Rules Governing Pharmacy Benefit Manager Licensure and Regulation

Agency Exhibits

September 2021

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Exhibits Overview

The Minnesota Department of Commerce ("Commerce" or the "Department") has proposed rules governing pharmacy benefit manager (PBM) licensing, regulation, and transparency reporting established under Minn. Stat. § 62W (hereinafter the "PBM Law" or the "Act").

The PBM Law was passed during the 2019 Minnesota legislative session and requires all PBMs contracting with plan sponsors doing business in Minnesota to be licensed as of January 1, 2020. Prior to this law being enacted, PBMs doing business in Minnesota did not require specific licensure. The PBM Law also extends rulemaking authority to the Department.

The Department has followed the rulemaking process according to the State's Administrative Procedure laws. The Department initiated the rulemaking process beginning with the publication of a Request for Comments in the State Register on September 30, 2019. The Department received a number of comments from individuals and organizations interested in the content of the proposed rules and utilized the feedback to inform planning and development of the current proposed rules.

Although not required, the Department formed an advisory committee following the initial Request for Comments in order develop and refine the proposed rules. The committee was made up of individuals representing PBMs, pharmacists, plan sponsors, health insurers, and third party administrators. Committee meetings were held between February and September 2020. The Department also opened committee meetings to the public to allow for additional feedback.

The comments that the Department received following the initial Request for Comments aided in the formation of the advisory committee, as well as in the development of the current proposed rules. The Department therefore is including the following exhibits for the rulemaking record, and in supplement to the Statement of Need and Reasonableness (SONAR):

- PBM Advisory Committee Handbook
- PBM Advisory Committee Agenda*

*Recognizing the difficulty with adjusting to new formats, as well as, the extensive and robust discussion on the topic, the Advisory Committee revisited agenda topics from March 5, 2020 again at its first virtual meeting on May 13, 2020.

These exhibits provide an overview of the rulemaking process undertaken by the Department, with input from relevant stakeholders. Additional information may be made available upon request.

ADVISORY COMMITTEE HANDBOOK

For Rules Pertaining to:

Minnesota Statutes 2019, Chapter 62W:

Minnesota Pharmacy Benefit Manager Licensure and Regulation Act

February 2020

Minnesota Department of Commerce

85 7th Place East – Suite 280

Saint Paul, MN 55101

https://mn.gov/commerce/

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I. Introduction

Welcome to the Pharmacy Benefit Manager (PBM) Licensure and Regulation Rulemaking Advisory Committee. The Department of Commerce, in partnership with the Department of Health thank you for taking the time to apply for and serve on the Committee. Your expertise and advice on rules for PBM licensure and regulation are an essential part of developing a set of rules that are informed, reasonable, and effective in implementing the law. The Department relies on your expertise and engagement in this important work.

The Department developed this handbook to be a one-stop source of information for Committee members. This handbook contains general background information pertinent to the subject of the rules, information on the Committee's purpose and scope, including how members were selected for the Committee, and what work is proposed for the rulemaking process. Additionally, this handbook contains information regarding expectations before, during, and after meetings for both Committee members and Department staff. Lastly, this handbook contains general information that should be useful to all members.

II. Background

The Minnesota Pharmacy Benefit Manager (PBM) Licensure and Regulation Act established Minnesota Statutes 2019, Chapter 62W. The law requires that PBMs doing business in Minnesota have a valid license beginning January 1, 2020. Although the requirement for licensure did not begin until January 1, 2020, the law has been effective since July 1, 2019. The Department of Commerce has worked with the Department of Health to implement the initial licensing requirements established by the law since its effective date. The Department of Commerce has overall licensing authority over PBMs, while the Department of Health is responsible for reviewing network adequacy and reporting this information to Commerce as part of the initial PBM application.

PBM Licensure Work

Work to date has included set-up and rollout of network adequacy reporting documents and requirements, as well as the rollout of Sircon for States for the initial PBM applications to be submitted. Commerce staff have also worked to develop an understanding of the scope of corporate entities requiring licensure in the state. Staff conducted research on actively licensed third party administrators (TPAs) in Minnesota and reviewed lines of business and services offered by each to determine whether or not the definition of a PBM would apply as specified under MN Statutes 2019, § 62W.03, Subd. 15.

