Wisconsin Legislative Council
Act Memo

Prepared by: Steve McCarthy, Senior Staff Attorney

April 9, 2021

2021 Wisconsin Act 9
[2021 Senate Bill 3]

Pharmacy Benefit Managers

2021 Wisconsin Act 9

The act creates a number of requirements related to pharmacy benefit managers (PBMs), health insurance policies and plans, and pharmacies as described below.

Licensing of PBMs

The act requires a PBM to be licensed by the Office of the Commissioner of Insurance (OCI) under the licensure framework that currently applies to employee benefit plan administrators.

Under the act, a PBM is defined to mean an entity that contracts to administer or manage prescription drug benefits on behalf of an insurer, another entity that provides prescription drug benefits, or a health care cooperative. In practice, the specific role of a PBM is determined by contract. A PBM is often tasked with negotiating drug prices and rebates, creating a pharmacy network, creating and operating a drug formulary, and handling claims payments.

If a PBM also performs services as an employee benefit plan administrator, only an administrator license is required. Specifically, if a PBM's responsibilities include collecting premiums or charges, effecting coverage, or settling claims, the PBM is required under current law to be licensed as an administrator.

The act specifies that a PBM is subject to many of the requirements that apply to administrators. An applicant for a PBM license must do all of the following: pay an annual fee of $100; supply a bond; show that the entity intends to act in good faith and that each officer is competent and trustworthy; and designate an individual to administer the plan. A PBM is subject to OCI's authority to examine or audit its records.

The act specifies that OCI may revoke, suspend, or limit the license of a PBM as it may for an administrator, for unprofessional conduct. OCI must first find that the PBM is unqualified to perform responsibilities; has repeatedly or knowingly violated an applicable law, rule, or order; has methods or practices that endanger the interests of the enrollees or the public; or has inadequate financial resources to safeguard the interests of the enrollees or the public. A revocation applies for five years, unless a lesser period is specified, and OCI may allow a PBM to continue providing services after revocation or during suspension for the purpose of providing continuity of care.

Annual Reporting

The act specifies that a PBM must submit an annual report to OCI that contains the aggregate rebate amount that the PBM received from all pharmaceutical manufacturers but retained and did not pass through to health benefit plan sponsors and the percentage of the aggregate rebate amount that is retained rebates. The act specifies that the reports are considered a trade secret under the Uniform

Trade Secret Act under s. 134.90, Stats., and information required to be included in the report is limited to contracts held with pharmacies located in this state.

OCI may expand on the reporting requirement only to the extent necessary to effectuate the requirement.

Disclosure of Drug Substitutions

The act requires a health insurance policy or governmental self-insured health plan, or a PBM that provides services under the policy or plan, to provide enrollees with written notice 30 days in advance of a formulary change that removes the enrollee's prescription drug from the formulary or that reassigns the drug to a benefit tier that has a higher deductible, copayment, or coinsurance. The notice must include information on the procedure for the enrollee to request an exception to the formulary change.

Notice of a drug substitution is not required in either of the following circumstances:

- The U.S. Food and Drug Administration (FDA) no longer approves the drug, has issued a warning or other similar statement regarding the drug, or has approved the drug for use without a prescription.
- One of the following is added to the formulary at the same benefit tier or at a benefit tier that has a lower deductible, copayment, or coinsurance:
    - A generic prescription drug that is approved by the FDA for use as an alternative to the prescription drug.
    - A prescription drug in the same pharmacologic class or with the same mechanism of action.

When a health insurance policy, governmental self-insured health plan, or PBM is not required to give notice of a drug substitution due to a generic prescription drug being approved by the FDA as an alternative, or a prescription drug being added in the same pharmacologic class or with the same mechanism of action, a pharmacist must notify an enrollee of the formulary change at the time the enrollee attempts to fill or refill the prescription.

Lastly, the act specifies that if an enrollee has had an adverse reaction to the generic prescription drug or the prescription drug that is being substituted for an originally prescribed drug, a pharmacist may fill one 30-day supply of the originally prescribed drug at the cost-sharing amount that applies to the drug at the time of the substitution.

Relationship Between PBM and Pharmacy

"Gag Clause" Prohibition

The act specifies that a health insurance policy or governmental self-insured health plan, or a PBM that provides services under the policy or plan, may not restrict or penalize a pharmacy from informing an enrollee of the difference between the out-of-pocket cost of a drug under the policy or plan and the amount the person would pay without using the policy or plan coverage.

Likewise, a health insurance policy or governmental self-insured health plan, or a PBM that provides services under the policy or plan, may not require an enrollee to pay at the point of sale an amount that is greater than the lower of either the cost-sharing amount for the drug under the policy or plan or the amount that a person would pay without using the policy or plan coverage.

PBM Network Notice

The act requires a PBM to provide written notice to a pharmacy of any certification or accreditation requirements used by the PBM as a determinant of network participation within 30 days of a receipt of a written request from the pharmacy for that information. A PBM may change its accreditation requirements no more frequently than every 12 months.

Audit Parameters

The act specifies certain procedures that apply when a health insurance policy or governmental self-insured plan, or a PBM that provides services under a policy or plan, audits a pharmacy or pharmacist. The act defines an "audit" to mean a review of the accounts and records of a pharmacy or pharmacist by or on behalf of an entity that finances or reimburses the cost of health care services or prescription drugs.

