Wisconsin Legislative Council
AMENDMENT MEMO

Memo published: February 17, 2020

Contact: Andrea Brauer, Staff Attorney

2019 Assembly Bill 114	Assembly Substitute Amendment 1, and Assembly Amendment 1 to Assembly Substitute Amendment 1

2019 Assembly Bill 114 creates a number of requirements related to the conduct of pharmacy benefit managers (PBMs). Assembly Substitute Amendment 1, as amended by Assembly Amendment 1 to Assembly Substitute Amendment 1, modifies the requirements under the bill as follows.

LICENSING AND REGISTRATION OF PBMS

The Bill

The bill requires PBMs to be registered with the Office of the Commissioner of Insurance (OCI), and requires OCI to promulgate rules governing the conduct of PBMs, using the 2018 National Association of Insurance Commissioner's Model PBM Act as a model, to the extent it does not conflict with state insurance laws. Under the bill, a PBM is defined to mean an entity doing business in Wisconsin that contracts to provide claims processing services, to otherwise administer or manage prescription drug benefits, or both, on behalf of an insurer or other entity that provides prescription drug benefits.

Specifically, the bill requires OCI's rules to include: (1) requirements for the development and maintenance of formularies and other PBM procedures (which may not allow insurers or PBMs to require enrollees to obtain specialty drugs by mail order); (2) information that PBMs must provide to consumers; (3) requirements and procedures for a standardized medical exceptions approval process; (4) requirements for nondiscrimination in PBM design; (5) record keeping and reporting requirements; (6) responsibilities for the PBM in oversight and contracting; and (7) required disclosures by a health benefit plan, self-insured health plan, or PBM. OCI is also granted authority to discipline a PBM for misconduct and to use its general enforcement authority under ch. 601, Stats.

The bill also specifies that a licensed pharmacy or licensed wholesale distributor that acts as a PBM is required to be registered as a PBM. However, the following are not required to be registered as a PBM: a person who is already licensed by OCI as an insurer, a licensed health care provider providing services to a patient, and entities that provide claims processing services or administration of prescription drugs only for the Medicaid program. [SECTION 16, pages 10-14.]

The Substitute Amendment

The substitute amendment deletes the registration requirements under the bill and instead requires PBMs to be licensed by OCI under the licensure framework that currently applies to employee benefits plan administrators, except that a PBM that also performs services as an administrator is only required to obtain an administrator license. [SECTION 38, page 20.]

There is overlap between the function of a PBM and that of an administrator. Under the substitute amendment, 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 incorporated under ch. 185, Stats. [SECTIONS 18 and 27, pages 12 and 18.] An administrator is defined as a person who directly or indirectly solicits or collects premiums or charges or otherwise effects coverage or adjusts or settles claims for a plan, subject to a list of exceptions such as insurers and employers acting on behalf of their employees. [SECTION 23, page 17; and s. 633.01 (1), Stats.] In practice, the specific role of each PBM is determined by contract. PBMs are often tasked with negotiating drug prices and rebates, creating a pharmacy network, creating and operating a drug formulary, and handling claims payments. PBMs can also play a role in determining when and in which order certain drugs are covered. If any of the PBM's responsibilities include collecting premiums or charges, effecting coverage, or settling claims, the PBM is already required under current law to be licensed as an administrator.[1]

The substitute amendment subjects PBMs that are not currently licensed as administrators to many of the requirements that apply to administrators, except for certain fiduciary responsibilities and standards for claims payments. An applicant for a PBM license must fulfill the same criteria as an applicant for an administrator license; the applicant must supply a bond, guarantee faithful performance of the PBM, designate an individual to directly administer the benefit, show that it intends to act in good faith through the designated individuals, and show that each officer is competent and trustworthy. [SECTION 39, pages 20-21.]

As compared to OCI's authority over registered PBMs under the bill, the substitute amendment does not authorize OCI to create rules governing the business conduct of licensed PBMs. However, under the substitute amendment, OCI can discipline PBMs as well as administrators for general misconduct, such as being unqualified to perform their responsibilities, or utilizing practices that endanger the interests of insureds or the public. [s. 633.15 (2), Stats.] The substitute amendment adds that if OCI suspends or revokes a PBM license, it can allow the PBM to continue to provide services for the purpose of providing continuity of care. [SECTION 43, page 24.]

