

OFFICE OF THE SECRETARY OF STATE

BEV CLARNO
SECRETARY OF STATE

JEFF MORGAN
INTERIM DEPUTY SECRETARY OF STATE



ARCHIVES DIVISION

STEPHANIE CLARK
DIRECTOR

800 SUMMER STREET NE
SALEM, OR 97310
503-373-0701

NOTICE OF PROPOSED RULEMAKING
INCLUDING STATEMENT OF NEED & FISCAL IMPACT

CHAPTER 836
DEPARTMENT OF CONSUMER AND BUSINESS SERVICES
INSURANCE REGULATION

FILED

10/28/2020 12:40 PM
ARCHIVES DIVISION
SECRETARY OF STATE

FILING CAPTION: Market Conduct Requirements for Pharmacy Benefit Managers

LAST DAY AND TIME TO OFFER COMMENT TO AGENCY: 11/30/2020 5:00 PM

The Agency requests public comment on whether other options should be considered for achieving the rule's substantive goals while reducing negative economic impact of the rule on business.

CONTACT: Karen Winkel
503-947-7694
karen.j.winkel@oregon.gov

350 Winter Street NE
Salem, OR 97301

Filed By:
Karen Winkel
Rules Coordinator

HEARING(S)

Auxiliary aids for persons with disabilities are available upon advance request. Notify the contact listed above.

DATE: 11/23/2020

TIME: 1:30 PM

OFFICER: Jesse O'Brien

ADDRESS: Labor & Industries Building

350 Winter Street NE

Salem, OR 97301

SPECIAL INSTRUCTIONS:

Conference call only due
to Covid-19.

Dial-in: 888-204-5984

Access code: 3319925#

In case of technical issues,
call Karen Winkel at 971-345-1108.

NEED FOR THE RULE(S):

2019 House Bill 2185 (the Act), enrolled at 2019 Oregon Laws Chapter 526, establishes new requirements for pharmacy benefit managers (PBMs) in Oregon. These requirements are effective January 1, 2021, and include the following:

- Prohibiting PBMs from requiring an enrollee to fill or refill prescriptions at a mail order pharmacy.

- Allowing PBMs to require enrollees to fill or refill prescriptions for specialty drugs at a specialty pharmacy.
- Requiring PBMs to reimburse the cost of a specialty drug that is filled or refilled at a long term care pharmacy.
- Requiring PBMs to allow network pharmacies to mail, ship, or deliver prescription drugs to their patients as an ancillary service.
- Specifying that PBMs are not required to reimburse delivery fees for drugs mailed, shipped, or delivered by network pharmacies.
- Prohibiting PBMs from requiring a patient signature as proof of delivery of a mailed or shipped drug if the pharmacy otherwise tracks shipping or delivery and is responsible for the cost of delivering the replacement of a drug that was mailed or shipped but not received by the enrollee.
- Prohibiting PBMs from penalizing a network pharmacy for informing enrollees about the difference between the out-of-pocket cost of a drug and the pharmacy's retail price.
- Specifying materials and information PBMs must supply to pharmacies relating to setting of maximum allowable cost.
- Prohibiting PBMs from reimbursing a 340B pharmacy differently than other network pharmacies based on 340B status.
- Prohibiting PBMs from retroactively denying or reducing a claim for reimbursement, with specified exceptions.
- Providing additional detail to the requirements regarding the maximum allowable cost appeal process by network pharmacies of PBM reimbursements.
- Defines or modifies existing definitions for terms including "enrollee," "long term care pharmacy," "mail order pharmacy," "pharmacy benefit," "specialty drug," "specialty pharmacy," and "generally available for purchase."

The Act also grants the Department of Consumer and Business Services (department) the authority to adopt rules to implement its provisions.

The department proposes a new administrative rule to implement key provisions of the Act. The proposed rule addresses the following issues:

- Clarifying that a contract between a PBM and a network pharmacy may limit the network pharmacy's mail delivery of drugs as an ancillary service, but that the limits may not entirely prohibit the mailing, shipment, or delivery of prescription medicines from a network pharmacy on the request of the enrollee.
- Clarifying the circumstances under which the department will consider a drug to meet the Act's definition of "specialty drug," and a pharmacy to meet the Act's definition of "specialty pharmacy."
- Specifying that the Act's requirement for PBMs to reimburse for specialty drugs provided by long term care pharmacies applies to drugs dispensed to residents of a long term care facility served by the pharmacy.
- Clarifying the circumstances under which a pharmacy may appeal a maximum allowable cost price for a drug on the basis that the price is only available if the drug is purchased in substantial quantities in excess of the pharmacy's business needs.