The law provides Commerce with authority to draft and adopt rules regarding PBM licensure and regulation. Commerce must complete the process before January 1, 2022. Commerce has identified areas of the law that will require rules for full implementation, and has taken note of other areas identified by stakeholders.

III. PBM Rulemaking Advisory Committee

Rules addressing definitions used in the law are important to all of the impacted parties. Specifically, the definition of a PBM and a plan sponsor require clarification to ensure consistent identification of the need for a PBM license in the state. The exact number of separate corporate entities subject to PBM licensure requirements in 2020 is not known.

The rulemaking process is governed by Minnesota Statutes, Chapter 14 and Minnesota Rules, Chapter 1400. Requirements for the rulemaking process include solicitation of input and comments from the general public, stakeholders, and individuals directly impacted by the content of proposed rules. The rulemaking process has specific requirements for identifying and reaching persons interested in the content of proposed rules. One way of reaching interested persons is through the formation of an advisory committee. Rulemaking procedure does not require that agencies form an advisory committee, but it is highly recommended—especially when the content of the rules requires advice from technical experts.

Advisory committees are generally a collection of individuals with unique knowledge and skills that can be transferred to leadership in an organization or government to make informed decisions regarding a variety of topics. The purpose of an advisory committee is to have each member uniquely represent an area of expertise pertinent to the subject matter at hand. The advisory committee generally does not make final decisions on issues; rather, the committee will review and recommend appropriate courses of action through consensus.

Advisory Committee Overview

The Pharmacy Benefit Manager (PBM) Licensure and Regulation Rulemaking Advisory Committee is a limited-duration standing committee commissioned by the Minnesota Department of Commerce (Commerce) for the purposes of advising on rule development. The work of the Advisory Committee shall be limited to advising on matters directly concerning content of proposed rules for PBM licensure and regulation established under Minnesota Statutes 2019, Chapter 62W. The Advisory Committee shall work primarily with the Commerce Department, but shall also work with the Minnesota Department of Health (MDH) when related to any proposed rules deemed necessary for implementation of network adequacy review standards found under MN Statutes 2019, § 62W.05.

Advisory Committee Purpose and Goals

The Advisory Committee's purpose is to provide advice and recommendations to Commerce on the content of the proposed rules for the Minnesota Pharmacy Benefit Manager Licensure and Regulation Act. The Advisory Committee shall have no legal responsibilities. Recommendations and advice from the Committee may be accepted or rejected by Commerce. Commerce, in consultation with MDH, has final authority to accept or reject recommendations from the Advisory Committee as the Departments propose and finalize rules.

The Advisory Committee's scope of work advising on rules includes but is not limited to the following areas of the law:

- Definitions;
- Requirements for initial PBM licensure and renewal;
- Transparency reporting procedures and requirements;
- Expected business practices of PBMs; and
- Regulatory and enforcement standards.

Committee Membership

The Advisory Committee was developed with considerations from the Minnesota Rulemaking Manual (24th Ed.) as well as language from Minnesota Statutes 2019, § 14.001. The Committee's membership would be expected to have individuals with subject matter expertise in the topic that also reflect demographics of the general population. Committee members will be expected to seek consensus when possible to move forward, requiring a commitment to assessing rules for rational need and reasonability. Committee members will have diverse backgrounds and will also be on opposing sides of the topic. The Committee therefore should:

- Include members with diverse skills and experiences;
- Advise on proposed rules with consideration to both overall reasonability and stakeholder interests;
- Provide feedback to aid in clarifying, refining, or improving proposed rules language;
- Advise based on the expertise and industry represented;
- Consider the reasonability and feasibility of all ideas first.

The Advisory Committee was proposed to consist of at least eight members, but not exceed 15 members. Prospective members were asked submit an application for consideration, including a resume or CV, as well as a statement of interest that addresses background and skills relevant to the Committee's purpose. The Department of Commerce, in consultation with MDH, reviewed applications and appointed members to the Advisory Committee, selecting from the following areas of need:

- Licensed Pharmacists[1]
- Legal Experts[2]
- Plan Sponsors
- PBMs and/or Drug Manufacturers
- Health Plans

[1] Specifically, licensed pharmacists that have experience working a retail, chain, or independent pharmacy; pharmacists with health plan or utilization review experience; pharmacists engaged in academic research with experience working with large volumes of data.