RELATIONSHIP BETWEEN PBMS AND PHARMACIES

"Gag Clause" Prohibition

Under the bill, any disability insurance policy or self-insured health plan, or any PBM that provides services under a contract with the policy or plan may not include in any contract for pharmacy services a provision that prohibits or penalizes a pharmacist from disclosing either the cost of the prescribed drug or device to the individual or the availability of any therapeutically equivalent alternative prescribed drugs or devices or alternative methods of purchasing the prescribed drug or device, including paying cash, that are less expensive to the individual. [SECTION 13, pages 7-8.]

Under the substitute amendment, any disability insurance policy or self-insured health plan, or any PBM that provides services under a contract with the policy or plan, may not restrict or penalize a pharmacy from informing a plan or policy enrollee of the difference between the out-of-pocket cost of a drug and the amount an individual would pay for the drug without using any health plan or health insurance coverage. [SECTION 15, pages 8-9.]

Claim Reductions

Under the bill, a PBM may not retroactively deny or reduce a pharmacist's or pharmacy's claim after adjudication of the claim unless the original claim was submitted fraudulently, the payment for the

[1] The substitute amendment does not significantly change licensure requirements for PBMs that are already licensed as administrators.

original claim was incorrect because the pharmacy or pharmacist had already been paid for the pharmacy services, or the pharmacy services were not rendered by the pharmacist or pharmacy. [SECTION 16, page 15.]

Under the substitute amendment, a PBM may not retroactively deny or reduce a pharmacist's or pharmacy's claim after adjudication of the claim unless the original claim was submitted fraudulently, the payment for the original claim was incorrect, the pharmacy services were not rendered by the pharmacist or pharmacy, the pharmacist or 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. [SECTION 21, page 13.]

PBM Networks

Under the bill, an insurer, self-insured health plan, or PBM is prohibited from requiring or penalizing a person who is covered under a disability insurance policy or self-insured health plan to use or for not using a specific retail, specific mail order, or other specific pharmacy provider within the network of pharmacy providers under the policy or plan. [SECTION 13, pages 8-9.]

The bill also requires that a PBM must provide a reasonably adequate and accessible pharmacy network for providing prescribed drugs or devices for a health benefit plan that allows convenient patient access to pharmacies within a reasonable distance from a plan participant's residence. A PBM may not include any mail-order pharmacy in its calculations of network adequacy. Additionally, a PBM must also submit to OCI a PBM network adequacy report describing the PBM network and accessibility to the network for health benefit plan participants. [SECTION 16, page 19.]

Additionally, under the bill, a PBM may not do any of the following:

- Unless approved by OCI, charge a pharmacist or pharmacy a fee related to the adjudication of a claim, including a fee for receiving and processing a pharmacy claim, developing or managing claims processing services in a PBM network, or participating in a PBM network.
- Unless approved by OCI after consulting with the Pharmacy Examining Board, require pharmacist or pharmacy accreditation standards or certification requirements in addition to, more stringent than, or inconsistent with any requirements of the Pharmacy Examining Board.
- Reimburse a pharmacy or pharmacist an amount less than the amount that the PBM reimburses an affiliate of the PBM for providing the same services.
- After termination of a pharmacy or pharmacist from a PBM, fail to make payments to a pharmacist or pharmacy for services that were properly rendered and provided before termination.
- Prohibit, restrict, or limit a pharmacy or pharmacist from disclosing information to OCI, law enforcement, or a state or federal governmental official that is investigating or examining a complaint or conducting a review of a PBM's compliance with the requirements under this section. [SECTION 16, pages 14-15.]

The substitute amendment requires only that a PBM must provide to a pharmacy, within 30 days of receipt of a written request from the pharmacy, a written notice of any certification or accreditation requirements used by the PBM as a determinant of network participation. A PBM may change its accreditation requirements no more frequently than once every 24 months. [SECTION 21, page 12.] **The amendment to the substitute amendment** replaces the 24-month limitation and provides instead that a PBM may change its accreditation requirements no more frequently than once every 12 months. This is the only change made by the amendment to the substitute amendment.

Audits of Pharmacy or Pharmacist

Both the bill and the substitute amendment include procedures that apply when certain entities,[2] including a defined network plan, insurer, self-insured plan, or PBM, conduct an audit of a pharmacist or pharmacy. The bill and the substitute amendment also specify what an auditor must do with the results of an audit of a pharmacist or pharmacy.

