Minn. Stat. § 14.131.

- (2) the probable costs to the agency and to any other agency of the implementation and enforcement of the proposed rule and any anticipated effect on state revenues;
 - (3) a determination of whether there are less costly methods or less intrusive methods for achieving the purpose of the proposed rule;
 - (4) a description of any alternative methods for achieving the purpose of the proposed rule that were seriously considered by the agency and the reasons why they were rejected in favor of the proposed rule;
 - (5) 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;
 - (6) the probable costs or consequences of not adopting the proposed rule, including those costs or consequences borne by identifiable categories of affected parties, such as separate classes of government units, businesses, or individuals;
 - (7) an assessment of any differences between the proposed rule and existing federal regulations and a specific analysis of the need for and reasonableness of each difference; and
 - (8) an assessment of the cumulative effect of the rule with other federal and state regulations related to the specific purpose of the rule and reasonableness of each difference.⁵⁵
- 1. Classes of Persons Affected, Benefitted, or Bearing Costs of the Proposed Rule**

56. The Department states that the persons and entities most affected by the rule includes PBMs, pharmacists and Pharmacy owners, enrollees, plan sponsors, Commerce, and Minnesota Department of Health (MDH).⁵⁶

(a) Classes of persons affected by the proposed rule

57. PBMs are the only group directly regulated by the proposed rules. The rules will require PBMs to become licensed, submit annual reports, and refrain from certain practices such as self-dealing, in furtherance of the goals of the PBM Law. PBMs, many of which have 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

⁵⁵ *Id.*

⁵⁶ Ex. D at 22.

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. Commerce notes that it is the PBM Law rather than these rules that drives these costs.⁵⁷

58. The Department anticipates that these rules will likely reduce indirect costs of the Department, PBMs and many TPAs by clarifying and standardizing compliance practices for all stakeholders and avoiding legal challenges to the Department's implementation of the PBM Law. Commerce predicts that the cost of the proposed rules will likely be minimal to PBMs, since most of the direct and indirect cost is dictated by the governing statute. One goal of the rules is to ensure that costs incurred by PBMs and the Department are reasonable, while providing usable data that aids the Department in meeting the intent of the PBM Law.⁵⁸

(b) Classes of persons benefitted by the proposed rules

59. Commerce asserts that the rules will benefit Minnesotans with insurance that provides prescription benefits via PBMs. Plan sponsors doing business in Minnesota and offering drug benefits to their employees will benefit from the rules by having increased access to their own PBM data. Transparency in pharmacy benefit management will improve plan sponsors' ability to budget costs, make informed pharmacy coverage and operational decisions, and select PBM partners. Researchers and policymakers will also benefit from annual transparency reporting.⁵⁹

2. Probable Costs to the Agency and Other Agencies for Implementation and Enforcement and Effect on State Revenues

60. According to the Department, these rules are not likely to increase agency cost. Rather, any cost incurred flows from the PBM Law and is covered by specific appropriations. Moreover, Commerce maintains it is possible that state revenues would increase due to civil penalties for violations of the statute and rules.⁵⁹

3. Less Costly or Less Intrusive Methods for Achieving the Purpose of the Proposed Rule

61. 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 PBM licensing under the PBM Law. Commerce relied on industry participants to guide the development of these rules, to achieve rules as narrow in scope as possible while still accomplishing the legislature's goals for the PBM Law. The Department states it knows

⁵⁷ *Id.*

⁵⁸ *Id.*

⁵⁹ *Id.* at 23.

no less costly or intrusive method for regulating and licensing PBMs in compliance with its legislative mandate other than the proposed rules.⁶⁰

4. Description of Alternative Methods for Achieving the Purpose of the Proposed Rule Considered by the Agency and Why Alternatives Were Rejected

62. Commerce states that it has, on occasion, used bulletins and legislative updates to provide guidance to industry. Commerce believes that issuing a bulletin or guidance to address PBM Law topics rather than rulemaking would be less time consuming and potentially cheaper. The number and breadth of issues arising from the PBM Law makes an informal approach like issuing industry guidance an inappropriate one. Commerce notes that informal guidance raises enforceability challenges. The rulemaking process, unlike the process of issuing a bulletin, is transparent and affords members of affected industries and the public the ability to participate in the process and shape the outcomes.⁶¹

63. Because the Department has been directed to make rules, it contends that adopting the standards in these rules is the only appropriate mechanism available.⁶²

5. Probable Costs of Complying with Proposed Rules, Including the Portion of the Total Costs Borne by Identifiable Categories of Affected Parties

64. The Department conducted an analysis of the costs and benefits of the proposed rules. Overall, the Department found a net benefit results from adopting the rules.⁶³

65. The probable costs of complying with the proposed rules are expected to be a minimal addition to the costs necessitated by compliance with the PBM Law. The proposed rules, by clarifying the statutory requirements, may reduce administrative costs borne by affected entities.⁶⁴

6. Probable Costs or Consequences of not Adopting the Proposed Rules, Including Costs Borne by Individual Categories of Affected Parties

66. Commerce concludes failure to adopt the proposed would have substantial consequences for regulated entities. Without the rules, the regulatory environment will be an uncertain one, leaving PBMs to guess how Commerce will enforce the PBM Law. This

⁶⁰ *Id.*

⁶¹ *Id.* at 23-24.

⁶² *Id.*

⁶³ *Id.* at 24.

⁶⁴ *Id.*

uncertainty can result in increased costs to PBMs, Plan Sponsors and other regulated entities who are left to guess at how to achieve compliance with the statute.⁶⁵

67. The legislative mandate to establish regulatory standards is a key provision of the PBM Law. Failure to adopt the rules not only injects uncertainty in the implementation of the PBM Law, but also undermines the legislature's intent in passing the PBM Law.⁶⁶

7. Assessment of Differences Between Proposed Rules and Existing Federal Regulations

68. Commerce recognizes that healthcare and insurance are fields subject to substantial regulation under state and federal law. 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 government has chosen to act, its laws are generally understood to preempt state laws.⁶⁷ In the area of health insurance, these issues typically arise with respect to the Medicare Act⁶⁸ and the Employee Retirement Income Security Act of 1974 (ERISA). In the context of the PBM Law, the question of whether it is preempted by the Employee Retirement Income Security Act of 1974 (ERISA) has been heavily debated.⁶⁹

69. 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.⁷⁰

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."⁷¹ The central question in determining whether ERISA preempts a state law is whether that law is related to an employee benefit plan.⁷²

⁶⁵ *Id.*

⁶⁶ *Id.*

⁶⁷ *Id.* at 25.

⁶⁸ 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)).

⁶⁹ See e.g., Exs. D, I and K.

⁷⁰ 29 U.S.C. § 1144(a).

⁷¹ 29 U.S.C. § 1144(b)(2)(A).

⁷² Ex. D at 25.

70. Commerce reviewed and thoroughly considered court opinions from across the nation in which ERISA preemption of PBM regulations was considered.⁷³ Commerce states that approximately thirty-eight states have passed some form of PBM regulations.⁷⁴

71. A recent decision by the United States Supreme Court, *Rutledge v. PCMA*,⁷⁵ suggests that in the context of PBM regulations, the Supreme Court does not view PBM regulation as preempted by ERISA. The Supreme Court held that Arkansas PBM regulation did not act immediately and exclusively on ERISA plans, because it applies to all PBMs irrespective of plan sponsor. The Court noted that the Arkansas law, like the proposed rules here, does not actually regulate any benefits plans at all. ERISA preemption does not arise simply because a state law attempts to regulate an area that falls within ERISA's coverage. State regulation that does not "forc[e] plans to adopt any particular scheme of substantive coverage" is not preempted by ERISA.⁷⁶

72. Commerce established that it complied with the directive of Minn. Stat. § 14.131 to consider differences between the proposed rules and federal regulations.

8. Cumulative Effect of the Rule with Other Federal and State Regulations

73. Minn. Stat. § 14.131 defines "cumulative effect" as "the impact that results from incremental impact of the proposed rule in addition to the other rules, regardless of what state or federal agency has adopted the other rules."

74. As has been noted, the health insurance is heavily regulated but PBMs doing business in Minnesota are not. The cumulative effect of the proposed rules is to have clear processes and requirements, which are neither duplicative of federal regulation nor in tension with federal regulation. Commerce notes it is mindful of established precedent which curtails its regulatory jurisdiction, such as Medicare Part D preemption.⁷⁷

B. Performance-Based Regulation

75. An agency is required to describe in its SONAR the manner in which the agency has considered and implemented the legislative policy supporting performance-based regulatory systems.⁷⁸ A performance-based rule is one that emphasizes superior achievement in meeting the agency's regulatory objectives and maximum flexibility for the regulated party and the agency in meeting those goals.⁷⁹

76. Commerce, in designing this rule, has kept in mind the directive to maintain flexibility. Commerce has made specific choices that retain flexibility and do not mandate

⁷³ See *id.* at 24-30.

⁷⁴ *Id.* at 25.

⁷⁵ 141 S.Ct. 474 (2020).

⁷⁶ *Id.* at 481.

⁷⁷ Ex. D at 30.

⁷⁸ Minn. Stat. §§ 14.002; .131.

⁷⁹ Minn. Stat. § 14.002.

current technologies or processes that may become obsolete. Throughout the development of the proposed rules and this SONAR, Commerce worked with plan sponsors, PBMs, pharmacists, and enrollees to ensure efficient and effective enforcement of the PBM Law. Further, the Department states it has fashioned rules that are clear in purpose and intent, flexible, and not overly prescriptive while allowing the state to fulfill its obligation of ensuring Minn. Stat. ch. 62W is carried out consistent with the intent of the legislature.⁸⁰

C. Consultation with the Commissioner of Minnesota Management and Budget

77. Minn. Stat. § 14.131 requires that agencies consult with the Commissioner of Minnesota Management and Budget (MMB) to help evaluate the fiscal impact and fiscal benefits of the proposed rule on local units of government.

78. The Department sent a letter to MMB's Commissioner, along with the proposed rules and SONAR, seeking the required consultation. On September 17, 2021, MMB issued a memorandum documenting its review, concluding that there is no anticipated fiscal impact to local units of government.⁸¹

D. Summary of Requirements Set Forth in Minn. Stat. § 14.131

79. The Administrative Law Judge finds that the Department has met the requirements established by Minn. Stat. § 14.131 for assessing the impact of the proposed rules, including consideration and implementation of the legislative policy supporting performance-based regulatory systems, and the fiscal impact on units of local government.

E. Cost to Small Businesses and Cities under Minn. Stat. § 14.127

80. Minn. Stat. § 14.127 (2020), requires the Department 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: (1) any one business that has less than 50 full-time employees; or (2) any one statutory or home rule charter city that has less than ten full-time employees.” The Department must make this determination before the close of the hearing record, and the Administrative Law Judge must review the determination and approve or disapprove it.⁸²

81. Commerce determined that the proposed rules do not directly regulate local units of government and will not impose costs on cities or small businesses in addition to costs originating from the PBM Law.⁸³

⁸⁰ Ex. D at 33.

⁸¹ Ex. K (MMB Memorandum).

⁸² Minn. Stat. § 14.127, subs. 1 and 2.

⁸³ Ex. D at 33.

82. The Administrative Law Judge finds that Commerce has made the determinations required by Minn. Stat. § 14.127 and approves those determinations.

F. Adoption or Amendment of Local Ordinances

83. Under Minn. Stat. § 14.128 (2020), the agency must determine if a local government will be required to adopt or amend an ordinance or other regulation to comply with a proposed agency rule. The agency must make this determination before the close of the hearing record, and the Administrative Law Judge must review the determination and approve or disapprove it.⁸⁴

84. The Department concluded that because PBMS are not regulated at the local level, no local government will be required to adopt or amend an ordinance or other regulation to comply with the proposed rules.⁸⁵

85. The Administrative Law Judge finds that Commerce has made the determination required by Minn. Stat. § 14.128 and approves that determination.