[2] Legal experts includes practicing attorneys and/or professors of law experienced with federal employment law, data privacy, and medical or pharmacy work, or any combination of these subjects.

- Expertise in health policy, particularly related to prescription drug pricing and healthcare spending
- Expertise in pharmacy and PBM data and claims
- Health Advocates/Directors of Rare or Chronic Disease Organizations[3]

Selection Criteria

Committee members were selected to ensure representation of a cross-section of impacted parties and subject matter experts related to PBM licensure. Criteria for selection of the candidates for the Committee were based on the number of applications received in each area of need for rulemaking and a combination of individual experience, committee availability, and expertise in sub-topics of each area.

IV. Roles, Responsibilities, and Expectations

Both Committee members and Department staff have set roles, responsibilities, and expectations for the duration of the Committee's work. The Department will have a set of work expectations for Committee members both during meetings and in-between. Department staff will hold itself accountable to expectations for the Committee itself.

Advisory Committee Role

The role of the Advisory Committee is to help draft and review proposed changes to rules related to PBM licensure and regulation. The Committee does not have full voting authority on what content goes into the rules. Advisory Committee Members are expected to represent their particular interest group or area of expertise. Members are encouraged to maintain contact with colleagues and others who share their interests to help provide feedback on the proposed rules.

Members are expected to attend meetings in-person a majority of the time and be ready to discuss draft work at each meeting.

Consensus on discussion is desirable, but the Department acknowledges there will be disagreement on some issues. The Department's goal is to ensure that rules are carefully considered, and expects that comments from members are given with the consideration that all rules must be justifiable as reasonable and necessary.

State Agency Role

The Department of Commerce is the primary agency involved in the rulemaking process for PBM licensure and regulation. Commerce staff convened the Committee and will manage its functions, including leading each Advisory Committee meeting. Commerce will take notes on Committee discussion, and will ensure that comments are made transparent for additional input from the public. Commerce will be available to Committee members for discussion and feedback. Commerce will also solicit expertise from partnering agencies, including

[3] The Department seeks individuals that are at an executive level of an organization focused on advocacy for individuals living with chronic disease, cancer, rare diseases, or conditions requiring regular use of high-cost prescriptions.

the Department of Health, and the Department of Human Services as required. Other state agency participation in meetings will be limited to providing expertise or background on content. Commerce has sole responsibility for the rules drafts.

Communications

Department staff will ensure that Committee deliberations, including edits and additions to rules will be made within seven business days following each meeting. Staff will also ensure that meeting minutes are sent within three business days following the date of the Committee meeting. Notification of meetings will be sent to Committee members and the public two weeks in advance of scheduled meetings to ensure maximum participation and attendance.

Public Data and Meetings

All meetings of the Advisory Committee will be open to the public. Any documents or data produced by the committee will be subject to Minnesota's Data Practices Act. This includes drafts of rules distributed by Commerce, communications between committee members where a Commerce employee is included in the communication, as well as meeting notes and minutes created and maintained by Commerce.

V. Work Plan and Timeline

The Committee will focus on two major items required for rulemaking—the actual draft of the rules and the Statement of Need and Reasonability (SONAR). These two items are developed concurrently throughout the rulemaking process and are pivotal to successful adoption of rules. Additional information will be provided throughout meetings. The following is an overview of rulemaking in Minnesota.

Rulemaking Overview

State agencies are generally delegated powers through the legislative process. State agencies have expertise and experienced personnel capable of developing the rules necessary to fully implement a legislative program, filling any gaps left by the original statute. Rulemaking powers for state agencies are limited and only appropriate under certain situations.

Statutory requirements for rulemaking in Minnesota can be found under Minnesota Statutes, **Chapter 14** – Administrative Procedure. The purpose of administrative procedure is to ensure that agencies may effectively execute duties assigned to them, while allowing for maximum transparency and public input. Transparency and public input are critical to the rulemaking process.

There are a number of ways in which rules may be adopted. The Department anticipates following the process for rules adopted after a public hearing. Rules adopted after a public hearing require significant input from a variety of stakeholders, as well as a formal public hearing before rules can be officially adopted.