Audit Requirements

The bill provides that an entity conducting an 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 seven days of a month unless the pharmacist or pharmacy consents to an audit during that time.
- If the audit involves clinical or professional judgement, conduct the audit by or in consultation with a pharmacist licensed in this state or the Pharmacy Examining Board.
- Limit the audit review to claims submitted no more than two years before the date of the audit.
- Audit each pharmacist or pharmacy under the same standards and parameters as other similarly situated pharmacists or pharmacies.
- Establish a written appeals process that allows appeals of preliminary and final reports and allows for mediation if either party is dissatisfied with the appeal.
- Allow the pharmacist or pharmacy to use records of a hospital, physician, or other health care provider to validate the pharmacist's or pharmacy's records and use any 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. [SECTION 16, page 16.]

The substitute amendment specifies that "audit" means 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 substitute amendment 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.

---

[2] Note that the bill, but not the substitute amendment, includes a "3rd-party payer" as an entity covered by the bill's auditing requirements.

- Allow the pharmacist or pharmacy to use authentic and verifiable records of a hospital, physician, or other health care provider to validate the pharmacist's or 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 or pharmacist to document the delivery of a prescription drug or pharmacist services to an enrollee under a health benefit plan 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 or the pharmacist a complete list of the pharmacy records reviewed. [SECTION 21, pages 13-14.]

Use of Audit Results

The bill 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 date of the conclusion of the audit.
- Allow a pharmacist or pharmacy that is the subject of an audit at least 30 days after the date the pharmacist or pharmacy receives the preliminary report to provide documentation to address any discrepancy found in the audit.
- Deliver to the pharmacist or pharmacy a final audit report 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.
- Refrain from assessing a recoupment or other penalty on a pharmacist or pharmacy until the appeal process is exhausted and the final report is delivered to the pharmacist or pharmacy.
- Base a finding of overpayment or underpayment of a claim on the actual overpayment or underpayment and not on a projection based on the number of patients served having a similar diagnosis or on the number of similar orders or refills for similar drugs.
- Exclude dispensing fees from calculations of overpayments.
- Refrain from using extrapolation in calculating the recoupments or penalties for an audit.
- Refrain from charging interest until the final report under has been delivered. [SECTION 16, pages 16-17.]

The substitute amendment 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 or pharmacist 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 or pharmacist and consider and address the pharmacy's or pharmacist's response.
- 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.
- Establish and follow a written appeals process that allows a pharmacy or pharmacist to appeal the final report of an audit and allow the pharmacy or pharmacist as part of the appeal process to arrange for, at the cost of the pharmacy or pharmacist, an independent audit.
- Refrain from subjecting the pharmacy or pharmacist to a recoupment or recovery for a clerical or record-keeping error in a required document or record, including a typographical or computer error, unless the error resulted in an overpayment to the pharmacy or pharmacist. [SECTION 21, pages 15-16.]

Other Provisions

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

- If an audit of a pharmacist or pharmacy identifies a clerical or record-keeping error in a required document or record, the entity conducting the audit may not request recoupment of funds from the pharmacist or pharmacy based on such an error unless the entity proves the pharmacist or pharmacy intended to commit fraud or unless the error by the pharmacist or pharmacy results in actual financial harm to the PBM, a health benefit plan, or a consumer.
- 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. An entity conducting an audit may have access to the previous audit reports on a particular pharmacy conducted by the same entity.
- Any entity that conducts an audit must provide to the health benefit plan a copy of the final report of the audit and a disclosure of any recoupment amount assessed as a result of 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. [SECTION 16, pages 17-18.]

The substitute amendment 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 substitute amendment's requirements in auditing a pharmacy or pharmacist, the pharmacy or pharmacist 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. [SECTION 21, pages 16-17.]

DISCLOSURES AND TRANSPARENCY REQUIREMENTS

The bill and substitute amendment include provisions that require certain disclosures and transparency requirements for both PBMs and pharmacies.

Requirements for PBMs

PBM Transparency Reporting

Under the bill, every PBM must submit an annual report to OCI and the Legislature that contains the aggregate amount of all rebates that the PBM received from all pharmaceutical manufacturers by each health benefit plan sponsor and for all health benefit plan sponsors combined, the aggregate administrative fee amount that the PBM received from all pharmaceutical manufacturers by each health benefit plan sponsor, and for all health benefit plan sponsors combined, 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 bill also provides that OCI must publish PBM transparency reports on OCI's website, but must do so in a manner that does not disclose any trade secrets. [SECTION 16, pages 18-19.]

