

Pharmacy Benefit Manager 101: Nebraska Licensure and Regulation

Housekeeping

- Continuing Education
 - 1 hour of Continuing Legal Education
 - Activity Number: 256450
- If you need the PowerPoint or any help during the presentation,
 - Message AJ Raaska (AJ.Raaska@Nebraska.gov)
 - She will be monitoring the chat
- Stay For The Poll At The End

Agenda

- Pharmacy Benefit Managers Basics
- The Nebraska Pharmacy Benefit Manager Licensure and Regulation Act
- State and Federal Legislation to Watch
- Federal PBM Jurisprudence
- Other Resources
- Questions

Pharmacy Benefit Manager (PBM)

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- PBMs are third-party administrators contracted by health plans, large employers, unions, and government entities to manage prescription drug benefits programs.
- PBMs engage in the **negotiation and financial transactions** between **pharmaceutical manufacturers, health plans, and pharmacies.**

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Pharmacy Benefit Manager (PBM)

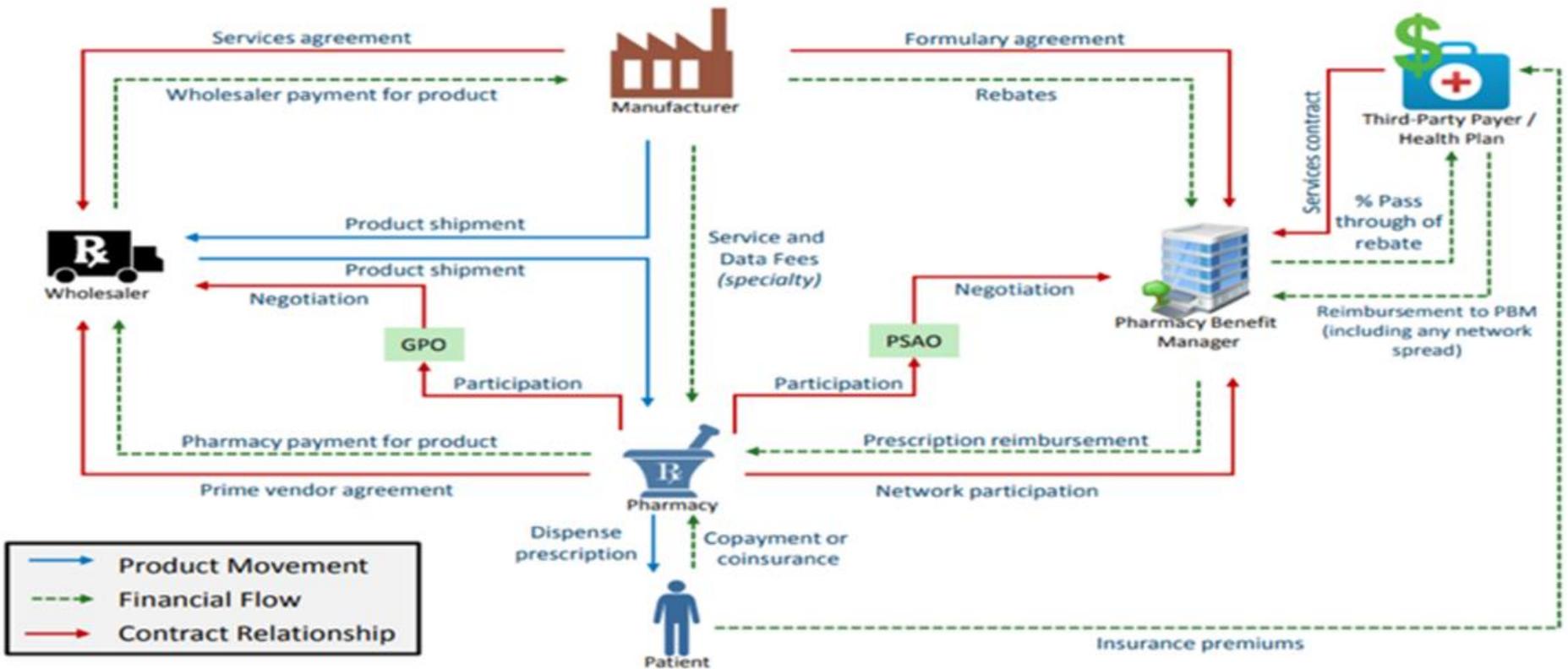
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Pharmacy Benefit Manager (PBM)