VI. Rulemaking Legal Standards

86. A rulemaking proceeding under the APA must include the following inquiries: whether the agency has statutory authority to adopt the rule; whether the rule is unconstitutional or otherwise illegal; whether the agency has complied with the rule adoption procedures; whether the proposed rule grants undue discretion to government officials; whether the rule constitutes an undue delegation of authority to another entity; and whether the proposed language meets the definition of a rule.⁸⁶

87. Under Minn. Stat. § 14.14, subd. 2, and Minn. R. 1400.2100 (2021), the agency must establish the need for, and reasonableness of, a proposed rule through an affirmative presentation of facts. In support of a rule, the agency may rely upon materials developed for the hearing record,⁸⁷ “legislative facts” (namely, general and well-established principles that are not related to the specifics of a particular case, but which guide the development of law and policy),⁸⁸ and the agency’s interpretation of related statutes.⁸⁹

88. A proposed rule is reasonable if the agency can “explain on what evidence it is relying and how the evidence connects rationally with the agency’s choice of action to be taken.”⁹⁰

⁸⁴ Minn. Stat. § 14.128, subd. 1.

⁸⁵ Ex. D at 33.

⁸⁶ See Minn. R. 1400.2100.

⁸⁷ See *Manufactured Hous. Inst. v. Pettersen*, 347 N.W.2d 238, 240 (Minn. 1984); *Minnesota Chamber of Commerce v. Minnesota Pollution Control Agency*, 469 N.W.2d 100, 103 (Minn. Ct. App. 1991).

⁸⁸ Compare generally *United States v. Gould*, 536 F.2d 216, 220 (8th Cir. 1976).

⁸⁹ See *Mammenga v. Agency of Human Servs.*, 442 N.W.2d 786, 789-92 (Minn. 1989); *Manufactured Hous. Inst.*, 347 N.W.2d at 244.

⁹⁰ *Manufactured Hous. Inst.*, 347 N.W.2d at 244.

89. By contrast, a proposed rule will be deemed arbitrary and capricious where the agency's choice is based upon whim or devoid of articulated reasons, or if it "represents its will and not its judgment."⁹¹

90. An important corollary to these standards is that, when proposing new rules, an agency is entitled to make choices between different possible regulatory approaches, so long as the alternative selected by the agency is a rational one. Thus, while reasonable minds might differ as to whether one or another particular approach represents "the best alternative," the agency's selection will be approved if it is one that a rational person could have made.⁹²

91. The delegation of rulemaking authority is drawn from the Minnesota Legislature and is conferred upon the agency. A judge does not fashion requirements that the judge regards as best suited for the regulatory purpose. The legal review under the APA begins with this important premise.⁹³

92. Because Commerce suggested changes to the proposed rule language after the date it was originally published in the *State Register*, it is also necessary for the Administrative Law Judge to determine if this new language is substantially different from that which was originally proposed.⁹⁴

93. On October 6, 2021, the Department detailed the revisions it would make to the proposed rules in response to the stakeholder feedback at the rulemaking hearing and during the later comment period.⁹⁵

94. The standards to determine whether any changes to proposed rules create a substantially different rule are found in Minn. Stat. § 14.05, subd. 2 (2020). The statute specifies that a modification does not make a proposed rule substantially different if:

- (1) the differences are within the scope of the matter announced . . . in the notice of hearing and are in character with the issues raised in that notice";

⁹¹ See *Mammenga*, 442 N.W.2d at 789; *St. Paul Area Chamber of Commerce v. Minn. Pub. Serv. Comm'n*, 251 N.W.2d 350, 357-58 (Minn. 1977).

⁹² *Minnesota Chamber of Commerce*, 469 N.W.2d at 103; *Peterson v. Minn. Dep't of Labor & Indus.*, 591 N.W.2d 76, 78 (Minn. Ct. App. 1999).

⁹³ See *Manufactured Housing Institute*, *supra*, 347 N.W.2d at 244 (instructing that the state courts are to restrict the review of agency rulemaking to a "narrow area of responsibility, lest [the court] substitute its judgment for that of the agency"); see also, *In the Matter of the Proposed Rules of the Minnesota Pollution Control Agency Governing Permits for Greenhouse Gas Emissions*, Minnesota Rules Chapters 7005, 7007 and 7011, Docket No. 8-2200-22910-1 at 20, REPORT OF THE ADMINISTRATIVE LAW JUDGE (Minn. Office Admin. Hearings Nov. 9, 2012).

⁹⁴ Minn. Stat. § 14.05

⁹⁵ See Initial Response to Comments Submitted During the Pre-Hearing Public Comment Period, at the September 20, 2021 Public Hearing, and During the Post-Hearing Public Comment Period up to October 6, 2021 (Response) (Oct. 6, 2021).

- (2) the differences “are a logical outgrowth of the contents of the . . . notice of hearing, and the comments submitted in response to the notice”; and
- (3) the notice of hearing “provided fair warning that the outcome of that rulemaking proceeding could be the rule in question.”⁹⁶

95. In reaching a determination regarding whether modifications result in a rule that is substantially different, the Administrative Law Judge is to consider whether:

- (1) persons who will be affected by the rule should have understood that the rulemaking proceeding . . . could affect their interests”;
- (2) the “subject matter of the rule or issues determined by the rule are different from the subject matter or issues contained in the . . . notice of hearing; and
- (3) the effects of the rule differ from the effects of the proposed rule contained in the . . . notice of hearing.”⁹⁷

VII. Rule by Rule Analysis

96. The Department’s proposed new rules chapter contains 18 rule parts that determine the scope, define key terms, establish licensing and compliance standards, and create reporting and enforcement measures.⁹⁸ Commerce states it is proposing adoption of the PBM rules “to address the following needs: first, create clarity for industry and Minnesotans of the meaning of key statutory provisions; second, increase predictability in the enforcement of the PBM statute; and third, provide greater detail to the processes required by statute[.]”⁹⁹

97. Commerce found that adoption of rules is needed and reasonable, since the PBM Law was 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. Over the course of 2020, Commerce solicited and considered extensive feedback from an advisory panel that included experts in pharmacology, health insurance, and law. Commerce also held listening sessions with interested parties. These meetings convinced the Department that rulemaking was needed to provide industry and other stakeholders with clarity and predictability in the enforcement of the PBM Law.¹⁰⁰

⁹⁶ Minn. Stat. § 14.05, subd. 2.

⁹⁷ *See Id.*

⁹⁸ Ex. C1.

⁹⁹ Response at 2; *see also* Ex. D.

¹⁰⁰ Ex. D at 6-7; Tr. at 11-15.

98. Commerce's experience with enforcing the PBM Law since it became effective at the beginning of fiscal year 2020 led it to conclude that rulemaking was necessary. Since the PBM Law became effective, Commerce has undertaken the initial license process, license renewal, and prepared and published transparency reports. This experience forms the basis for Commerce's determination of a need for rulemaking, which is particularly acute for licensure, data reporting, and PBM business practices.¹⁰¹

99. Sections of the PBM Law 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. Many of the components of the PBM Law 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.¹⁰²

100. The Department 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 the PBM Law and other insurance laws. In consultation with MDH, Commerce has proposed network adequacy standards for PBMs that are more closely aligned with consumer interests and industry standards.¹⁰³

101. The Department also seeks to ensure that the data transparency requirements placed upon PBMs will enable 1) standardized submission formats from PBMs, 2) timely understanding of expected versus actual rebates over 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.¹⁰⁴

102. Finally, Commerce believes rulemaking is needed because PBM regulation is a relatively new area of law. Commerce notes that many other states are similarly focused on topics surrounding PBMs, yet 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. Commerce believes that rulemaking will further the development of PBM regulation nationwide.¹⁰⁵

103. The Administrative Law Judge finds that the Department has demonstrated by an affirmative presentation of facts the need for and reasonableness of all rule provisions that are not specifically addressed in this Report.

¹⁰¹ Ex. D at 6-7.

¹⁰² *Id.* at 7.

¹⁰³ *Id.*

¹⁰⁴ *Id.*

¹⁰⁵ *Id.* at 7-8.

104. Further, the Administrative Law Judge finds that all provisions that are not specifically addressed in this Report are authorized by statute and that there are no defects that would bar the adoption of those rules.

A. Minn. R. 2737.0100 DEFINITIONS

105. This rule has five subparts defining terms to aid the Department in regulating under the rule.¹⁰⁶

106. Commerce submits that Subpart 3 is necessary to define the term “doing business in Minnesota.” Subpart 3 is meant to alleviate potential confusion as to entities subject to the PBM Law’s reporting requirements. The statute requires that a PBM report on behalf of any plan sponsor who does business in Minnesota. The first round of the required reporting demonstrated uncertainty among PBMs as to whether and how much data needed to be reported. PBMs often provide services across multiple states and sought clarity as to whether they would be required to report under Minn. Stat. § 62W.06, subd. 2. The Department observes that this problem is particularly acute in Minnesota because it has 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.¹⁰⁷

107. The Department proposed a definition it believes is consistent with similar definitions elsewhere in statute and provides sufficient ground for a PBM to determine 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 or under inclusive in its determination of entities subject to the PBM rules. The Department believes its reliance on Minnesota statutes for guidance on this question is the best approach to ensure that the Department receives robust and relevant data under Minn. Stat. § 62W.06, subd. 2.¹⁰⁸

108. In response to comments regarding insufficient clarity of the proposed definition from PCMA,¹⁰⁹ Commerce proposed the following revision:

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

109. PCMA also commented that the meaning of clause (2) was unclear.¹¹⁰ Commerce responded it did not share the concern and explained that the phrase is used

¹⁰⁶ Ex. D at 8-10; see Ex. C1 at 1.

¹⁰⁷ Ex. D at 8-9.

¹⁰⁸ *Id.* at 9.

¹⁰⁹ Ex. I at PCMA Comment.

¹¹⁰ *Id.*

elsewhere in Minnesota statutes without causing undue confusion.¹¹¹ Commerce intends the definition to function:

[. . .] as a limiting device to alleviate PBMs from having to (1) register for a license or (2) submit transparency reports for its client—the plan sponsor—where that client is not a Minnesota entity, and whose only connection to Minnesota is an enrollee who performs all work outside of Minnesota.¹¹²

110. Commerce has established that this subpart is reasonable and necessary. The modifications do not make this subpart substantially different. It is **APPROVED**.

111. Minn. R. 2737.0100, subp. 5, defines the phrase “owned pharmacy.”¹¹³ The Department identified the phrase “owned pharmacy” as one featuring prominently in both the statute and these rules. Commerce notes that 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.”¹¹⁴

112. PCMA objected to this definition as unnecessary.¹¹⁵ The Pharmacists support the inclusion of this definition.¹¹⁶

113. Commerce responded that the proposed definition of owned pharmacy increases the rules’ readability and is useful “because §62W’s regulation of pharmacy ownership interests is not unidirectional.” Commerce explained that “the statute applies to a ‘health carrier or pharmacy benefit manager [that] has an ownership interest in a pharmacy or [a] pharmacy [that] has an ownership interest in [a] pharmacy benefit manager.’”¹¹⁷

114. This subpart is needed and reasonable. Therefore, it is approved.

B. Minn. R. 2737.0200 AUTHORITY, SCOPE, AND PURPOSE

115. Commerce submits that 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.¹¹⁸

¹¹¹ Response at 8; see *also* Ex. D at 9.

¹¹² Response at 8.

¹¹³ Ex. C1 at 1.

¹¹⁴ Ex. D at 10.

¹¹⁵ Ex. I at PCMA Comment.

¹¹⁶ Ex. I at Pharmacists Comment.

¹¹⁷ Response at 8 (*citing* Minn. Stat. § 62W.07 (b) and (d)).

¹¹⁸ Ex. D at 10.