The proposed rule is necessary to clarify potentially ambiguous provisions in the Act and to establish a clear and consistent framework for the implementation and enforcement of the Act's requirements that will help ensure fairness and consistent treatment for PBMs and pharmacies in Oregon.

DCBS convened a rulemaking advisory committee, which included representatives of PBMs, pharmacies and insurers.

The rulemaking advisory committee met on October 14, November 4 and December 11 of 2019, and January 7, July 22, August 18 and September 15 of 2020.

DCBS requests public comment on the proposed rule.

DOCUMENTS RELIED UPON, AND WHERE THEY ARE AVAILABLE:

Draft rules are available from Karen Winkel, Rules Coordinator located at 350 Winter St. NE, Salem, OR 97301 and are available on the division's website:

<https://dfr.oregon.gov/laws-rules/Pages/proposed-rules.aspx>.

2019 Oregon Laws Chapter 526 (Enrolled House Bill 2185) may be found on the Oregon Legislative Assembly website: <https://olis.oregonlegislature.gov/liz/2019R1/Downloads/MeasureDocument/HB2185/Enrolled>.

FISCAL AND ECONOMIC IMPACT:

2019 Oregon Laws Chapter 526 and the proposed rule will have a significant direct economic impact on PBMs and pharmacies, and an indirect economic impact on health insurers and pharmacists. Some pharmacies are small businesses.

Based on the information available to DCBS, the proposed rule will not likely have a fiscal or economic impact on state agencies, local governments, or the public.

COST OF COMPLIANCE:

(1) Identify any state agencies, units of local government, and members of the public likely to be economically affected by the rule(s). (2) Effect on Small Businesses: (a) Estimate the number and type of small businesses subject to the rule(s); (b) Describe the expected reporting, recordkeeping and administrative activities and cost required to comply with the rule(s); (c) Estimate the cost of professional services, equipment supplies, labor and increased administration required to comply with the rule(s).

(1) Based on information currently available to DCBS, the proposed rule would not have a fiscal or economic impact on state agencies, local government units, nor the public.

The underlying statutory provisions may have an impact on DCBS through modifying the department's regulatory authority in the area of PBM oversight, which may lead to changes in the pattern and frequency of complaints, or compliance and enforcement actions undertaken. However, the proposed rule will not. The proposed rule provides finer details regarding the implementation of the law's requirements and is expected to have a negligible impact on costs to the department.

The proposed rule does not add any new requirements on public entities, but instead clarifies DCBS's supervisory expectations with regard to PBMs. Other state agencies and local governments are not expected to incur any fiscal impact, because the requirements established by the law are not applicable to these entities.

Based on the information currently available to DCBS, the proposed rule does not have an economic impact on the

general public beyond the underlying statutory requirements.

(2)(a) The proposed rule establishes requirements for PBM market conduct in multiple areas. Compliance may require significant costs for PBMs. DCBS does not have data on the specific number of employees employed by PBMs doing business in Oregon, but based on the feedback of the rulemaking advisory committee convened by the department, it is unlikely that any of the PBMs to which this rule applies are small businesses.

The proposed rule will also affect pharmacies in Oregon, some of which are small businesses. However, since the rule does not impose regulatory requirements on pharmacies in addition to the underlying statutory requirements, the proposed rule is not expected to impose significant costs on pharmacies.

DCBS convened a rulemaking advisory committee, which included representatives of PBMs, pharmacies and insurers. Committee feedback suggested that the rule is unlikely to impose costs on small businesses in Oregon.

(2)(b) The proposed rule does not impose additional requirements in the areas of reporting and recordkeeping.

(2)(c) The proposed rule establishes requirements for PBM market conduct in multiple areas. Compliance may require significant labor and administrative costs for PBMs. DCBS does not have data on the specific number of employees employed by PBMs doing business in Oregon, but based on the feedback of the rulemaking advisory committee, it is unlikely that any of the PBMs to which this rule applies are small businesses.