- **Over 40 states require PBMs to be licensed by or register with the state's Department of Insurance.** In addition, a few states require PBMs to register as a Third-Party Administrator (TPA.)
- PBMs maintain relationships with key stakeholders in the pharmaceutical supply chain:
 - **Drug Manufacturers**
 - **Health Payors/Health Plan**
 - **Pharmacies**

Pharmacy Supply Chain Workflow

U.S. Distribution and Reimbursement System: Patient-Administered, Outpatient Drugs



Source. Fein, Adam J., *The 2018 Economic Report on U.S. Pharmacies and Pharmacy Benefit Managers*, Drug Channels Institute, 2018.

Nebraska

- LB 767, enacted during the 2022 Legislative Session, created the Pharmacy Benefit Manager Licensure and Regulation Act (The Act), [Neb. Rev. Stat. § 44-4601 to 44-4612](#)
- ***44-4602(1) The Pharmacy Benefit Manager Licensure and Regulation Act establishes the standards and criteria for the licensure and regulation of pharmacy benefit managers providing a claims processing service or other prescription drug or device service for a health benefit plan.***
- Application for Certificate of Authority Pharmacy Benefit Manager is completed online at https://appengine.egov.com/apps/ne/doi_pharmacy_benefit_manager

Nebraska PBM Checklist

- 11 pages with live links to the Act

PHARMACY BENEFIT MANAGER APPLICATION CHECKLIST 2023

This checklist must be submitted with the Pharmacy Benefit Manager Application.

These standards are summaries only. Review of the entire statute may be necessary. Complete the far right column to direct reviewers to the page of your submitted documents that demonstrates compliance with the described standard.

FILER: PLEASE TYPE INFORMATION IN THE AREA DIRECTLY BELOW.				
Company name:				
Federal ID Number:				
(DOI reviewer) Check as completed	Standard	Reference (§ 44 refers to Neb. Rev. Stat. Chapter 44, Nebraska's Insurance Code)	Description	Applicant: Provide page number and specific reference to the contract provision
Pharmacist/Pharmacy Participation Contracts Application Question 9(f)				
<input type="checkbox"/>	Maximum Allowable Cost (MAC) price list	§ 44-4608(1)(c)	Contract states how pharmacies can access the MAC list; must be in a readily accessible format that can be used by the contracted pharmacy.	
<input type="checkbox"/>	MAC price list updated at least every seven business days	§ 44-4608(1)(a)	Contract includes commitment that MAC list will be updated at least every seven business days with changes in price from previous list specifically noted.	
<input type="checkbox"/>	MAC price lookup	§ 44-4608(1)(a)	Contract states the means a pharmacy can use to review a current price in an electronic, print, or telephonic format within one business day of any such change at no cost to the pharmacy.	
<input type="checkbox"/>	Prices not allowed on MAC list	§ 44-4608(2)	Contract includes statement that a drug will not be placed on the MAC list unless that drug is available for purchase by pharmacies in Nebraska from a national or regional drug wholesaler and is not obsolete.	

Reasons for the Act

- 44-4602(2) The purposes of the act are to:
 - (a) Promote, preserve, and protect public health, safety, and welfare through effective regulation and licensure of pharmacy benefit managers;

Reasons for the Act

- 44-4602(2) The purposes of the act are to:
 - (b) Promote the solvency of the commercial health insurance industry, the regulation of which is reserved to the states by the federal McCarran-Ferguson Act, 15 U.S.C. 1011 to 1015, as such act and sections existed on January 1, 2022, as well as provide for consumer savings and encourage fairness in prescription drug benefits;

Reasons for the Act

- 44-4602(2) The purposes of the act are to:
 - (c) Provide for powers and duties of the director; and

Reasons for the Act

- 44-4602(2) The purposes of the act are to:
 - (c) Provide for powers and duties of the director; and
 - (d) Prescribe monetary penalties for violations of the Pharmacy Benefit Manager Licensure and Regulation Act

Applicability

- 44-4604(1) The Pharmacy Benefit Manager Licensure and Regulation Act applies to any contract or health benefit plan issued, renewed, re-credentialed, amended, or **extended on or after January 1, 2023**, including any health carrier that performs a claims processing service or other prescription drug or device service through a third party.



Who Must be Licensed as a PBM in Nebraska?