The process for rules adopted after a public hearing requires an agency to work with the Governor's Office, Revisor's Office, and Office of Administrative Hearings (OAH).

The process for adopting rules after a public hearing is long, and is generally used in situations where the subject of the rules is either likely to generate significant public interest, or is potentially controversial. If there are 25 or more individuals that request a hearing after the agency provides notice of intent to adopt rules, then a hearing is required by law.

The process begins with the publication of a request for comments in the State Register. This must be done by the agency within 60 days of the effective date the law granting rulemaking authority. An agency must also wait at least 60 days before having a notice of intent to hold a hearing published. During this time, the agency should solicit comments and expertise from stakeholders to guide drafting the rules. The required statement of need and reasonability (SONAR) should be drafted during this time as well.

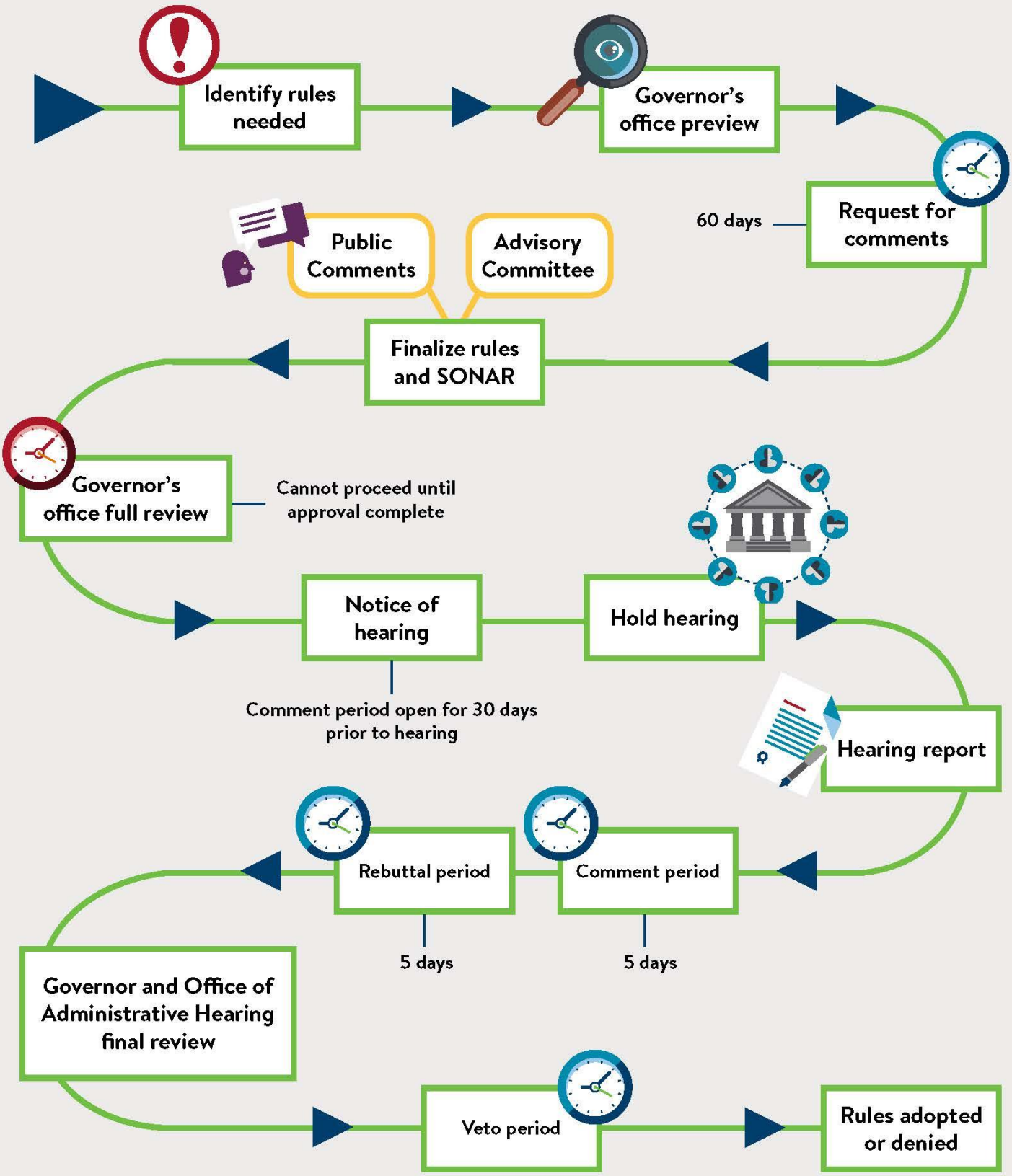
Required documentation, including the rules themselves and the SONAR, should be submitted once completed to the Revisor's Office before publishing a notice of a request for hearing. The request for a hearing must be finalized with the OAH before the notice is published. Once a date is set for the hearing, and notice has been provided, the agency needs to compile all documents related to the rulemaking process for the hearing. Generally, a representative will appear at the hearing on its scheduled date.