Under the substitute amendment, every 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. Information required to be included in the report is limited to contracts held with pharmacies located in this state.

The substitute amendment also provides that these reports must be considered a trade secret under the uniform trade secret act under s. 134.90, Stats. Lastly, the substitute amendment provides that OCI may not expand upon the specified reporting requirement, except that OCI may effectuate the transparency reporting requirements. [SECTION 21, page 17.]

Conflicts of Interest and Regulation of Certain Business Practices

The bill provides that, if a PBM makes a formulary substitution in which the substitute drug costs more than the originally prescribed drug, the PBM must disclose to the health benefit plan sponsor the cost of the drugs and any benefit that accrues, directly or indirectly, to the PBM related to the substitution. A PBM is also prohibited from requiring that a pharmacy or pharmacist enter into one contract in order to enter into another contract. Lastly, a PBM must notify a health benefit plan sponsor in writing of any activity, policy, or practice of the PBM that presents a conflict of interest, directly or indirectly, with either of the requirements described above. [SECTION 16, page 15.]

The substitute amendment does not include any of the above provisions relating to conflicts of interest or PBM business practices.

Requirements for Pharmacies

Pharmacy Disclosures to Consumers

The bill does not include any provisions relating to disclosures by a pharmacy to consumers.

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

The substitute amendment also requires that the Pharmacy Examining Board must 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 the U.S. Food and Drug Administration's (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 no less frequently than monthly, of the 100 most commonly prescribed prescription drugs, which includes brand name and generic equivalent drugs and biological products and interchangeable biological products, that are available for purchase at the pharmacy. [SECTIONS 7-9, pages 6-7.]

OTHER COVERAGE REQUIREMENTS

Drug Substitutions

The bill prohibits a disability insurance policy or self-insured health plan, or any PBM that provides services under a contract with the policy or plan, to require covered individuals to pay an increased cost-sharing amount for a newly prescribed drug or device, if: (1) the substitution for the originally prescribed drug or device is suggested by the plan or PBM; and (2) the newly prescribed drug is a therapeutic equivalent to the originally prescribed drug or device that is being substituted. In addition, the bill requires plans and PBMs to develop a procedure to ensure that, within a coverage year, the policy or plan does not deny coverage, or add new exclusions, limitations, deductibles, copayments, or coinsurance if the prescribing provider states in writing that the prescribed drug is more suitable for the person's condition than alternative drugs or devices that are covered under the policy or plan. [SECTION 13, page 9.]

The substitute amendment requires a disability insurance policy or self-insured health plan, or any PBM that provides services under a contract with 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 enrollee's prescription drug to a benefit tier that has a higher deductible, copayment, or coinsurance, except that no notice is required in either of the following circumstances:

- The FDA no longer approves the drug, has issued a warning or other 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 than the benefit tier from which the prescription drug is being removed or reassigned: (1) a generic prescription drug that is approved by the FDA for use as an alternative to the prescription drug; or (2) a prescription drug in the same pharmacologic class or with the same mechanism of action. In either of these circumstances, if an enrollee attempts to fill or refill the drug, the pharmacist or pharmacy must notify the enrollee of the formulary change.

The substitute amendment also provides that if an enrollee has had an adverse reaction to the substituted drug, the pharmacist or pharmacy may fill one 30-day supply of the originally prescribed drug at the cost-sharing amount that applies for the prescription drug at the time of the substitution. [SECTION 15, pages 9-11.]

Cost-Sharing Limitations

The bill states that a disability insurance policy, self-insured plan, or PBM may not require an enrollee to pay at the point of sale for a covered prescription drug an amount that is greater than the lowest of: (1) the cost-sharing amount for the drug under the policy or plan; or (2) the amount that a person would pay for the drug if purchased without using any health plan or health insurance coverage. [SECTION 13, page 8.] This requirement is the same in **the substitute amendment**. [SECTION 15, page 9.]

BILL HISTORY

Representative Schraa introduced the bill on March 25, 2019, and offered the substitute amendment on February 5, 2020. On February 13, 2020, the Assembly Committee on Health offered the amendment to the amendment. On that same day, the committee recommended adoption of the amendments, each on a vote of Ayes, 10; Noes, 5. The committee then unanimously recommended passage of the bill, as amended.

AB:ksm