Pharmacy Benefit Manager (PBM) Licensure Requirements

Technical Guidance Session

Department of Commerce | Department of Health

8/27/2019
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III. Requirements (Upcoming and Ongoing)

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SF 278 was introduced during the 2019 Minnesota legislative session, proposing licensing requirements for pharmacy benefit managers (PBMs) doing business in Minnesota.

SF 278 had its first hearing on January 17, 2019 in the Minnesota Senate and moved forward with bipartisan support into the House as HF 728.

The bill was signed into law by Governor Tim Walz on May 17, 2019, creating a new chapter in Minnesota Statutes – 62W.

The revisor site is not updated yet, so the bill can be found as Chapter 39: https://www.revisor.mn.gov/laws/2019/0/Session+Law/Chapter/39/
The bill as signed into law addresses the following significant areas:

- Licensing requirements for PBMs
- Network adequacy requirements
- Plan design requirements
- Operational requirements
- Transparency reporting
  - To plan sponsors
  - To the Minnesota Department of Commerce
Several states have recently adopted proposals requiring licensure and greater transparency of PBMs.

- Public interest regarding the overall rise of prescription drug prices has driven policy.

Both the Departments of Commerce (Commerce) and Health (MDH) were tasked with implementing parts of the new law.

- Commerce has overall licensing authority, transparency reporting and enforcement over PBMs;
- MDH provides crucial analysis and approval of network adequacy reporting required by the law.
Chapter 62W.02 defines a PBM as “a person, business, or other entity* that contracts with a plan sponsor to perform pharmacy benefits management, including but not limited to:

1. contracting directly or indirectly with pharmacies to provide prescription drugs to enrollees or other covered individuals;
2. administering a prescription drug benefit;
3. processing or paying pharmacy claims;
4. creating or updating prescription drug formularies;
5. making or assisting in making prior authorization determinations on prescription drugs;
6. administering rebates on prescription drugs; or
7. establishing a pharmacy network.

*Pharmacy benefit manager does not include the Department of Human Services. Engaging in any one of these functions will require a license.
• The Commerce Department currently provides licensure for Third Party Administrators (TPAs) operating in Minnesota.

• Some services provided by TPAs fall under the scope of Chapter 62W.

• TPAs providing PBM services must obtain licensure as a PBM in Minnesota when their plan sponsors are domiciled in Minnesota, and/or where any covered beneficiaries reside in Minnesota.

• Entities requiring PBM licensure should already be licensed as a TPA in Minnesota. If not, that is an important first step that should be pursued immediately.
• **Licensing Requirements**
  
  • All entities doing PBM business activities in Minnesota must be licensed on January 1, 2020.
  
  • Initial PBM application must be submitted with a $8,500 non-refundable fee.
    
    • Licenses are valid for one year. Renewal applications must be submitted for review and include an additional $8,500 non-refundable fee.
  
  • Commerce may require additional information within 30 days. Commerce will either approve and issue a license or deny licensure within 90 days after the application is deemed complete.

• **Network Adequacy**

  • PBMs must file a report of network adequacy to be reviewed by the MDH.
• **Transparency Reporting**

  • Beginning June 1, 2020, and annually thereafter, PBMs must submit data to Commerce regarding aggregate and claims-level pharmacy data, including information on wholesale costs, rebates received and passed on, and discounts and fees.

    • Commerce is working on data repository, formats, processes and rules.

  • Commerce must publish a report on the data received from the transparency reports on the Commerce website.

  • Transparency reporting is required of PBMs at the request of plan sponsors as well.
• Plan Design and Operational Requirements:
  • Prohibition of incentivizing enrollees to use PBM-owned pharmacies or penalizing enrollees for not using PBM-owned pharmacies.
  • Transparency of cost to enrollees—enrollees may obtain an estimate of anticipated costs for using a network pharmacy from a PBM when requested.
  • Rules around how PBMs audit pharmacies.
  • Gag clause provision.
  • Rulemaking authority granted to Commerce.
Bill Requirements – Next Steps

- **Network Adequacy Reporting Requirements Finalized (8/20/2019)**
- **Technical Guidance from the Departments (ongoing)**
- **Final Application Deadlines for 2020 licensure:**
  - Network Adequacy Reports 9/13/2019
  - Commerce Online Application 10/1/2019
- **Commerce approves or denies applications within 90 days after application is deemed complete.**
To begin the process, send an email to: PBM.Licensing@state.mn.us
• (Use the Subject line: "MN PBM License – Network Adequacy")

This email must include the following information:
• PBM Corporate Entity name
• PBM Federal Employer Identification Number (FEIN)
• The total number of networks to be submitted under the license application
• A network name for each network
• Primary contact name, phone number and email address

In response to this email, the Health Department will provide a partially completed network template, which establishes the applicant's unique network ID(s) with instructions on how to submit network adequacy documents to the Health Department's Network Adequacy web portal.
Enter PBM corporate name for "Carrier Name"

Enter the PBM network ID for "SERFF Network ID"
Network Adequacy – Required Documentation

• Required forms and templates for network adequacy data submissions:
  • Network template
  • Provider template
  • Geographic Access maps (Created by PBM Applicant)
  • Attestation form
  • Network Adequacy Waiver Request Form (if requesting a waiver from statutory network adequacy requirements)
• Geographic Access slides must include:
  • Map identifying all counties in the network service area.
  • Map identifying in network Retail Pharmacy locations measured against the service area using a 60 mile standard.
  • Map identifying the location of in network Long Term Care pharmacies
  • Map identifying the location of in network Specialty pharmacies
  • Map identifying the location of in network Tribal pharmacies (if available)

• All forms/templates, and link to data submission portal, will be made available at: https://mn.gov/commerce/industries/insurance/licensing/

• Network adequacy documents must be submitted by 09/13/2019
Questions Received

• The Departments have received several questions regarding PBM licensure and network adequacy requirements.

• PBM licensure inquiries have included requests for:
  • Clarification of what entities are considered PBMs;
  • Guidance on what lines of business include PBM services;
  • Understanding on what pharmacy services fall within the scope of 62W.

• The Departments defer to explicit indications in 62W regarding the definition of a PBM and licensure requirements.
• TPAs or other entities unsure of their potential status as a PBM in 2020 should review the definition in Chapter 62W and consult the Departments as soon as possible.
  • The Departments will work with currently licensed TPAs and other entities regarding the definition of a PBM and licensing requirements as requested;
  • In cases where there is a question about the applicability of the PBM licensure requirements to your organization, the Departments will review company-provided analyses justifying the applicability of provisions. At this time, we will only accept analyses pertaining to initial licensure (including network adequacy reporting).

• Network adequacy report requirements are continuing to be finalized. Please see the contact information on the previous slides for more information.
• The Departments will continue to add information and relevant updates to the Commerce Licensing web site:

https://mn.gov/commerce/industries/insurance/licensing/

• All questions regarding licensure may be directed to PBM.Licensing@state.mn.us

• Notify other parties that may be subject to the requirements of 62W.
Questions?