Following a public hearing, any required revisions need to be made to the rules. Once the rules are finalized, after revisions based on the hearing, the OAH reviews approved rules and files with the Secretary of State. During this period, the rules are forwarded to the Governor's Office, allowing 14 days after receipt of the rules to veto. If the rules have not been vetoed by the Governor, the Revisor's Office will prepare a notice of adoption for publication in the State Register. Adopted rules are then effective five days after notice is published in the State Register.

RULEMAKING PROCESS

Rules Adopted with Public Hearing

COMMERCE DEPARTMENT



Draft Rules and Requirements

The development of an agency's rules is a very lengthy process, taking anywhere from six months to two years to complete. Statutory authority for rulemaking often expires after 18 months of the effective date of a law authorizing an agency to engage in rulemaking. A limited timeline for rulemaking requires agencies to pay close attention to requirements of the process upfront, while consistently working on drafts of the actual rules. Maintaining quality work and attention to detail throughout this process will help an agency succeed at having their rules adopted. The Department's rulemaking authority expires beginning January 1, 2022.

When in the process of developing rules, agencies should always be considering the statutory authority granted to them in the law, while balancing the need to ensure rules do not conflict with existing laws. Most importantly, agencies must always pay attention to the reasonability of the rules themselves so that they cannot be dismissed as arbitrary.

Rule development can and should be conducted with the advice of subject matter experts related to the content of the rules. As mentioned previously, agencies may convene an advisory committee for the purposes of improving the rules themselves.

In addition to the rules themselves, the other major item needed in the rulemaking process is the Statement of Need and Reasonability, which can be drafted concurrently with the rules.

Statement of need and reasonability (SONAR) Requirements

The state agency must prepare a statement of need and reasonability (SONAR) as part of the rulemaking process. The purpose of the SONAR is to provide a summary of evidence and arguments justifying why the rules that the agency requires are reasonable.

In developing the SONAR, it is required to provide a thorough regulatory analysis that addresses who will be impacted by proposed rules, costs associated, whether or not there are alternative means to the rules, and how the rules compare to existing state and federal regulations.

The SONAR requires a description of how the agency developed the rules, as well as its efforts to engage the public and other individuals potentially impacted by the rules.

The agency developing rules must also consult with the Minnesota Management and Budget (MMB) office to consult on economic impact of the potential rules.

The SONAR is a crucial part of the rules, and a significant amount of attention and time should be paid to this required document. The SONAR does not need to contain the "best" solutions regarding rules, but it should always be reasonable.

VI. Resources

Committee Member List

Name	Organization
Andrew Behm, PharmD, BCGP	Express Scripts
Michael Dewberry	Blue Cross Blue Shield of Minnesota
Richard Bruzek, RPh, PharmD	Independent Consultant
Stacey Drentlaw	Taft Stettinius & Hollister
Nathan Gansen	Medica
Margaret Kasting	SFM Mutual Insurance Company
Amy Monahan, JD	University of Minnesota Law School
Alyssa Poehls	ClearScript
James Read, PhD	College of Saint Benedict/Saint John's University
Stephen Schondelmeyer, BS, PharmD, MA, PhD, FAPhA	University of Minnesota
Laura Schwartzwald, RPh	GuidePoint Pharmacy
Steven Simenson, BPharm, FAPhA, FACA, FACVP, DPNAP	Goodrich Pharmacy
Jay Warmuth	Faegre Baker Daniels, LLP
Stuart Williams	Henson & Efron

Agency Contact Information

General Contact:

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651-539-1500 or 1-800-657-3602

Advisory Committee and Rules Contact:

Andrew Kleinendorst
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651-539-1734

Directions and Building Information

The Department of Commerce is located at the Golden Rule Building in downtown Saint Paul, Minnesota.