- A PBM is defined by what it does, the type of plan for which it provides those services, and who the plan covers:
 - Defined in the Act in 44-4603(11)
 - (a) Pharmacy Benefit Manager means a person, business, or entity, including a wholly or partially owned or controlled subsidiary of a pharmacy benefit manager, that provides a **claims processing service or other prescription drug or device service** for a **health benefit plan** to a covered person who is a resident of this state; and

Who Must be Licensed as a PBM in Nebraska?

- A PBM is defined by what it does, the type of plan for which it provides those services, and who the plan covers:
 - Defined in the Act in 44-4603(11)
 - (b) Pharmacy Benefit Manager does not include:
 - (i) A health care facility licensed in this state;
 - (ii) A health care professional licensed in this state;
 - (iii) A consultant who only provides advice as to the selection or performance of pharmacy benefit manager; or
 - (iv) A health carrier to the extent that it performs any claims processing service or other prescription drug or device service exclusively for its enrollees

Who is NOT Required to be Licensed as a PBM in Nebraska?

- These entities do not meet the definition of a PBM:
 - Workers Compensation Plans
 - Self-Insured ERISA (Employee Retirement Income Security Act) Plans.
 - They are subject to federal insurance laws and do not meet the definition of a health carrier under the Act.
 - Medicaid/Medicaid Managed Care Organizations
 - Medicare Part D



How does the Act Provide for Consumer Savings?

- **Increases Transparency by Prohibiting Gag Clauses in Pharmacy Contracts**
- Neb. Rev. Stat. § 44-4606(1) – A participation contract between a pharmacy benefit manager and any pharmacist or pharmacy providing prescription drug coverage for a health benefit plan shall not prohibit or restrict any pharmacy or pharmacist from or penalize any pharmacy or pharmacist for disclosing to any covered person any health care information that the pharmacy or pharmacist to such treatment;

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How does the Act Provide for Consumer Savings?

- **Increases Transparency by Prohibiting Gag Clauses in Pharmacy Contracts**
 - (a) the nature of treatment, risks, or an alternative to such treatment;
 - (b) the availability of an alternative therapy, consultation, or test;
 - (c) the decision of a utilization reviewer or similar person to authorize or deny a service;

How does the Act Provide for Consumer Savings?

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 - (a) the nature of treatment, risks, or an alternative to such treatment;
 - (b) the availability of an alternative therapy, consultation, or test;
 - (c) the decision of a utilization reviewer or similar person to authorize or deny a service;
 - (d) the process that is used to authorize or deny a health care service or benefit; or

How does the Act Provide for Consumer Savings?

- **Increases Transparency by Prohibiting Gag Clauses in Pharmacy Contracts**
 - (e) information on any financial incentive or structure used by the health carrier. Neb. Rev. Stat. § 44-4606(2), A pharmacy benefit manager shall not prohibit a pharmacy or pharmacist from discussing information regarding the total cost for a pharmacist service for a prescription drug or from selling a more affordable alternative to the covered person if a more affordable alternative is available.

Places a Limit on Patient Cost-Sharing

- **Neb. Rev. Stat. § 44-4606(5)(a)** – A pharmacy benefit manager shall not require a covered person purchasing a covered prescription drug to pay an amount greater than the lesser of the covered person's cost-sharing amount under the terms of the health benefit plan or the amount the covered person would pay for the drug if the covered person were paying the cash price.

Places a Limit on Patient Cost-Sharing

- Any amount paid by a covered person under subdivision (5)(a) of this section shall be attributable toward any deductible or, to the extent consistent with **section 2707 of the federal Public Health Service Act, 42 U.S.C. 300gg-6**, as such section existed on January 1, 2022, the annual out-of-pocket maximum under the covered person's health benefit plan.

How does the Act Encourage Fairness in Prescription Drug Benefits?

- Establishes Maximum Allowable Cost (MAC) list requirements (**Neb. Rev. Stat § 44-4608**)
 - MAC lists must be updated every seven days, noting changes from the previous list and outlines the required timelines for appeals challenging the MAC price.
- Creates requirements for a PBM's audit of a pharmacy (**Neb. Rev. Stat. § 44-4607**)
 - Requirements include requiring a PBM giving notice to a pharmacy before conducting an audit; requires PBMs to audit similarly situated pharmacies under the same standards and lists the process that must be met before recoupment.