116. No written comments were received pertaining to Minn. R. 2737.0200.¹¹⁹ The Pharmacists suggest that this rule would be improved by the addition of a specific reference to enforcement of Minn. Stat. § 62W.04's mandate that PBMs exercise good faith and fair dealing.¹²⁰ Commerce believes the PBM Law and other portions of the rules adequately address this question and declined to adopt this proposal.¹²¹

117. Commerce has established that Minn. R. 2737.0200 is reasonable and necessary, and it is approved.

C. Minn. R. 2737.0300 GOVERNMENT PROGRAMS

118. In this proposed rule part, the Department exempts government agencies directly providing pharmacy management services from the reach of the rules.¹²² The Department maintains this part is designed to clarify when an entity may rely on the legislature's government exemption (often referred to as the "DHS exemption") from the plan sponsor definition.¹²³

119. 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.¹²⁴

120. PCMA comments that the term "pharmacy management services" should be defined, and that the meaning of the phrase "directly provides" is unclear.¹²⁵ NACDS and Pharmacists comments urged inclusion of this rule, noting that allowing managed care organizations (MCOs)—and their PBMs—in contract with DHS to provide Medicaid services to Minnesotans should not exempt them from regulation by Commerce.¹²⁶

¹¹⁹ See Ex. I.

¹²⁰ Tr. at 20-21.

¹²¹ Response at 23-24.

¹²² Ex. C1 at 2.

¹²³ Ex. D at 10.

¹²⁴ *Id.*

¹²⁵ Ex. I at PCMA Comment; see also Ex. I at NACDS Comment, MCHP Comment, Pharmacists Comment, and Pharmacists Rebuttal.

¹²⁶ Ex. I at NACDS Comment, Pharmacists Comment.

121. Commerce responds that both phrases are subject to their plain and ordinary meanings. To increase clarity, Commerce proposes to add a statutory reference to Subpart 1 as suggested by MCHP:

Where an agency of the state of Minnesota directly provides pharmacy management services, the agency is extended the exemption granted to the Department of Human Services under Minnesota Statutes, section 62W.06, subdivision 16.¹²⁷

122. Commerce has established that Minn. R. 2737.0300, subp. 1, is reasonable and necessary. The modifications proposed by Commerce do not render this subpart substantially different from the published draft of the rule. Minn. R. 2737.0300, subp. 1, is approved.

123. The Department asserts Subpart 2 clarifies that this proposed rule does not extend the exemption to nongovernmental 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 providers to circumvent the PBM Law by relying on the exemption of government agencies from the plan sponsor definition would frustrate the legislature's intent.¹²⁸

124. The PCMA objects to this subpart, contending that it conflicts with the PBM Law's definition of "plan sponsor" and, accordingly, the Department lacks authority to adopt Minn. R. 2737.0300, subp. 2.¹²⁹ MCHP commented, requesting clarification regarding the applicability of the exemption to managed care organizations. The Pharmacists and NACDS offered comments to support inclusion of this subpart.¹³⁰

125. AHIP similarly comments that excluding managed care organizations from the DHS exemption is not supported by the text of the PBM Law. AHIP cites to the statutory language in Minn. Stat. § 62W.07(f) in support of its comment.¹³¹

126. With respect to the MCHP comment's request for clarification regarding the applicability of the exemption to managed care organizations, Commerce believes that the government agency exemption should be limited to state agencies engaged directly in pharmacy management services, while the managed care organizations should not be entitled to the exemption.¹³²

127. Commerce disagrees that the subpart is unclear or in conflict with the PBM Law. It responds that this subpart serves to clarify that managed care organizations that

¹²⁷ Response at 9.

¹²⁸ Ex. D at 10.

¹²⁹ Ex. I at PCMA Comment.

¹³⁰ Ex. I at NACDS Comment, Pharmacists Comment.

¹³¹ Ex. I at AHIP Comment.

¹³² Response at 9-10.

are otherwise subject to PBM regulation are not exempt by virtue of being party to a contract with DHS to provide services.¹³³

128. In response to AHIP's comment regarding Minn. Stat. § 62W.07(f), Commerce responds that this paragraph makes clear that entities providing pharmacy management to organizations in contract with DHS are PBMs. The rules clarify that the DHS exclusion in Minn. Stat. § 62W.02, subd. 16, cannot be used by a PBM providing services to a managed care organization to avoid regulation as a PBM.¹³⁴

129. Minn. R. 2737.0300, subp. 2, is needed and reasonable. Commerce has authority to enact this subpart. It is approved.

D. Minn. R. 2737.0400 BUSINESS LICENSE REQUIREMENTS; INITIAL APPLICATION

130. This proposed rule has five subparts and establishes the requirements related to licensing and the application process.¹³⁵ According to the Department, 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. Commerce relies heavily on its experience with implementing the PBM Law in 2019 and 2020, prior to this rulemaking, to establish the need for and reasonableness of this rule (and related rules Minn. R. 2737.0500, .0600).¹³⁶

131. Subpart 1 restates portions of the PBM Law and clarifies 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, Commerce anticipates that a PBM will seek Minnesota licensure only if subsequently becomes subject to the PBM Law, such as by contracting with plan sponsors for Minnesota enrollees. The PBM Law provides that Commerce must review an initial license application within 90 days. Minn. Stat. § 62W.03, subd. 6, makes acting without a license punishable by a substantial fine. This rule is intended to align the time frame within which Commerce must review an initial application with the application submission timelines to ensure that a PBM would not be subject to a fine while its application is pending.¹³⁷

132. Commerce asserts that Subpart 2 is reasonable and necessary to provide additional detail with respect to the contents of an application for PBM licensure. This subpart is meant to mirror the process and content of applications Commerce uses to license TPAs, which operate similarly to PBMs. Subpart 2(D) identifies the categories of information that Commerce considers necessary to make an informed review of PBM license applications. 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

¹³³ *Id.* at 9.

¹³⁴ Final Response to Comments (Final Response) (October 15, 2021) at 5-6.

¹³⁵ Ex. C1 at 2-4.

¹³⁶ Ex. D at 10-11.

¹³⁷ *Id.* at 11.

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 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 and incorporated changes into the draft text to do so.¹³⁸

133. Subpart 3 that a PBM must provide a recent Network Adequacy Report from MDH as part of its application for PBM licensure. 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 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.¹³⁹

134. Subpart 4 provides clarification that to afford applicants an efficient and effective experience in application submission, a small fee in addition to the statutorily mandated fee may be applicable to cover the cost associated with the use of a service provider and its software.¹⁴⁰

135. Subpart 5 requires an applicant to alert Commerce to changes in information provided in its application related to ownership, key personnel, fiscal and professional matters, and network adequacy. Commerce believes this information is unlikely to change frequently and is the type of information that would lead the agency to reconsider granting a license had the information been disclosed at the time of the application. This requirement is consistent with the text of the statute, notably Minn. Stat. § 62W.03, subd. 4, which provides the Commissioner with substantial oversight authority. That statute allows the Commissioner to “suspend, revoke, or place on probation a pharmacy benefit manager license” if, among other things, “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 ensure that licenses are granted as intended by the PBM Law.¹⁴¹

136. Subpart 5 also requires that a PBM report to MDH any changes in the make-up of the pharmacy network(s) it submitted with its application. Minn. Stat. § 62W.05 requires that a PBM's network of pharmacies meets certain guidelines. Where it fails to meet such guidelines, MDH is authorized to place restrictions on the network's geographic reach. Those restrictions become a condition of the PBM license, 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)

¹³⁸ *Id.*

¹³⁹ *Id.*

¹⁴⁰ *Id.*

¹⁴¹ *Id.* at 11-12.

undergo change during the license term, both MDH and Commerce are aware and can take remedial steps as necessary. Although 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.¹⁴²

137. PCMA and the Prime object to some of the proposed disclosure requirements, arguing that they are inappropriate inasmuch as they request PBMs to disclose allegations of misconduct rather than final adjudications of misconduct. Additionally, the PCMA comment raises concerns about the types of information requested and the fee charged. The Prime also raises a concern about the interplay between deadlines at MDH—related to the network adequacy review—and deadlines at Commerce. The PCMA and MCHP raise concerns about ongoing reporting requirements. The Pharmacists’ comment suggests a lower license fee to increase access to the Minnesota Market for smaller PBMs.¹⁴³ AHIP raises three concerns: (1) the use of the term “key employees” in the rules, (2) the breadth of information sought, and (3) the requirement to update Commerce on changes to information on the application.¹⁴⁴

138. With respect to the commenters’ concerns about reporting misconduct allegations, Commerce responds that information an applicant is required to produce in its initial application is consistent with other license applications and disclosure forms used by Commerce. In each case, the applicant is asked to describe pertinent allegations, investigations and demands. Providing such information permits the Commissioner to make appropriate licensing decisions, including whether to grant a license and the propriety of licensing conditions, if any. The PBM Law provides that the Commissioner may seek additional information, and the statute provides that the Commissioner must state the basis for the denial of an application. An applicant aggrieved by such a decision is entitled to challenge it. The information sought by the application pertains to conduct that the statute indicates can form the basis for suspension, revocation, or probationary status, as allowed by Minn. Stat. § 62W.03, subd. 4(a)(1).¹⁴⁵

139. Commerce further responds that the objection to Subpart 5 by the PCMA and MCHP is unpersuasive. Commerce, after consulting with industry stakeholders—and recognizing the annual nature of renewal—decided to limit the scope of the request for updated information to only those categories which it considers most material as described in Subpart 2(C-E) and explained in the SONAR.¹⁴⁶

140. Commerce also disagrees with the PCMA’s comment that the proposed rule—which makes the restrictions placed on a PBM’s network by MDH applicable to the PBM—is beyond the authority of Commerce. Commerce believes that the PCMA’s proposed remedy would render the network adequacy inquiry meaningless. The network adequacy report issued by MDH is directly related to the licensure of a PBM. If MDH reviews a network and determines that the network is only adequate in certain counties,

¹⁴² *Id.* at 12.

¹⁴³ Ex. I at PCMA Comment, Prime Comment; Tr. at 29-30.

¹⁴⁴ Ex. I at AHIP Comment.

¹⁴⁵ Response at 10.

¹⁴⁶ *Id.*

but the Commissioner of Commerce is unable to enforce those restrictions, then the entire network adequacy process would be meaningless.¹⁴⁷

141. Commerce points to its authority found in Minn. Stat. § 62W.04, subd. (4)(b), which expressly provides the Commissioner of Commerce the power to subject a license to certain restrictions. The proposed rule clarifies that where MDH has determined the PBM's network is insufficient to meet the requirements of Minn. Stat. § 62W.05, the license shall be subject to the restrictions determined by MDH.¹⁴⁸

142. With respect to comments regarding the fees, the Department responds that the PBM Law establishes the license fee, which must be deposited into the general fund. This rule establishes a mechanism to permit the Department to collect costs it incurs in the event a third-party service provider is necessary to administer the application process.¹⁴⁹

143. As to comments related to the provision of the Network Adequacy Report, Commerce asserts that the rules attempt to provide new applicants as much guidance as possible to ensure that a new PBM will be able to begin operations with minimal delay. As noted in the SONAR, an application for an initial license is not complete without a Network Adequacy Report approved by MDH. MDH, however, is not subject to the same time constraints that Commerce is, under the text of the statute. This subpart thus makes clear that the onus is on the entity seeking licensure as a PBM to first have the network reviewed by MDH, and upon receipt of an approval or limited network report from MDH, submit its application for a PBM license. Additionally, Commerce recognizes the concern raised by the Prime regarding delays beyond a PBM's control as a serious one, and as such, with respect to the renewal process, it has proposed Minn. R. 2737.0600, subp. 5, which allows for license continuity in an event where a PBM has timely filed for renewal but the application has not yet been approved.¹⁵⁰

144. Commerce, responding to comments regarding the use of the term "key employees," states that it is intended to minimize the potential for unwieldy application files for stakeholders like AHIP. Commerce included this term of art to minimize the number of persons subjected to the application requirements to those who are central to the administration of the PBM and charged with high level decision-making authority, not to expand the universe of persons subjected to reporting. During the advisory committee's meeting on licensure, Commerce worked closely with stakeholders to determine what "each person responsible for the conduct of affairs of the pharmacy benefit manager" as used in the PBM Law, specifically Minn. Stat. § 62W.03, means to the industry. Limiting the most exacting reporting obligations to key employees helps facilitate this understanding.¹⁵¹

¹⁴⁷ *Id.* at 10-11.

¹⁴⁸ *Id.* at 11.