From I-94 Eastbound (Minneapolis):

Take Exit 241B for 5th Street; continue on W 5th Street; turn left onto N Minnesota Street; turn tight on 7th Place East.

From I-94 Westbound (Eastern Suburbs):

Take Exit 242D for 6th Street; continue on 6th Street E; turn right onto N Minnesota Street; turn right onto 7th Place East.

From I-35 E Southbound (Northern Suburbs):

Take Exit 107A for US-52/US-10E/I-94/10th Street/Wacouta Street; follow middle lane signs for Wacouta Street; turn right onto 6th Street E; turn right onto N Minnesota Street; turn right onto 7th Place East.

From I-35 E Northbound (Southern Suburbs):

Take Exit 242C toward 7th Street; turn right onto 6th Street E; turn right onto Minnesota Street; turn right onto 7th Place East.

Metered street parking is available. Parking is also available at the Robert Street Municipal Ramp at 95 E 7th Street, connected by skyway to the Golden Rule Building.

Pharmacy Benefit Manager (PBM) Licensure and Regulation Advisory Committee

Date: February 12, 2020 4:00-6:00 PM

Minnesota Department of Commerce
Golden Rule Building
85 7th Place East
Saint Paul, MN 55101

Conference Room 295

WebEx Link Meeting Number: 968 928 319 Meeting Password: 7k7wSw7ycJT

1. Welcome and Introductions — 30 Minutes
Advisory Committee Members
Commerce Staff

2. Advisory Committee Overview — 45 Minutes
Commerce Staff
- Responsibility of committee members
- Responsibility of Commerce Staff
- Consensus building
- Data practices

3. Overview of Rulemaking Process — 15 Minutes
Commerce Staff
- Rulemaking types
- Drafting rules
- Review process
- Issues in rulemaking

4. Review Committee Purpose — 30 Minutes
Commerce Staff
Advisory Committee Members
- Priorities for rulemaking
- Priorities for Statement of Need and Reasonability

Agenda

Pharmacy Benefit Manager (PBM) Licensure and Regulation Advisory Committee

Date: March 5, 2020
Time: 4:00-6:00 PM

Location
Golden Rule Building, Conference Room 295
85 7th Place East
Saint Paul, MN 55101

WebEx Information
WebEx Login
Meeting Number: 962 074 647
Meeting Password: cSMkcva9M4

1. Welcome and Introductions — 15 Minutes
Advisory Committee Members
Commerce Staff
- Recap of Feb. 12 meeting
- Today's work

2. Transparency Reporting Requirements — 45 Minutes
Andy Kleinendorst
Advisory Committee Members
- General feedback of draft
- Cataloguing of definitions

5 Minute Break

3. Draft Review — 45 Minutes
Andy Kleinendorst
Advisory Committee Members
- §62W.06, Subdivision 2
- §62W.06, Subdivision 1

4. Public Comments/Next Steps — 15 Minutes

5. Adjourn

Agenda:

Pharmacy Benefit Manager (PBM) Licensure and Regulation Advisory Committee

Date: June 11, 2020 4:00-6:00 PM

WebEx Link Meeting Number: 146 798 9946 Meeting Password: PBMCommittee

1.	**Check-in and Recap** *Advisory Committee Members* *Commerce Staff* - Review of edits to draft language for Minn. Stat. 62W.06	30 Minutes
2.	**Review of PBM Business Requirements** *Advisory Committee Members* *Commerce Staff* - Initial Licensure - Renewal - PBM Business Practices	30 Minutes
3.	**Review of Network Adequacy Requirements** *Advisory Committee Members* *Commerce Staff* *MDH Staff*	30 Minutes
	Break	15 Minutes
4.	**Public Comments**	15 Minutes