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- Prohibits discrimination against 340B-covered entities (Neb. Rev. Stat. § 44-4609)
 - Prohibits a PBM from reimbursing a 340B-covered entity in an amount less than the PBM would reimburse a non-340B pharmacy in their network; prohibits a PBM from refusing to contract with a 340B entity if it interferes with an individual's choice of pharmacy; prohibits assessing any fee, chargeback, or other adjustment on a 340B entity on the basis of participating in the 340B program.

Continued...

- Prohibits the exclusion of an accredited specialty pharmacy from the PBM specialty pharmacy network (Neb. Rev. Stat. § 44-4610)
 - Prohibits a PBM from excluding a pharmacy that holds specialty pharmacy accreditation from a nationally recognized accrediting organization that is willing to accept the terms and conditions of the PBM's agreement with other specialty pharmacies.



Enforcement

- Neb. Rev. Stat. § 44-4611(1) The director shall enforce compliance with the requirements of the Pharmacy Benefit Manager Licensure and Regulation Act.
 - (2)(a) Pursuant to the Insurers Examination Act, the director may examine or audit the books and records of a pharmacy benefit manager providing a claims processing service or other prescription drug or device service for a health benefit plan to determine compliance with the act.

Enforcement

- Neb. Rev. Stat. § 44-4611(1) The director shall enforce compliance with the requirements of the Pharmacy Benefit Manager Licensure and Regulation Act.
 - (b) Information or data acquired during an examination under subdivision (2)(a) of this section is:
 - (i) Considered proprietary and confidential;
 - (ii) Not subject to sections 84-712, 84-712.01, and 84-712.03 to 84.712.09
 - (iii) Not subject to subpoena; and
 - (iv) Not subject to discovery or admissible as evidence in any private civil action

Continued...

- (3) The director may use any document or information provided pursuant to subsection (3) or (4) of section 44-4606 in the performance of the director's duties to determine compliance with the Pharmacy Benefit Manager Licensure and Regulation Act.

Complaints

- Complaints against a Pharmacy Benefit Manager can be submitted online at <https://doi.Nebraska.gov/consumer/consumer-help>
- **How filing a complaint with the Nebraska Department of Insurance can help:**
 - Complaints allow the Department of Insurance to evaluate whether a PBM has complied with Nebraska Law
- **What the Nebraska Department of Insurance can't do:**
 - Order the company to pay a claim or change a health plan's drug formulary
 - Address issues the Department isn't authorized to enforce
 - Provide legal advice

Penalties

- **Neb. Rev. Stat. § 44-4611(4)** The director may impose a monetary penalty on a pharmacy benefit manager or the health carrier with which a pharmacy benefit manager is contracted for a violation of the Pharmacy Benefit Manager Licensure and Regulation Act. The director shall establish the monetary penalty for a violation of the act **in an amount not to exceed one thousand dollars per entity for each violation.**



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Penalties

- **Neb. Rev. Stat. § 44-4605(5)** The director may refuse to issue or renew a license if the director determines that the applicant or any individual responsible for the conduct of affairs of the applicant is not competent, trustworthy, financially responsible, or of good personal and business reputation, has been found to have violated the insurance laws of this state or any other jurisdiction, or has had an insurance or other certificate of authority or license denied or revoked for cause by any jurisdiction.

Third-Party Administrators are regulated under the Third-Party Administrator Act, Neb. Rev. Stat. § 44-5801 to 44-5816.

**Is a PBM Also
Required to be
Licensed as a TPA?**

A PBM that only “provides a **claims processing service or other prescription drug or device service** for a health benefit plan to a **covered person** who is a resident of this state” only needs a PBM license

A PBM that provides additional services will still need to renew or obtain a Nebraska TPA License.

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Relationship to Other Insurance Laws

- The PBM Licensure and Regulation Act is not a substitution for other state laws regulating insurance.
 - Nebraska Laws regulating insurers apply, even when an insurer contracts for services with a third-party (whether a TPA or PBM). The Health Plan is held responsible for the actions of their contracted entity
 - Neb. Rev. Stat. § 44-5807(2) it shall be the sole responsibility of the insurer to provide for competent administration of its programs

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Relationship to Other Insurance Laws

- The PBM Licensure and Regulation Act is not a substitution for other state laws regulating insurance.
 - One example is the Health Carrier External Review Act, Neb. Rev. Stat. § 44-1301 to 44-1318, which provides for an independent review of an adverse determination on a covered benefit by a health carrier or their contracted utilization review organization (which may be a PBM for pharmacy benefits) after internal appeals are denied.
 - When seeking independent review of a denial of coverage of a prescription as not medically necessary or appropriate, it is not under PBM Regulation and Licensure Act.