¹⁴⁹ *Id.*

¹⁵⁰ *Id.*

¹⁵¹ *Id.*

145. Last, Commerce responds to AHIP's objection to the requirement for ongoing updates. As noted in the SONAR and Initial Response, Commerce, after much discussion with stakeholders, believes it has scoped the update requirements to only those things that are most important, such as the departure of persons that are central to the administration of the PBM's affairs or the hiring of a key employee who has engaged in some sort of fraud. This type of information is essential to Commerce's ability to regulate and to ensure that appropriate license conditions are in place.¹⁵²

146. Commerce has established that Minn. R. 2737.0400 is reasonable and necessary. This rule is approved.

E. Minn. R. 2737.0500 BUSINESS LICENSE REQUIREMENTS; RENEWAL APPLICATION

147. This proposed rule has four parts, which largely replicate the requirements of an initial application for the renewal process.¹⁵³

148. Commerce supports this rule as reasonable and necessary, noting that its primary goal for this part is to clarify 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 the PBM Law's provisions for initial and renewal applications provide that an application must be on forms prescribed by the Commerce and require a network adequacy report approved by MDH and a fee of \$8500, the PBM Law does not speak to the timing requirements for renewals.¹⁵⁴

149. Subpart 1 clarifies that a renewal application must continue to meet licensing requirements, as intended by Minn. Stat. § 62W.03, subd. 3(c)(1).¹⁵⁵

150. Subpart 2 establishes the steps that PBM applicants must take to submit a renewal application. As with Minn. R. 2737.0400, subp. 3, this subpart makes clear to an applicant that it must first seek approval of its proposed networks from MDH, prior to submitting a renewal application.¹⁵⁶

151. Subpart 3 and Subpart 4 impose the same information requirements on renewal applications as Commerce proposes to place on initial applicants. Commerce submits that the basis supporting Minn. R. 2737.0400, subps. 4 and 5 supports these subparts for renewal applications.¹⁵⁷

152. The PCMA comment raises similar concerns about information required for initial licensing as it offers pertaining to license renewal, which are fully addressed above. Additionally, the PCMA comment argues that the rules are impermissible inasmuch as the form and manner of the application for license renewal are subject to Minn. Stat.

¹⁵² Response at 10; Final Response at 6-7.

¹⁵³ Ex. C1 at 4-6.

¹⁵⁴ Ex. D at 12-13.

¹⁵⁵ *Id.* at 12.

¹⁵⁶ *Id.*

¹⁵⁷ *Id.* at 13.

ch. 14. The PCMA comment states that it is “likely” that manner and form would themselves be rules, and subject to a rulemaking under chapter 14.¹⁵⁸

153. Commerce responds that PCMA relies upon Minn. Stat. § 62W.03, subd. 3, which states: “To renew a license, an applicant must submit a completed renewal application **on a form prescribed by the commissioner[,]**” Minn. Stat. § 14.02, subd. 4, defines a rule as “every agency statement of general applicability and future effect, including amendments, suspensions, and repeals of rules, adopted to implement or make specific the law enforced or administered by that agency or to govern its organization or procedure.” The concern that animates the PCMA comment—that future renewal applications could change dramatically—supports the basis for this rule, which creates clarity and specificity around the information the license application must include. Commerce disagrees that an agency would be required to undergo rulemaking to implement license application forms, which are necessarily informed by the information the Department may require from a PBM.¹⁵⁹

154. Minn. R. 2737.0500 is reasonable and necessary. This rule is approved.

F. Minn. R. 2737.0600 REVIEW BY COMMISSIONER

155. Commerce’s proposed rule covering renewal applications is intended to harmonize the process and timelines with the initial application process. To that end, Minn. R. 2737.0600 contains five subparts governing the commissioner’s review of the initial and renewal application processes.¹⁶⁰

156. Subpart 1 provides that the Commissioner’s ability to seek additional information from an applicant is limited to 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.¹⁶¹

157. Subpart 2 mirrors the 90-day period provided to Commerce to make a determination on an application in Minn. Stat. § 62W.03, subd. 2. It also provides applicants with clear outcomes of an application. Subitem C requires Commerce to articulate the basis for rejection. The rule provides an avenue for applicants to remedy the basis for denial of a renewal application, without incurring 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 provides an immediate process by which an applicant can contest a denial based upon a condition that has been remedied by the applicant.¹⁶²

¹⁵⁸ Ex. I at PCMA Comment; Tr. at 31.

¹⁵⁹ Response at 11-12; *see also* Pharmacists Rebuttal.

¹⁶⁰ Ex. C1 at 6-8; Ex. D at 13.

¹⁶¹ Ex. D at 13.

¹⁶² *Id.*

158. Commerce describes the purpose of Subpart 3 as clarifying that a geographical or other restriction placed on a PBM's network by MDH is a condition 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.¹⁶³

159. Subpart 4 creates a process for appeal of the Commissioner's decision. Commerce believes 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 is intended to define what is a final agency determination for a party aggrieved wishing to seek judicial review.¹⁶⁴

160. 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, like 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. In the SIRCON system, 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 expiration 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. This proposed rule is designed to provide for continued licensure 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.¹⁶⁵

161. PCMA argues that Subpart 4 impermissibly curtails the due process rights of applicants. PCMA notes that the proposed appeal process does not comply with Minn. Stat. ch. 14, which requires a contested case hearing before an administrative law judge. PCMA believes that the summary process runs afoul of a PBM applicant's right to due process.¹⁶⁶

162. Commerce responds that the proposed rules set forth the process for an agency hearing on the denial of a license, after which "the agency issues a final determination." Commerce believes the rules clarify when a license decision is final and subject to contested case proceedings. Contrary to the PCMA comment, Commerce believes this process is intended to provide additional due process to applicants.

¹⁶³ *Id.*

¹⁶⁴ *Id.*

¹⁶⁵ Ex. D at 14.

¹⁶⁶ Ex. I at PCMA Comment.

Commerce points to the SONAR, which it contends establishes that none of the remedies of chapter 14 are removed.¹⁶⁷

163. Subpart 4, as drafted, states:

Subp. 4. **Appeals process.** The commissioner's decision to deny a license, deny a renewal, or issue a limited or restricted license may be appealed subject to the following procedure:

A. within 30 days of the date the denial or limited or restricted license is issued, a pharmacy benefit manager must make a written request to the commissioner for a hearing to determine whether the decision or action complies with this chapter and Minnesota Statutes, chapter 62W;

B. the commissioner must conduct a hearing within 30 days after the date the hearing request is made and must give not less than ten days' written notice of the hearing date, time, and location;

C. within 15 days after the hearing date, the commissioner must affirm, reverse, or modify the denial or limited or restricted license issuance and specify in writing the reasons for the decision or action. The effective date of the commissioner's action or decision may be suspended or postponed pending the completion of the hearing before the commissioner;

D. nothing in this subpart requires the commissioner to observe formal rules of pleading or evidence at any hearing; and

E. the commissioner's order or decision is a final decision subject to appeal under Minnesota Statutes, chapter 14.¹⁶⁸

164. Subpart 4 cannot be approved as drafted. Minn. Stat. § 62W.03, subd. 6, requires the Department to enforce the PBM Law as provided in Minn. Stat. ch. 45. In turn, Minn. Stat. § 45.024 (2020) states “In any case in which the commissioner of commerce is required by law to conduct a hearing, the hearing must be conducted in accordance with chapter 14[.]” Pursuant to Minn. Stat. § 14.57 “an agency shall initiate a contested case¹⁶⁹ proceeding when one is required by law[.]” which shall be conducted “only in accordance with the contested case procedures of the Administrative Procedure Act.” Because Department proposes a hearing process for “a case” that is not a “contested case” process, those provisions violate the statutory guarantees in

¹⁶⁷ Response at 12.

¹⁶⁸ Ex. C1 at 7.

¹⁶⁹ “‘Contested case’ means a proceeding before an agency in which the legal rights, duties, or privileges of specific parties are required by law or constitutional right to be determined after an agency hearing.” Minn. Stat. § 14.02, subd. 3.

Chapters 45 and 62W.¹⁷⁰ To the extent that an agency proposes a rule that contravenes a statute, it is *ultra vires* and illegal.

165. The proposed Subpart 4 appeal process for license application denials conflicts with Minn. Stat. §§ 14.57, 45.024, and 62W.03, subd. 6, and, therefore, cannot be approved as proposed.

166. The Department established that Subparts 1-3 and 5 of this proposed rule part are needed and reasonable. Minn. R. 2737.0600, subps. 1-3, 5 are **APPROVED**.

167. The Administrative Law Judge recommends that the proposed rule be clarified to ensure due process rights to the applicant under Minn. Stat. ch. 14. The Judge recommends the following language:

Subp. 4. **Appeals process.** The commissioner's decision to deny a license, deny a renewal, or issue a limited or restricted license may be appealed subject to the following procedure:

A. within 30 days of the date the denial or limited or restricted license is issued, a pharmacy benefit manager must make a written request to the commissioner for a hearing to determine whether the decision or action complies with this chapter and Minnesota Statutes, chapter 62W;

B. ~~the commissioner must conduct a hearing~~ within 30 days after the date the hearing request is made, the commissioner must notice a hearing to be conducted under Minnesota Statutes, chapter 14, and must give not less than ten days' written notice of the hearing date, time, and location; and

C. ~~within 15 days after the hearing date, the commissioner must affirm, reverse, or modify the denial or limited or restricted license issuance and specify in writing the reasons for the decision or action. The effective date of the commissioner's action or decision may be suspended or postponed pending the completion of the hearing before the commissioner;~~

D. ~~nothing in this subpart requires the commissioner to observe formal rules of pleading or evidence at any hearing; and~~

E. the commissioner's order or decision is a final decision subject to appeal under Minnesota Statutes, chapter 14.¹⁷¹

168. The suggested changes clarify the procedures set forth in Minn. Stat. ch. 14 and further clarify an applicant's right to challenge the denial of an application or the imposition of license conditions. These changes harmonize Commerce's stated intention

¹⁷⁰ If Commerce establishes a process of agency reconsideration, it should consider *In the Matter of the Application of Kimberly Baker*, 907 N.W.2d 208 (Minn. Ct. App. 2018). Due process demands that the Commissioner not be placed in both an adversarial and adjudicative role.

¹⁷¹ Ex. C1 at 7.

to comply with the legislature's determination that an applicant is entitled to a contested case proceeding with the text of the rule.

169. The changes recommended herein are for clarification only and do not result in a substantially different rule. In addition, they are logical outgrowths of the rules noticed and are in response to stakeholder comment. Subject to the recommended changes, Minn. R. 2737.0600, subp. 4, is **APPROVED**.

G. Minn. R. 2737.0700 ENFORCEMENT BY COMMISSIONER

170. This rule provides for enforcement actions under Minn. R. ch. 2737.¹⁷²

171. Minn. Stat. § 62W.03, subd. 4, provides for enforcement against a PBM license. The statutory text reads:

The commissioner may suspend, revoke, or place on probation a pharmacy benefit manager license issued under this chapter for any of the following circumstances: (1) the pharmacy benefit manager has engaged in fraudulent activity that constitutes a violation of state or federal law; (2) the commissioner has received consumer complaints that justify an action under this subdivision to protect the safety and interests of consumers; (3) the pharmacy benefit manager fails to pay an application license or renewal fee; and (4) the pharmacy benefit manager fails to comply with a requirement set forth in this chapter.

172. During the advisory committee process, Commerce engaged with its stakeholders to craft a rule that was specific and provided clear notice of prohibited conduct. Commerce identified the areas of Federal and State law sufficiently connected to the administration of pharmacy benefits to impact licensure. To that end, Commerce proposes this rule, which provides a nonexclusive but specific list of violations of law which could result in the suspension, revocation, or probation of a PBM license.¹⁷³

173. The PCMA, Prime and AHIP comments argue that the list of state and federal laws with which a PBM must comply varies too greatly from the "limited" basis on which a license may be suspended, revoked or placed in probationary status.¹⁷⁴ These commenters maintain the rule subjects PBMs to adverse licensing action for, among other things, the violation of "pharmacy laws." This appears to be based upon a misreading of the proposed language. The rule, as drafted, does not subject PBMs to all pharmacy and healthcare law, but rather, to the specific statutes referenced in items (a)-(d) of Minn. R. 2737.0700, subp. 2.¹⁷⁵

¹⁷² *Id.* at 8-9.