The act provides that an entity conducting an on-site or desk audit of pharmacist or pharmacy records must do all of the following:

- If the audit is an audit on the premises of the pharmacist or pharmacy, notify the pharmacist or pharmacy in writing of the audit at least two weeks before conducting the audit.
- Refrain from auditing a pharmacist or pharmacy within the first five business days of a month unless the pharmacist or pharmacy consents to an audit during that time.
- If the audit involves clinical or professional judgment, conduct the audit by or in consultation with a pharmacist licensed in any state.
- Limit the audit review to no more than 250 separate prescriptions.
- Limit the audit review to claims submitted no more than two years before the date of the audit, unless required otherwise by state or federal law.
- Allow the pharmacy to use authentic and verifiable records of a hospital, physician, or other health care provider to validate the pharmacy's records relating to delivery of a prescription drug and use any valid prescription that complies with requirements of the Pharmacy Examining Board to validate claims in connection with a prescription, refill of a prescription, or change in prescription.
- Allow the pharmacy to document the delivery of a prescription drug or pharmacist services to an enrollee using either paper or electronic signature logs.
- Before leaving the pharmacy after concluding the on-site portion of an audit, provide to the representative of the pharmacy a complete list of the pharmacy records reviewed.

The act provides that an entity that has conducted an audit of a pharmacist or pharmacy must do all of the following:

- Deliver to the pharmacist or pharmacy a preliminary report of the audit within 60 days after the date the auditor departs from an on-site audit or the pharmacy submits paperwork for a desk audit. A preliminary report must include claim-level information for any discrepancy reported, the estimated total amount of claims subject to recovery, and contact information for the entity or person that completed the audit so the pharmacist or pharmacy subject to the audit may review audit results, procedures, and discrepancies.
- Allow a pharmacist or pharmacy that is the subject of an audit to provide documentation to address any discrepancy found in the audit within 30 days after the date the pharmacist or pharmacy receives the preliminary report.

- Deliver to the pharmacist or pharmacy a final audit report, which may be delivered electronically, within 90 days of the date the pharmacist or pharmacy receives the preliminary report or the date of the final appeal of the audit, whichever is later. The final audit report must include any response provided to the auditor by the pharmacy and consider and address the pharmacy's response.
- Establish and follow a written appeals process that allows a pharmacy to appeal the final report of an audit and allow the pharmacy as part of the appeal process to arrange for, at the cost of the pharmacy, an independent audit.

The act also provides all of the following relating to audits of a pharmacy or pharmacist:

- Information obtained in an audit is confidential and may not be shared unless the information is required to be shared under state or federal law and except that the audit may be shared with the entity on whose behalf the audit is performed. An entity conducting an audit may have access to the previous audit reports on a particular pharmacy only if the audit is conducted by the same entity.
- If an entity is conducting an audit that is complying with the act's requirements in auditing a pharmacy, the pharmacy that is the subject of the audit may not interfere or refuse to participate in the audit.
- A PBM or entity conducting an audit may not pay an auditor employed by or contracted with the PBM or entity based on a percentage of the amount recovered in an audit.

PBM Recoupment Parameters

Regarding recoupment, the act specifies that a PBM must:

- Refrain from subjecting a pharmacy to a recoupment or recovery for a clerical or recordkeeping error in a required document or record, including a typographical or computer error, unless the error resulted in an overpayment to the pharmacy.
- Refrain from assessing a recoupment or other penalty on a pharmacist or pharmacy until the appeal process is exhausted and the final report delivered to the pharmacist or pharmacy.
- Refrain from accruing or charging interest between the time the notice of the audit is given and the final report has been delivered.
- Exclude dispensing fees from calculations of overpayments.

Additionally, the act specifies that a PBM may not retroactively deny or reduce a pharmacy's claim after adjudication of the claim except in the following circumstances: the original claim was submitted fraudulently; the payment for the original claim was incorrect; the services were not rendered by the pharmacy; the pharmacy violated state or federal law in making the claim or performing the service that is the basis for the claim; or the reduction is permitted in a contract between a pharmacy and a PBM and is related to a quality program.

Requirements for Pharmacies

The act requires that a pharmacy post a sign that describes a pharmacist's ability to substitute a less expensive drug product equivalent or interchangeable biological product.

The act also requires the Pharmacy Examining Board to create a list of the 100 most commonly prescribed generic drug product equivalents and provide the list to each pharmacy on an annual basis. Each pharmacy must make available to the public information on how to access the list. Each pharmacy must also make available for the public information on how to access FDA lists of all currently approved interchangeable biological products.

Lastly, each pharmacy must have available for the public a listing of the retail price, updated at least monthly, of the 100 most commonly prescribed prescription drugs. The list must include brand name and generic equivalent drugs and biological products and interchangeable biological products that are available for purchase at the pharmacy.

Mail Order Plan

The act repeals a provision under current law that requires a mail order plan to allow coverage of a prescription drug when filled at a pharmacy selected by the enrollee at the same cost as covered under the plan.

Effective Date and Initial Applicability

The act takes effect on January 1, 2022, except as follows:

- The "gag clause" provision that allows a pharmacy to notify an enrollee about the difference between covered out-of-pocket costs and costs without applying coverage takes effect March 28, 2021.
- The point-of-sale provision that allows an enrollee to pay the lower of either the covered out-of-pocket costs or the cost without applying coverage takes effect on June 30, 2021.
- The audit parameters and certain limits on recoupment take effect on June 30, 2021.

The act applies to a provision in a policy or plan that is inconsistent with the provisions of the act in the next policy or plan years beginning January 1, 2022.

OCI may also specify a later date, after January 1, 2022, by which a PBM must be licensed and must comply with the audit and recoupment parameters.

SM:mca;jal