DESCRIBE HOW SMALL BUSINESSES WERE INVOLVED IN THE DEVELOPMENT OF THESE RULE(S):

DFR convened a rulemaking advisory committee, which included representatives of PBMs, pharmacies and insurers. Some pharmacies are small businesses.

WAS AN ADMINISTRATIVE RULE ADVISORY COMMITTEE CONSULTED? YES

ADOPT: 836-200-0440

RULE SUMMARY: Adopted new requirements for Pharmacy Benefit Managers (PBMs) in Oregon.

CHANGES TO RULE:

836-200-0440

Market Conduct Requirements for Pharmacy Benefit Managers

(1) A pharmacy benefit manager shall allow a network pharmacy to mail, ship or deliver prescription drugs to its patients as an ancillary service. A contract between a pharmacy benefit manager and a network pharmacy may establish limits and parameters on the pharmacy's mail, shipment and/or delivery of prescription drugs on the request of enrollees based on the pharmacy's total prescription volume. A pharmacy benefit manager is not required to reimburse a delivery fee charged by a network pharmacy unless the fee is specified in the contract between the pharmacy benefit manager and the pharmacy.¶

(2) Except as provided in subsection (6) of this section, a pharmacy benefit manager may require a prescription for a specialty drug to be filled or refilled at a specialty pharmacy as a condition for the reimbursement of the cost of a

drug.[¶]

(3) For the purposes of subsection (2) of this section, the department will consider a prescription drug to meet the definition of "specialty drug" under Oregon Laws 2019, chapter 526, section 4 if, to be properly dispensed according to standard industry practice, the drug:[¶]

(a) Requires specialized preparation, administration, handling, storage, inventory, reporting or distribution;[¶]

(b) Is associated with difficult or unusual data collection or administrative requirements; or[¶]

(c) Requires a pharmacist to manage the patient's use of the drug by monitoring, provide disease or therapeutic support systems, provide care coordination including collaboration with patients or other health care providers to manage adherence, identify side effects, monitor clinical parameters, assess responses to therapy, or document outcomes.[¶]

(4) For the purposes of subsection (2) of this section, the a pharmacy may demonstrate to the department that it meets the definition of "specialty pharmacy" under Oregon Laws 2019, chapter 526, section 4 by showing that:[¶]

(a) Its business is primarily providing specialty drugs and specialized, disease-specific clinical care and services for people with serious or chronic health conditions requiring complex medication therapies; or[¶]

(b) It has been validated for meeting quality, safety and accountability standards for specialty pharmacy practice through accreditation in specialty pharmacy by a nationally recognized, independent accreditation organization such as URAC or the Accreditation Commission for Health Care (ACHC).[¶]

(5) Nothing in subsection (4) of this section shall be construed to prohibit a pharmacy benefit manager from specifying additional terms and conditions for a specialty pharmacy network contract, including terms and conditions related to reimbursement.[¶]

(6) A pharmacy benefit manager shall reimburse the cost of a specialty drug that is filled or refilled at a network pharmacy that is a long term care pharmacy, provided that the specialty drug is dispensed to an enrollee who is a resident of a long term care facility served by the long term care pharmacy.[¶]

(7) A network pharmacy may appeal its reimbursement from a pharmacy benefit manger for a drug subject to maximum allowable cost pricing on the basis that the drug is only available at the specified price if purchased in substantial quantities in excess of its business needs. For the purposes of this subsection, a quantity in excess of the business needs of a network pharmacy is defined as a purchase quantity greater than a 3-month supply based on the pharmacy's total dispensing history over the most recent rolling 12 months. A pharmacy benefit manager may require a network pharmacy appealing its reimbursement for a drug in accordance with this subsection to submit applicable evidence of its dispensing history to the pharmacy benefit manager as part of the appeal process. A pharmacy benefit manager's compliance with this subsection is sufficient to demonstrate compliance with Oregon Laws 2019, chapter 526, section 4(1)(a)(B)(iii).[¶]

(8) If a prescription drug subject to a specified maximum allowable cost is available at that price if purchased in quantities that are consistent with the business needs of some pharmacies but inconsistent with the business needs of others, nothing in subsection (7) shall be construed to prohibit a pharmacy benefit manager from applying the maximum allowable cost to pharmacies that can purchase the drug in the necessary quantities consistent with their business needs.

Statutory/Other Authority: Or Laws 2019, ch 526

Statutes/Other Implemented: Or Laws 2019, ch 526