¹⁷³ Ex. D at 14.

¹⁷⁴ Ex. I at PCMA Comment, Prime Comment; Tr. at 31-32.

¹⁷⁵ See Ex. C1 at 8-9.

174. The NACDS notes in its comment that this proposed rule is beneficial to ensure PBM compliance with the statute and rules.¹⁷⁶ The Pharmacists Rebuttal notes:

The statute does not limit the federal and state laws that Commerce should monitor to enforce that statute. We submit that Commerce has been given in the statute not only the right, but the responsibility to assure that their licensees comply with any law related to the operation of a PBM and the pharmacies that PBMs own and operate.¹⁷⁷

175. Commerce engaged industry and stakeholders to craft a rule that provides more specificity as to the violations of federal and state laws that may subject a PBM to adverse licensing action. Commerce submits that, with respect to Subpart 2(E), it did not intend to create rules that would allow Commerce to assume regulatory oversight over those laws. Rather, Commerce intended that if the appropriate regulatory body determined a violation of the subject statutes, laws, regulations, or rules, the Commissioner could consider such a violation as part of the renewal process. To clarify, Commerce proposes the following edit to Subpart 2(A) (line 8.14):

failure to comply with relevant state and federal law, as determined by the relevant regulatory body:¹⁷⁸

176. The PCMA also argues that the statute itself is unconstitutionally vague. The PCMA requests additional rules that would limit Minn. Stat. § 62W.05, subd. 4(a)(2).¹⁷⁹ Commerce believes that the statutory language is drafted sufficiently clear.¹⁸⁰ In any event, limiting the reach of a statute through the rulemaking process is not appropriate. Because, among other things, an administrative law judge lacks the power to declare a statute unconstitutional on its face, the rulemaking process is not the appropriate venue to adjudicate whether a statute is unconstitutionally vague.¹⁸¹

177. These rules, like Minn. Stat. ch. 62W, are to be enforced pursuant to Minn. Stat. ch. 45.¹⁸² Minn. Stat. § 45.024 states “In any case in which the commissioner of commerce is required by law to conduct a hearing, the hearing must be conducted in accordance with chapter 14[.]” To ensure clarity, it is recommended that Commerce add language that Chapter 2737 will be enforced by the same means as Chapter 62W.

178. The Department established that this proposed rule part is needed and reasonable. The modification was proposed in response to stakeholder commentary and does not render the rule substantially different. Minn. R. 2737.0700 is **APPROVED**.

¹⁷⁶ Ex. I at NACDS Comment.

¹⁷⁷ Ex. I at Pharmacists Rebuttal; *see also* Tr. at 22 (indicating strong support for enforcement measures).

¹⁷⁸ Response at 13; *see also* Final Response at 7.

¹⁷⁹ Ex. I at PCMA Comment; Tr. at 32.

¹⁸⁰ Response at 13.

¹⁸¹ *See, e.g., In re Rochester Ambulance Service*, 500 N.W.2d 495, 499-500 (Minn. Ct. App. 1993).

¹⁸² *See* Minn. Stat. § 62W.03, subd. 6.

179. The Administrative Law Judge respectfully recommends **ADDING** a subpart, as Minn. R. 2737.0700, subp. 4, to clarify that orders issued under this part are subject to review under the contested case process, as required by Minn. Stat. §§ 62W.03, subd. 6 and 45.024.

H. Minn. R. 2737.0800 ADEQUATE NETWORK

180. Minn. Stat. § 62W.05, subd. 1, requires PBMs to “provide an adequate and accessible pharmacy network for the provision of prescription drugs that meet the relevant requirements in section 62K.10.” The PBM Law does not define an adequate and accessible network. Minn. R. 2737.0800 is intended to make the text of Minn. Stat. § 62W.05, subd. 1, specific and enforceable. To create greater transparency on the network adequacy review process, Commerce proposes this rule to describe what constitutes an adequate network. Because MDH makes the adequacy and accessibility determination, Commerce worked with MDH to ensure that the proposed rules were consistent with its policies and procedures.¹⁸³

181. Subpart 1 recognizes that the pharmacy industry is not limited to retail pharmacies but also includes specialty and other pharmacies. To adequately meet the needs of enrollees, a pharmacy network must be able to provide enrollees with access to all types of drugs, 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 advance the legislature’s intent of ensuring that enrollees have adequate access to pharmacies.¹⁸⁴

182. Subpart 2 provides PBMs a mechanism to seek an exemption from Subpart 1, where extenuating circumstances result in a network lacking one or more pharmacy types. Commerce asserts this subpart is consistent with MDH’s authority under Minn. Stat. § 62W.05, subd. 2, which allows MDH to issue waivers to the network adequacy requirement.¹⁸⁵

183. This proposed rule elicited substantial feedback.¹⁸⁶ The issues can be divided into three broad categories: (1) authority to promulgate rules; (2) pharmacy type for network adequacy; and (3) distance requirements.¹⁸⁷

184. Commenters focusing on the authority of Commerce note that the network adequacy review is performed by MDH, and as such should not be subject to rulemaking by Commerce. They consider the language of Subpart 1 to be confusing, as the first part appears to indicate all pharmacy types must be included, but that the use of ‘or’ on line 10.5 suggests otherwise.¹⁸⁸ The Prime suggests that the reference to Minn. Stat.

¹⁸³ Ex. D at 14-15.

¹⁸⁴ *Id.* at 15.

¹⁸⁵ *Id.*

¹⁸⁶ See Ex. I; see also Tr. at 35.

¹⁸⁷ *Id.*; Tr. at 33.

¹⁸⁸ See Ex. I at Prime Comment, PCMA Comment, AHIP Comment.

§ 62K.10 only applies to retail networks.¹⁸⁹ The MCHP comment proposed an edit to Subpart 2.¹⁹⁰

185. The Department observes that multiple comments argue that Commerce cannot promulgate rules relating to network adequacy because the network adequacy provisions are governed by MDH. Commerce responds that these comments ignore the plain language of the law granting rulemaking authority to Commerce, which explicitly provides for rules related to “network adequacy” “for pharmacy benefit manager licensing under Minnesota Statutes, chapter 62W.”¹⁹¹

186. Commerce believes that the wide range of comments on what constitutes network adequacy and the “relevant requirements” of Minn. Stat. § 62K.10 (2020) to be applied to the network adequacy review highlights the need for rulemaking.¹⁹² Commerce notes that Minn. Stat. § 62W.05, subd. 1, refers to requirements in the plural. Commerce rejects the Prime’s argument that the only requirement to achieve an adequate network is that the network includes retail pharmacies, as unsupported by a plain reading of Minn. Stat. § 62W.05, subd. 1. Contrary to the Prime’s contention, Commerce believes that the legislature intended that Minnesotans have access to specialty pharmacies and home infusion pharmacies when they deal with serious illness.¹⁹³

187. Instead, Commerce agrees with the NACDS and Pharmacists¹⁹⁴ comments that one such relevant portion of Minn. Stat. § 62K.10, is subd. 4. This subdivision requires that “[e]ach designated provider network must include a sufficient number and type of providers . . . to ensure that covered services are available to all enrollees without unreasonable delay.” Commerce proposes to delete the ‘or’ on line 10.5 of Subpart 1(E) to clarify that an adequate network requires at least one of each type of pharmacy. Many commenters agreed that the ‘or’ on line 10.5 should be deleted. In the same way that a primary care physician is not the only health care provider an enrollee may need, a retail pharmacy is not the only pharmacy an enrollee may need. Different pharmacies serve different needs, and it is imperative that enrollees have access to each type of pharmacy, to have an adequate network. Commerce’s rule, with the deletion of the ‘or’ on line 10.5, achieves this end.¹⁹⁵

188. As to comments regarding Minn. R. 2737.0800, subp. 2, Commerce responds that it is necessary and reasonable to provide a means for an exemption from the requirements of Subpart 1. Subpart 2 is consistent with MDH’s authority in Minn. Stat. § 62W.05, subd. 2, which grants MDH the authority to issue waivers to the network adequacy requirement. Specifically, the statute requires that for a waiver to be granted, the requesting PBM must provide information on its attempts to remedy the shortcoming. In the context of a network failing to have certain types of pharmacies, such as home

¹⁸⁹ Ex. I at Prime Comment; Tr. at 35-37.

¹⁹⁰ Ex. I at MCHP Comment.

¹⁹¹ Response at 14 (citation omitted).

¹⁹² *Id.* at 14-15.

¹⁹³ *Id.*

¹⁹⁴ See Ex. I; see also Tr. at 22.

¹⁹⁵ Response at 14-15.

infusion, it is imperative that MDH be able to ascertain if the PBM has a plan to provide the requisite services to enrollees should the need arise.¹⁹⁶

189. Commerce has authority to adopt rules relating to network adequacy in the context of PBM licensing. Commerce established that Minn. R. 2737.0800 is needed and reasonable. The proposed modification does not impermissibly alter the rule. This rule, with the modification proposed by Commerce, is approved.

I. Minn. R. 2737.0900 ACCESSIBLE NETWORK

190. This proposed rule, along with Minn. R. 2737.0800, elicited substantial feedback. Commerce believes that the proposed rule was necessary and reasonable, for the reasons articulated in the SONAR. However, after reviewing the comments made, and in consultation with MDH, Commerce has decided to strike this proposed rule as unnecessary.¹⁹⁷

191. Commerce found the Prime's comment on this rule to be persuasive. Minn. Stat. § 62W.05 instructs MDH to "use the relevant portions of Minn. Stat. § 62K.10" to determine accessibility. While Commerce believes that pharmacy services are more akin to primary care than "ancillary services," the term ancillary services is a defined term under MDH's health plan market rules:

Subp. 3a. Ancillary services. "Ancillary services" means laboratory services, radiology services, durable medical equipment, **pharmacy services**, rehabilitative services, and similar services and supplies dispensed by order or prescription of the primary care physician, specialty physician, or other provider authorized to prescribe those services.¹⁹⁸

In light of the comments submitted, and the existence of Minn. R. 4685.0100, Commerce withdrew proposed rule 2737.0900.¹⁹⁹

192. The NACDS, Pharmacists, and Essentia comments raise important concerns about reasonable access to pharmacies and suggest pharmacy access should follow the federal government's standards for the Medicare Part D program.²⁰⁰ While this approach is reasonable and may be a better one, it likely requires an amendment to Minn. Stat. § 62W.05, subd. 1(a) (2020).

J. Minn. R. 2737.1000 TRANSPARENCY REPORTS TO PLAN SPONSORS

193. The PBM Law, in Minn. Stat. § 62W.06, requires "transparency reports" in which PBMs share certain categories of data with both the plan sponsors they serve and

¹⁹⁶ Response at 14-15; *see also* Final Response at 7-8.

¹⁹⁷ Response at 16.

¹⁹⁸ Minn. R. 4685.0100 (emphasis supplied).

¹⁹⁹ Response at 16.

²⁰⁰ *See* Ex. I at NACDS Comment, Pharmacists Comment, Essentia Comment.

Commerce. This proposed rule governs the requirements for reporting to plan sponsors.²⁰¹

194. Commerce submits that this rule 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 for plan sponsors seeking to enforce their rights under Minn. Stat. § 62W.06, subd. 1.²⁰²

195. Subpart 1 proposes that Commerce will create a standardized form for plan sponsors to use to request the data made available to it under Minn. Stat. § 62W.06, subd. 1. Based on the comments from industry and the advisory committee, Commerce does not believe it is necessary to make use of this form mandatory. While some plan sponsors may not make use of the form, Commerce anticipates that providing a form will be beneficial to plan sponsors with limited resources as well as to PBMs concerned that a lack of clarity may subject them to enforcement action.²⁰³

196. Commerce submits that Subparts 2 and 3 are necessary to give effect to the enforcement provisions of Minn. Stat. § 62W.06, subd. 3. That provision allows the commissioner to impose a penalty of up to a thousand dollars a day for such violations. Subdivision 3 requires the annual submission of reports to Commerce, as well as to plan sponsors on request. The penalty accrues for each day a PBM is in violation. Subpart 2 of this rule establishes a timeline for submission of transparency reports to plan sponsors. Without 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. Similarly, subitems A and B provide clarity on when a request for data is complete, triggering the PBM's obligation to respond. In the advisory committee process, it became clear that certain portions of the data contained in the PBM law routinely pass between PBMs and plan sponsors, and many PBMs expressed the concern that relatively low-level staff arguably trigger portions of the PBM Law in these routine transactions.²⁰⁴

197. The PCMA urges Commerce to remove timelines for disclosure by PBMs to plan sponsors of the data required under § 62W.06 and to remove Subpart 2(B).²⁰⁵ In response, Commerce refers to the SONAR. The public engagement process undertaken by Commerce as part of its rulemaking process laid bare that the PBM-plan sponsor relationship is one that needs minimal additional oversight by Commerce. The rules reflect an attempt to balance that reality with the need to create fixed clear rules around the statutorily required duties the two parties owe one another, and to provide a

²⁰¹ Ex. D at 16.