Nebraska Legislation to Watch

- **LB 778** was introduced during the 2023 Legislative Session to amend the Pharmacy Benefit Manager Licensure and Regulation Act
 - Referred to the Banking, Commerce, and Insurance Committee of the Nebraska Legislature
 - A public hearing was held on March 21, 2023, and remains in the Committee
 - The bill will carryover to the 2024 Legislative Session

Nebraska Legislation to Watch

- **LR 137** – Interim study to examine whether additional legislation should be enacted to provide for comprehensive regulation of the business practices of pharmacy benefit managers and to address best practices for the delivery of pharmacy benefit management services.
 - The study would examine issues raised during the consideration of LB 778
 - The study would be conducted by the Banking, Commerce, and Insurance Committee
 - The Committee would make a report of its finding with any recommendations to the Legislative Council

Federal Legislation to Watch



House:

Energy and Commerce; Ways and Means;
Education and the Workforce, H.R. 5378
“Lower Costs, More Transparency Act”



Senate:

HELP Committee, S. 1339
“Pharmacy Benefit Manager Reform Act”
Finance Committee S. 2973
“Modernizing & Ensuring PBM Accountability
Act”

- The general focus has been on increased transparency and accountability through increased data collection and reporting
- Has favored pass-through pricing models and prohibiting spread-pricing for PBMs working under Medicaid

Federal PBM Jurisprudence

- Challenges to State Regulation of PBMs
 - **Rutledge v. Pharmaceutical Care Management Association (PCMA)**, 141 S.Ct. 474 (2020)
 - Upheld an Arkansas law, which required pharmacy benefits managers (“PBMs”) to reimburse pharmacies at a price equal to or higher than what the pharmacy paid to buy the drug

Federal PBM Jurisprudence

- Challenges to State Regulation of PBMs
 - **Rutledge v. Pharmaceutical Care Management Association (PCMA)**, 141 S.C.T. 474 (2020)
 - Prior to this, federal courts had struck down state attempts to regulate PBM activities related to ERISA plans
 - Held that “State rate regulations that merely increase costs or alter incentives for ERISA plans without forcing plans to adopt any particular scheme of substantive coverage are not preempted by ERISA.” 141 S.C.T. 474, 480, citing *Travelers*, 514 U.S. at 668. (2020)

Federal PBM Jurisprudence

- Challenges to State Regulation of PBMs
 - **Rutledge v. Pharmaceutical Care Management Association (PCMA)**, 141 S.Ct. 474 (2020)
 - *Rutledge* did not create an open-ended approval of state pharmacy benefit regulation and did not present an issue of Medicare Part D pre-emption

Continued...

- **PCMA v. Wehbi**, 18 F.4th 956 (2021), Eighth Circuit
 - Challenged two North Dakota laws that regulate a variety of PBM activities on the grounds that the laws were preempted by ERISA and Medicare Part D
 - Upheld the challenged provisions were not preempted by ERISA and set forth a test on Medicare Part D preemption:
 - 1. Do the laws regulate the same subject matter as a federal Medicare Part D standard? If so, the state law is expressly preempted; or
 - 2. Do the state laws otherwise frustrate the purpose of a federal Medicare Part D standard? If yes, then they are impliedly preempted

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Continued...

- **PCMA v. Mulready,**
 - On Aug. 15, 2023, the Tenth Circuit held that ERISA and Medicare Part D preempt the four provisions of the Oklahoma law that were challenged. The provisions were held to functionally mandate benefit structures
 - 1. Access Standards
 - 2. Any Willing Provider
 - 3. Discount Prohibition
 - 4. Probation Prohibition
 - Oklahoma filed an en banc petition for rehearing with the 10th Circuit Court.
 - <https://www.ca10.uscourts.gov/sites/ca10/files/opinions/010110903570.pdf>

Other Resources

- National Association of Insurance Commissioners
 - [Compilation of State Pharmacy Benefit Manager Business Practice Laws](#)
 - [PBM White Paper](#)



Q & A

Contact Information

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