²⁰² *Id.*

²⁰³ *Id.*

²⁰⁴ *Id.* at 16-17.

²⁰⁵ Ex. I at PCMA Comment.

predictable metric for the parties to reference when in dispute about the relevant statutory obligations.²⁰⁶

198. Last, Commerce recognizes that it is likely to become common practice for a PBM to require a nondisclosure agreement prior to releasing the plan sponsor transparency reports, the statute itself does not make execution of a non-disclosure mandatory. To that end, Commerce thinks it would be inadvisable to enshrine in the rules a requirement by a plan sponsor to sign such an agreement, where the statute only allows for a PBM to make it mandatory. Commerce believes additional rulemaking is unnecessary because Minn. Stat. § 62W.06 is sufficiently clear on this issue, allowing a PBM which elects to require a non-disclosure agreement signed by a plan sponsor to withhold the transparency reports until such an agreement is properly executed.²⁰⁷

199. This rule is reasonable and necessary. It is approved.

K. Minn. R. 2737.1100 TRANSPARENCY REPORTS TO THE COMMISSIONER

200. This part of the rules relates to a PBM's requirement to submit an annual transparency report to the commissioner and the commissioner's obligation to make certain data publicly available, pursuant to Minn. Stat. § 62W.06, subd. 2.²⁰⁸

201. Commerce believes this rule is necessary and reasonable to clarify the manner in which responsive data should be reported, and how the public facing portion of the data should be shared. Commerce relied on the advisory committee and input received in public comments, as well as its experience in overseeing the collection of the first transparency reports in 2020. During the process of collecting transparency reports for 2020, the Department held meetings with PBMs, at which the Department solicited feedback. That early feedback is reflected in the draft rules.²⁰⁹

202. Subpart 1 requires Commerce to publish three templates for PBMs to use to report data. The first template will cover aggregate data required by Minn. Stat. § 62W.06 subd. 2(a)(1)-(6). The second template covers claims-level data required by Minn. Stat. § 62W.06 subd. 2(a)(7). The third template pertains to the data the Commissioner must publicly report pursuant to Minn. Stat. § 62W.06, subd. 2(b).²¹⁰

203. 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 PBMs report this data in uniform fashion and separated by purpose. Using standardized templates makes

²⁰⁶ Response at 16-17.

²⁰⁷ *Id.*

²⁰⁸ C1 at 11-13.

²⁰⁹ Ex. D at 17.

²¹⁰ *Id.*

determinations of compliance easier. Commerce anticipates the burden placed on PBMs to use these forms will be minimal.²¹¹

204. Subpart 3 is proposed based upon Commerce's experience in its first year administering the transparency reporting process. The definition of a PBM in the PBM Law includes seven distinct activities. The performance of any one of these activities requires a PBM license. Most of these activities would result in collection of data that a PBM is required to report to Commerce under the PBM Law. However, some would not, such as establishing a pharmacy network. In these cases, a PBM would not have anything to report. In 2020, there were 13 licensed PBMs that did not submit a report. It is unknown whether those PBMs failed to report, in violation of the PBM Law, or lacked reportable data. Non-reporting PBMs is a concern that has been repeatedly raised by stakeholders.²¹² Commerce suspects that many of these PBMs did not report because they had no reportable data, or their data was duplicative of another PBM's (which is address by Subpart 6). Requiring PBMs who have no reportable data to submit a statement to that effect alleviates this ambiguity. 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 minimizes Commerce's duty to investigate and the PBM's obligation to respond.²¹³

205. Commerce considers Subpart 4 to be reasonable and necessary because it allows the data Commerce collects to be consistent and usable. Minn. Stat. § 62W.06, subd. 2(a), requires PBMs to present data according to its therapeutic category. Within the pharmacy industry there are myriad different therapeutic classification systems. Absent a uniform system, the data collected would prohibit meaningful comparisons from one to another PBM, or to draw conclusions about a therapeutic category as the statute intends. 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 the flexibility to choose an appropriate system already in use by the industry, limiting the burden on industry.²¹⁴

206. Subpart 5 proposes to allow Commerce to hire third-party vendors or another state agency to assist with data collection and analysis, where appropriate.²¹⁵

207. Commerce believes Subpart 6 is needed to prevent the submission of duplicative data in the annual transparency reports. As noted above, the PBM statute covers multiple duties. Those duties are not uncommonly split or shared between multiple PBMs for a single plan sponsor, resulting in multiple PBMs having all or part of the data related to the same enrollees. It is Commerce's understanding that the legislature's intent in creating the transparency reporting requirement was to obtain and share accurate data

²¹¹ *Id.*

²¹² *See, e.g.,* Tr. at 22.

²¹³ Ex. D at 17.

²¹⁴ *Id.* at 18.

²¹⁵ *Id.*

concerning prescription benefits in Minnesota. That aim would be frustrated by the reporting of duplicative data. Based on feedback from the advisory committee and other industry participants, Commerce understands that PBMs working together will often determine, by contract, which party is responsible for reporting. Where such an agreement does not exist, this subpart creates a default rule requiring the party to process claims to report the data.²¹⁶

208. Minn. Stat. § 62W.06, subd. 3, imposes civil penalties for failing to timely transparency reports. Subpart 7 clarifies when a PBM becomes subject to civil penalties.²¹⁷

209. This rule prompted divergent comments from stakeholders. The PCMA comment suggests that format of the reports submitted to the commissioner should be subject to rulemaking requirements contained in Minnesota Statute chapter 14.²¹⁸ Similarly, the AHIP comment expresses concern that the forms prescribed by Commerce may change from year to year hindering compliance because Subpart 1 lacks “any substantive limits.”²¹⁹ The MCHP comment requests an addition to Subpart 4.²²⁰ The Pharmacists comment includes extensive feedback on the first transparency reports published in 2020 by Commerce, as well as proposed two edits to the proposed rules.²²¹

210. As to the PCMA’s concern, the Department notes that the rules specifically limit the information sought to the categories of information authorized by statute. There is no basis to believe that creation of a form to capture that information in a standardized way comes within the definition of rulemaking.²²² Similarly, Commerce believes that Minn. R. 2737.1100, subp. 1 provides substantive limits by establishing data categories.²²³

211. With respect to the MCHP comment, Commerce responds that it believes the proposed addition is unnecessary. As noted in the SONAR, Commerce initially intended to create its own therapeutic category system. Stakeholder feedback convinced Commerce to abandon that approach in favor of selecting an existing system. Had Commerce endeavored to build its own system, the mandatory consultation with PBMs and plan sponsors MCHP advocates would likely have been advisable. By electing to use a “preexisting and commonly used” system, which is consistent with industry standards and periodically reviewed, Commerce believes the rule has sufficient protections to avoid selection of a problematic or unduly burdensome system.²²⁴

212. The Pharmacists request that Subpart 3 specify the conditions under which a PBM would have no reportable data. The Pharmacists urge Commerce to limit the

²¹⁶ *Id.*

²¹⁷ *Id.*

²¹⁸ Ex. I at PCMA Comment.

²¹⁹ Ex. I at AHIP Comment.

²²⁰ Ex. I at MCHP Comment.

²²¹ Ex. I at Pharmacists Rebuttal.

²²² Response at 17.

²²³ *Id.*; Final Response at 8.

²²⁴ Response at 17.

reporting exemption to PBMs with no claims in the state during the reporting period.²²⁵ Commerce believes this definition would exclude other reasons why PBMs may not have reportable data. During the rulemaking process, Commerce learned that PBMs often supply very narrow services and may subcontract out other PBM activities. In these cases, more than one PBM may provide services to a single plan sponsor doing business in Minnesota. Recognizing this industry practice, Commerce crafted a rule that would allow capture of multiple reasons for not being subject to reporting. The modification proposed by the Pharmacists would potentially lead to Commerce receiving reports covering the same underlying transactions from multiple sources. Moreover, Commerce believes that the way the rule is currently drafted is sufficient to identify the failure to report that forms the basis of the Pharmacists' concerns. Similarly, Commerce does not believe the replacement of the word "like" with "uniform" in Subpart 4 makes the rule clearer.²²⁶

213. The Department established that this rule is reasonable and necessary. Minn. R. 2737.1100 is approved.

L. Minn. R. 2737.1200 PHARMACY OWNERSHIP INTEREST

214. Commerce proposes this rule to implement and clarify Minn. Stat. § 62W.07.²²⁷

215. Subpart 1 is necessary to clarify when an enrollee is "required" to use a network pharmacy as described in Minn. Stat. § 62W.07(a). This subpart is necessary and needed to make plain that a network which includes only owned pharmacies, as defined in Minn. R. 2737.0100, subp. 5, constitutes a requirement that the enrollee use a pharmacy owned by the PBM.²²⁸

216. Subpart 2 establishes circumstances under which a PBM is exempt from the prohibitions in Minn. Stat. § 62W.07(b). Commerce explains that this subpart is necessary to minimize the ability of PBMs to steer business towards its own corporate group through special incentives and discounts, as intended by the legislature. Commerce views this statute as requiring a PBM to treat owned and non-owned pharmacies similarly. Thus, under this subpart, to offer an incentive at an owned retail pharmacy, the PBM must make available that same incentive to 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 they choose to fill their prescriptions. This subpart is needed to prevent frustration of that aim. Without this rule, Commerce explains that 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 much greater incentive (\$25.00 off of a copay) at an owned mail order

²²⁵ Ex. I at Pharmacists Comment.

²²⁶ Response at 17-18.

²²⁷ Ex. D at 18.

²²⁸ *Id.*

pharmacy. This rule's requirement that the incentives (or disincentives) be made available pharmacies of the same type achieves the legislative aim of the law.²²⁹

217. Subpart 3, like Subpart 2, attempts to clarify the statutory language, and achieve the legislature's aims. The Department seeks to make clear that the imposition of a quantity or refill limit is only permissible if the PBM has set those same limits at owned and non-owned pharmacies of the same type.²³⁰

218. Commerce asserts that Subpart 4 is necessary to clarify that the provisions of Minn. Stat. § 62W.07 must be read together. A PBM cannot rely on Minn. Stat. § 62W.07(e) in isolation to establish a network consisting only of its own mail order pharmacy, 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 and intent of Minn. Stat. § 62W.07. This subpart is likewise reasonable in that it forecloses a PBM's ability to evade the requirements of the statute, contrary to the legislature's goals.²³¹

219. The Department received comments supporting and opposing this rule.²³² The NACDS, while supportive, suggests that the rule may not sufficiently proscribe the behavior the legislature sought to prohibit.²³³ The Pharmacists and Essentia comments, also supportive, advocate specific revisions to make this rule more prohibitive.²³⁴ The Whittier comment raises concerns about fairness across pharmacy type, rather than within pharmacy type.²³⁵ Other commenters, such as the Prime and PCMA, believe the statutory language is sufficiently clear and accordingly contend that this rule is unnecessary.²³⁶ Additionally, the Prime and the Chamber request that the rule reiterate the statutory language requiring a non-owned network pharmacy to accept the same pricing terms, conditions and requirements as the owned pharmacy to be offered the same financial incentives.²³⁷ The Chamber calls into question the "like for like" requirement of Subpart 2.²³⁸

220. In response to the Pharmacists and Essentia comments pertaining to Subpart 1, Commerce does not agree that the proposed edits add to the existing subpart. Commerce states that the current language already makes clear that if a network—which as noted above must contain a mix of pharmacy types—is made up only of owned pharmacies, the PBM is requiring its enrollees to use its owned pharmacies.²³⁹

²²⁹ *Id.* at 19.

²³⁰ *Id.*

²³¹ *Id.*

²³² See Ex. I.

²³³ Ex. I at NACDS Comment.

²³⁴ Ex. I at Pharmacists Comment, Essentia Comment; Tr. at 23-25.

²³⁵ Ex. I at Whittier Comment.

²³⁶ Ex. I at PCMA Comment, Prime Comment; Tr. at 39-40.

²³⁷ Ex. I at Prime Comment, Chamber Comment.

²³⁸ Ex. I at Chamber Comment.

²³⁹ Response at 18; Final Response at 9.

221. The Department considered Mr. Whittier's comments regarding Subpart 2. Mr. Whittier seeks edits because "If the proposed rules stay as written [PBMs] will still be able to charge lower copays thru their mail order owned pharmacies to incentivize funneling business AWAY from local MN pharmacies of ALL types." Commerce understands and appreciates this concern but believes that its ability to make rules to prevent this would run afoul of § 62W.07(e), which expressly allows PBMs to vary copays and quantity limits based on mail versus retail status—subject to restrictions. The changes Mr. Whittier seeks must come from the legislature.²⁴⁰

222. Commerce, having reviewed the Pharmacists' proposed edits to Subpart 3, agree that these suggestions improve the rule. As drafted, the current rule says a PBM can only impose limits on an owned pharmacy when it has already placed those limits on a non-owned pharmacy. The proposed change would instead all a PBM to impose refill limits on a non-owned pharmacy where the limits have already been placed on an owned pharmacy. Commerce agrees that the Pharmacists' proposed language better reflects the statutory language and intent. Therefore, Commerce proposes to modify Minn. R. 2737.1200, subp. 3, as follows:

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

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

B. Mail order. A pharmacy benefit manager or health carrier may only impose quantity limits or refill frequency limits at a nonowned ~~an owned~~ mail order pharmacy when ~~where~~ the pharmacy benefit manager or health carrier has imposed ~~provides the enrollee access to a nonowned retail pharmacy with the same limits at its owned mail order pharmacies.~~²⁴¹

223. Commerce is likewise persuaded to modify Subpart 4 in response to the valid concerns of the NACDS and Pharmacists, which point out that, as drafted, Subpart 4 could permit a PBM to evade the PBM Law by creating a network comprised of two or more of its owned mail order pharmacies. In response, Commerce proposes to make the following edits to the Subpart 4 of the proposed rule:

Subp. 4. ~~Single~~ Exclusively owned mail order pharmacy networks. If a pharmacy benefit manager administers a network with a single only mail order pharmacies ~~pharmacy~~ that is are ~~an owned~~ pharmacies ~~pharmacy~~, the pharmacy benefit manager is prohibited from (1) offering financial

²⁴⁰ Response at 18; see also Final Response at 9 (recognizing similar concerns raised by Essentia and NCPA).

²⁴¹ Response at 19.

incentives to use the mail order pharmacies pharmacy, or (2) imposing limits on an enrollee's access to medication.

Commerce does not believe the additional edits proposed by NACDS are necessary as this rule is specifically designed to address mail order pharmacies and network arrangements that would frustrate the intent of Minn. Stat. § 62W.07.²⁴²

224. In response to comments that Minn. Stat. § 62W.07 is sufficiently specific to render this rule unnecessary, Commerce responds that there are multiple types of pharmacies providing many types of services enrollees may need. As Commerce noted in the SONAR, and as recognized by comments like the Chamber comment, the purpose of this section of the PBM Law is to provide enrollees with greater choice and flexibility in the pharmacies filling their prescriptions. This rule is needed to prevent frustration of that important goal. Commerce believes the rule's requirement that the incentives (or disincentives) be made available at the same type of pharmacy is the best way to achieve the legislative aim of the law.²⁴³

225. The Department established that Minn. R. 2737.1200 is needed and reasonable. The proposed modifications are promoted by stakeholders and arise out of the rulemaking process. These modifications are permissible. Accordingly, this rule, as modified by the Department, is approved.

M. Minn. R. 2737.1300 SECTION 340B PARTICIPANTS

226. Commerce believes this proposed rule is reasonable and needed to clarify the language of Minn. Stat. § 62W.07(f). The statutory language contains a sort of double negative—must not prohibit—which can lead to contradictory interpretations of the statute. This subpart clarifies that paragraph (f) does not require entry of one or all pharmacies in the 340B program into a PBM network. Instead, the statute prohibits a PBM from categorially prohibiting pharmacies from inclusion in a network due to their participation in the 340B program. The rule further clarifies that a PBM may not condition a pharmacy's continued access to a network on agreements to not participate in the program or require participants to agree to specific terms or reimbursement rates due to their participation. 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.²⁴⁴

227. Sanford, Pharmacists, Essentia, HCMC, Allina, North Memorial, Fairview and MHA offer comments supportive of this rule. Sanford urges inclusion of this rule as necessary to protect pharmacies that participate in the federal 340B Drug Pricing Program.²⁴⁵ Sanford notes it is “crucial” for participating entities, including critical access

²⁴² *Id.*

²⁴³ *Id.*

²⁴⁴ Ex. D at 19.

²⁴⁵ See Ex. I.

hospitals, rural health clinics and disproportionate share hospitals, among others to be able to contract with pharmacies to provide 340B drugs to their patients.²⁴⁶

228. Many of these commenters seek additional language in the rule to prohibit certain actions by PBMs that may dissuade participation in the 340B program.²⁴⁷ Those proposals are summarized as requesting: (1) a rule that PBMs must include 340B pharmacies in the same networks as non-340B pharmacies, (2) a rule that sets reimbursement rates for 340B pharmacies at the same level as non-340B pharmacies, (3) a rule prohibiting PBMs from requiring 340B transactions from being identified except to prevent duplicative discounts, and (4) a rule prohibiting point of sale identification of 340B transactions.²⁴⁸

229. Commerce responds that the rule as proposed represents the full exercise of its rulemaking authority to provide protection to 340B pharmacies. Further, Commerce believes that the statutory language, which references identification at “the point of sale,” to allow point of sale identification and that to adopt such a rule would conflict with the statute. The additional protections urged by the healthcare providers likely require amendment of the PBM Law.²⁴⁹

230. Commerce has demonstrated this rule is reasonable and necessary. Minn. R. 2737.1300 is approved.

N. Minn. R. 2737.1400 OUT-OF-POCKET COST COMPARISONS

231. Minn. Stat. §§ 62W.076 and 62W.077 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. This proposed rule is meant to implement these sections of the PBM Law.²⁵⁰

232. Commerce maintains that Subpart 1 is needed to ensure that access to the information provided for by statute is easily available to enrollees. This subpart allows a PBM to create forms, guidelines and rules, so long as they are not onerous or burdensome.²⁵¹

233. Subpart 2 creates requirements for a PBM’s response to an enrollee. Commerce submits this subpart is reasonable because it requires PBMs, where they have not established any system, to respond in a manner consistent with the enrollee’s 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, how the

²⁴⁶ Ex. I at Sanford Comment.

²⁴⁷ See Ex. I.

²⁴⁸ *Id.*

²⁴⁹ Response at 19; Final Response at 9-10.

²⁵⁰ Ex. D at 19.

²⁵¹ *Id.* at 20.

enrollee will receive the response. Finally, the rule requires that any response use plain language that is easily understood by the enrollee making the request.²⁵²

234. Subpart 3 establishes a time frame within which the PBM must respond to the request of the enrollee. Because a decision on where to fill a prescription is usually a time sensitive one, Commerce believes the rules proposed in this part are needed to effectuate the legislative goal of empowering enrollees to make an informed decision.²⁵³

235. Subpart 4 was added by Commerce after early feedback from PBMs and industry participants. Many PBMs commented that they already maintain an online system that provides this information. 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.²⁵⁴

236. No comments addressing this rule were offered.²⁵⁵

237. This rule is reasonable and necessary. It is approved.

O. Minn. R. 2737.1500 MAXIMUM ALLOWABLE COST PRICING

238. Minn. Stat. § 62W.08 establishes Minnesota's Maximum Allowable Cost (MAC) pricing requirements for contracts between a pharmacy benefit manager and a pharmacy. The statute requires that a PBM create a MAC list, which it must provide along with additional information to a pharmacy with which it contracts. Discussion with the advisory committee and industry participants led Commerce to conclude that rulemaking is needed to establish the technical process of delivering the MAC lists to pharmacists.²⁵⁶

239. Subpart 1 establishes specific requirements for a PBM's MAC list. Because there are many multi-source drugs,²⁵⁷ Commerce believes an easily accessible and searchable format for these lists is of utmost importance. The rule is reasonable because it is unlikely to place additional burdens on PBMs. Most PBMs already maintain a MAC list in an electronic format consistent with the practice of their industry. Moreover, the requirement that the list be in a machine-readable format is likewise 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 locate the specific drug at issue.²⁵⁸

240. Subpart 2 prohibits a PBM from conditioning network inclusion on either waiving or diminishing the rights afforded to pharmacists under Minn. Stat. § 62W.08.

²⁵² *Id.*

²⁵³ *Id.*

²⁵⁴ *Id.*

²⁵⁵ See Ex. I.

²⁵⁶ Ex. D at 20.

²⁵⁷ A "multi-source drug" is one that is available from more than one source, including brand name and generic drugs. Only multi-source drugs are subject to MAC pricing requirements under the PBM Law.

²⁵⁸ Ex. D at 20.

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. Minn. Stat. § 62W.08 establishes a floor for those contracts in Minnesota, and it is reasonable to establish a rule prohibiting waiver of these minimum standards.²⁵⁹

241. In its comment, PCMA suggests replacing the word “paper” on line 16.7 with the word “print.”²⁶⁰ Commerce agrees with this proposed modification.²⁶¹

242. The Chamber comments that the statutory requirements for MAC pricing are specific and clear, and it questions the necessity of this rule.²⁶² Commerce responds that it believes putting prohibitions on abrogating the statutory requirements of the statute into the rules is necessary to effectuate the overall aims of the PBM Law and increases clarity. Allowing PBMs to contract around these provisions would frustrate the law.²⁶³

243. The Pharmacists question which entity chooses the format of a requested MAC list. They also express concern regarding allowable claim amounts and request that Commerce add language to define the term.²⁶⁴ Commerce responds that this rule provides that the PBM must allow a pharmacy to review the list in any of the three (3) formats: electronic, telephonic or print/paper. The rule is written to provide the pharmacy with access to all three depending on the pharmacy’s preference. As to adding additional requirements for the list, Commerce believes it is constrained by the text of the statute.²⁶⁵

244. The Department has established that this rule is reasonable and necessary. The proposed modification does not impermissibly alter the draft rule. Accordingly, proposed Minn. R. 2737.1500 is approved.

P. Minn. R. 2737.1600 PHARMACY AUDITS

245. Minn. Stat. § 62W.09 provides for conducting and reporting of pharmacy audits. Commerce considers this section of the PBM to be largely self-implementing. However, multiple stakeholders provided feedback to Commerce that pharmacies needed to know the standards by which an audit would be conducted to give full effect to the PBM Law.²⁶⁶

246. Subpart 1 is intended to address that concern. This subpart requires that a PBM conducting a pharmacy audit must provide the pharmacy with the standards under which the audit will be conducted, as well as with the process by which a pharmacy may challenge the audit results. The rules are needed to ensure that pharmacists have full understanding of how they will be reviewed, to prevent arbitrary audit standards, and to

²⁵⁹ *Id.* at 20-21.

²⁶⁰ Ex. I at PCMA Comment.

²⁶¹ Response at 20.

²⁶² Ex. I at Chamber Comment.

²⁶³ Response at 20.

²⁶⁴ Ex. I at Pharmacists Comment; Tr. at 25.

²⁶⁵ Response at 20-21.

²⁶⁶ Ex. D at 21.

provide pharmacies with the procedural safeguards of an appeals process. This rule is reasonable, insomuch as it requires disclosure of existing information and places no additional burden on PBMs.²⁶⁷

247. Subpart 2 clarifies that a PBM and pharmacy may not contractually waive the protections afforded pharmacies in Minn. Stat. § 62W.09. This rule is needed and reasonable to effectuate the intent of the PBM law. This rule establishes certainty that public policy prohibits waiver of these rights.²⁶⁸

248. The PCMA objects to providing the appeals process each time a pharmacy under audit is provided with an appealable audit report.²⁶⁹ The Chamber does not see the need for rulemaking in this area, because a contract waiving the protections of § 62W.09 would violate the PBM Law.²⁷⁰

249. In response to the PCMA's comments, Commerce relies on the SONAR and the feedback it received from multiple stakeholders on this question. This rule achieves the aim of effectuating the legislative intent of the law, while minimally burdening PBMs. Subpart 1 requires only that the process be included with an appealable report issued by the auditing entity.²⁷¹

250. The Chamber comments that the rule is unnecessary because a contract waiving statutory rights would be void and unenforceable.²⁷² However, Minnesota law generally permits waivers.²⁷³ Commerce believes prohibiting waivers is necessary to maintain the effectiveness of the PBM Law and clarifies that public policy does not allow such waiver. Allowing regulated entities to contract around these provisions would frustrate the intent of the PBM Law and leave open the question of whether public policy prohibits waiver.²⁷⁴

251. The Department established that Minn. R. 2737.1600 is reasonable and necessary. The rule is approved.

Q. Minn. R. 2737.1700 ALLOWABLE CLAIM AMOUNT

252. Minn. Stat. § 62W.12 creates a ceiling for the amount an enrollee may be charged to purchase a prescription drug at a pharmacy. The statute includes three means by which the charge can be calculated. Minn. Stat. § 62W.12 (2) authorizes use of an "allowable claims amount," which has the potential to be subject to multiple calculations. To create uniformity in the marketplace, and allow enrollees, pharmacists and PBMs to

²⁶⁷ *Id.*

²⁶⁸ *Id.*

²⁶⁹ Ex. I at PCMA Comment.

²⁷⁰ Ex. I at Chamber Comment.

²⁷¹ Response at 21.

²⁷² Ex. I at Chamber Comment.

²⁷³ The law in Minnesota has long been that "except as limited by public policy a person may waive any legal right, constitutional or statutory." *State ex rel. Johnson v. Independent School Dist. No. 810, Wabasha County*, 260 Minn. 237, 246, 109 N.W.2d 596, 602 (1961).

²⁷⁴ Response at 21.

operate with predictable results, this subpart is intended to set forth a precise method that allows anyone to easily determine what the allowable claim amount would be.²⁷⁵

253. Many commenters expressed concerns about Commerce's proposed formula for determining an "allowable claim amount."²⁷⁶ Commenters proposed alternative language. The NACDS and Pharmacists propose this definition: "full point of sale reimbursement amount contracted between the pharmacy benefits manager and the pharmacy[.]" The PCMA proposes this definition: "the health plan contracted rate for purposed of compliance with Minn. Stat. § 62W.12."²⁷⁷

254. In response, the Department submits that the commenters' divergence of opinion as to what constitutes an allowable claim amount evidences the need for rulemaking on this issue. The goal of Minn. Stat § 62W.12 is to ensure that at the point of sale the enrollee attains the lowest cost for a prescription drug. To provide greater clarity, Commerce proposes the following edit:

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

This new definition incorporates elements from both the NACDS comment and PCMA comment's definitions and establishes a workable definition for regulated entities.²⁷⁸

255. Commerce established that this rule is reasonable and necessary. The proposed modification is in response to comments and does not impermissibly alter the draft rule. Minn. R. 2737.1700 is approved.

R. Minn. R. 2737.1800 RETROACTIVE ADJUSTMENTS

256. This part of the rules proposed rules relates to Minn. Stat. § 62W.13, which prohibits a PBM from retroactively adjusting a claim, except where such an adjustment is tied to either a pharmacy audit under Minn. Stat. § 62W.09, or a technical billing error.²⁷⁹

257. Commerce proposes Subpart 1 to prohibit PBMs and pharmacies from contractually waiving the prohibitions of the statute, in the interest of public policy and the intent of the PBM Law.²⁸⁰

258. Subpart 2 requires that a claim of a technical error be supported and accompanied by proof. Commerce considers this rule to be necessary to facilitate administration of the statute. Commerce believes the burden on the regulated parties will be minimal, since, because a PBM must necessarily have had evidence to conclude a

²⁷⁵ Ex. C1 at 17; Ex. D at 21.

²⁷⁶ See Ex. 1; see also Tr. at 26.

²⁷⁷ Ex. I at PCMA Comment, NACDS Comment, Pharmacists Comment, AHIP Comment, Pharmacists Rebuttal.

²⁷⁸ Response at 22.

²⁷⁹ Ex. C1 at 17.

²⁸⁰ Ex. D at 21-22.

billing error occurred. This subpart requires that to invoke this exception, proof must be provided to a pharmacy subject to a retroactive adjustment on this basis.²⁸¹

259. Subpart 3 is designed to prevent a PBM from using retroactive adjustments to achieve what would not be allowable under the statutory and regulatory audit provisions or fees that are paid separate and apart from the reimbursement of drug prices.²⁸²

260. Commenters disagreed on whether this rule was necessary. The PCMA and AHIP argued that the statute was sufficiently clear.²⁸³ AHIP believes that retaining data to support error determinations will be onerous.²⁸⁴ The NACDS and Pharmacists support the intent behind the proposed rule but believe the draft language could be improved upon.²⁸⁵ The Chamber does not see the need for rulemaking in this area, particularly the prohibition against contracting around the provisions of Minn. § 62W.13.²⁸⁶ The Pharmacists also suggest edits to Subpart 3 to improve clarity.²⁸⁷

261. Commerce responds that this proposed rule is designed to ensure that PBMs do not retroactively claw back fees based upon performance or quality-related performance metrics. The rule also helps to bridge Minn. Stat. § 62W.09, governing pharmacy audits, and § 62W.13, governing retroactive adjustments. Commerce explains that the audit provisions set the parameters around the manner and timing governing a PBM's opportunity to recoup improperly paid benefits from a pharmacy. The retroactive adjustment provisions, on the other hand, establish the parameters for a PBM to seek a retroactive adjustment or "clawback." This proposed rule makes explicit what is implicit in the statutes: other types of clawbacks are impermissible. Various types of clawbacks are regularly seen in the industry and were brought repeatedly to the attention of Commerce during the rulemaking process and early implementation of the PBM Law. Commerce submits this proposed rule is necessary to prevent PBMs from using their greater bargaining power to require small or non-owned pharmacies to waive their rights under Minn. Stat. § 62W.13.²⁸⁸

262. Retroactive adjustments, including clawbacks for "billing errors," can result in substantial financial losses to pharmacies. Commerce states it is sympathetic to AHIP's concern about retaining data, concludes that without the requirement "there would be nothing to prevent a PBM from cloaking otherwise impermissible clawbacks in the guise of a technical billing error."²⁸⁹

263. While Commerce is supportive of the additional measures the Pharmacists advocate to strengthen these protections, it believes adopting the additional language proposed would push the rule beyond the Department's authority. In response to the

²⁸¹ *Id.* at 22.

²⁸² *Id.*

²⁸³ Ex. I at PCMA Comment.

²⁸⁴ Ex. I at AHIP Comment.

²⁸⁵ Ex. I at Pharmacists Rebuttal, NACDS Rebuttal.

²⁸⁶ Ex. I at Chamber Comment.

²⁸⁷ Ex. I at Pharmacists Rebuttal.

²⁸⁸ Response at 22-23.

²⁸⁹ Final Response at 11; see *also* Tr. at 20.

Chamber's comment, Commerce reiterates that putting prohibitions on abrogating the statutory requirements of the statute into the rules is necessary to effectuate the overall aims of the PBM Law. Allowing PBMs to contract around these provisions would be contrary to legislative intent. The rule clarifies that public policy is not furthered by waivers of these protections.²⁹⁰

264. With respect to the Pharmacists' proposed modifications of Subpart 3, Commerce responds it disagrees the proposed addition of "positive reward" enhances the rule. However, Commerce is persuaded that the second sentence in Subpart 3 does not add value to the rules and may in fact cause confusion. To that end, Commerce proposes to delete the second sentence in Subpart 3:

Subp. 3. Fees not subject to adjustment. Payment for quality performance metrics included in a prescription drug plan that are based on a pharmacy's quality performance and calculated on prescription count are not retroactive claim adjustments. ~~Retroactive adjustments must not include payments to the pharmacy based on meeting certain performance metrics and must not be based on related prescription count.~~²⁹¹

265. Commerce established that Minn. R. 2737.1800 is reasonable and necessary. The proposed modification does not render the rule substantially different. It is approved.

Based upon the Findings of Fact and the contents of the rulemaking record, the Administrative Law Judge makes the following:

CONCLUSIONS

1. The Administrative Law Judge has authority and jurisdiction to review these rules under Minn. Stat. §§ 14.14, .15, .50, and Minn. R. 1400.2100.

2. The Department gave notice to interested persons in this matter and fulfilled its additional notice requirements.

3. The Department fulfilled the procedural requirements of Minn. Stat. § 14.14 and all other procedural requirements of law or rule.

4. The Department demonstrated it has statutory authority to adopt the proposed rules, except for proposed Minn. R. 2737.0600, subp. 4, and it fulfilled all other substantive requirements of law or rule within the meaning of Minn. Stat. §§ 14.05, subd. 1, 14.50(i), (ii).

5. The Notice of Hearing, the proposed rules, and the SONAR complied with Minn. Stat. § 14.131, Minn. R. 1400.2080 (2021).

²⁹⁰ Response at 22-23.

²⁹¹ *Id.*

6. The Department has demonstrated the need for and reasonableness of its proposed rules by an affirmative presentation of facts in the record, as required by Minn. Stat. §§ 14.14 and 14.50(iii).

7. Except for Minn. R. 2737.0600, subp. 4, the record does not establish a basis for disapproval of the rules under Minn. R. 1400.2100. Minn. R. 2737.0600, subp. 4 conflicts with the rule's enabling statute and must be disapproved pursuant to Minn. R. 1400.2100(D) (2021).

8. Minn. R. 2737.0600, subp. 4, may only be approved if it provides for a contested case proceeding consistent with Minn. Stat. ch. 14.

9. As part of the public comment process, a number of stakeholders urged the Department to adopt revisions to the proposed rules. In each instance, Commerce's rationale in making or declining to make the requested revisions to its rules was well grounded in this record and reasonable. None of the proposed modifications renders the rule "substantially different" under Minn. Stat. § 14.05, subd. 2.

10. A finding or conclusion of need and reasonableness with regard to any particular rule does not preclude, and should not discourage, the Department from further modification of the proposed rules – provided that the rule finally adopted is not "substantially different" (under Minn. Stat. § 14.05, subd. 2) and is based upon facts in the rulemaking record.

Based upon the foregoing Conclusions, the Administrative Law Judge makes the following:

IT IS HEREBY DETERMINED:

If Minn. R. 2737.0600, subp. 4, is revised consistent with the legal conclusions and recommendation herein, it is **APPROVED**. All other proposed rules are **APPROVED**.

IT IS HEREBY RECOMMENDED that the approved rules be **ADOPTED**.

Dated: November 12, 2021


KIMBERLY MIDDENDORF
Administrative Law Judge

NOTICE

This Report must be available for review to all affected individuals upon request for at least five working days before the agency takes any further action on the rules. The Agency may then adopt the final rules or modify or withdraw its proposed rules. If the Agency makes any changes in the rules, it must submit the rules to the Chief Administrative Law Judge for a review of the changes prior to final adoption. Upon adoption of final rules, the Agency must submit a copy of the Order Adopting Rules to the Chief Administrative Law Judge. After the rules' adoption, the Office of Administrative Hearings will file certified copies of the rules with the Secretary of State. At that time, the Agency must give notice to all persons who requested to be informed when the rules are adopted and filed with the Secretary of State.