2016 REPORT OF THE

DEPARTMENT OF CONSUMER AND BUSINESS SERVICES REGARDING PHARMACY BENEFIT MANAGER COMPLIANCE AND RECOMMENDATIONS FOR STATUTORY AND RULE CHANGES

TO

THE SEVENTY-EIGHTH LEGISLATIVE ASSEMBLY

In Accordance with Senate Bill 5701 Budget Note (2016)

2016 REPORT OF THE DEPARTMENT OF CONSUMER AND BUSINESS SERVICES REGARDING PHARMACY BENEFIT MANAGER COMPLIANCE AND RECOMMENDATIONS FOR STATUTORY AND RULE CHANGES

In Accordance with Senate Bill 5701 Budget Note (2016)

BACKGROUND

Pharmacy benefit managers (PBMs) are intermediaries in a contractual relationship between wholesalers and manufacturers and health insurers or employers to administer drug benefit programs. Some services PBMs provide include processing and analyzing prescription claims, contracting with a network of pharmacies, and managing formularies and prior authorization programs. Currently, there are more than 40 entities registered as a PBM in Oregon. Nationally, PBMs manage the drug benefits for an estimated 95 percent of all patients with drug coverage.

In 2013, the Oregon Legislature enacted House Bill 2123, which 1) required PBMs to register with the Department of Consumer and Business Services and annually renew their registration; 2) established requirements for PBM reimbursement of pharmacies for generic drugs that use a maximum allowable cost pricing methodology; and 3) established requirements for entities or their third-party contractors that audit the claims of pharmacies. Oregon became one of the early adopter states placing requirements on certain PBM-related practices, including generic drug pricing and reimbursement.

In the 2016 Regular Session, the Oregon Legislature introduced Senate Bill 1505, which was intended to strengthen and clarify aspects of House Bill 2123 (2013). The bill did not pass in the short session as further exploration and discussion was needed to address concerns and questions in the bill. Consequently, the Legislature included a **budget note to Senate Bill 5701**, which directed the department to convene a workgroup to develop recommendations for rulemaking regarding PBM compliance. Based on the budget note, the department was charged with drafting rules, as well as recommending statutory changes or clarifications necessary to fully implement the draft rules, and report to the Legislature by November 1, 2016.

PHARMACY BENEFIT MANAGER WORKGROUP PROCESS

The department convened a diverse stakeholder workgroup comprised of five pharmacy representatives: an urban and rural independent pharmacy, a national chain pharmacy, a pharmacy association, and an entity representing multiple independent pharmacies. In addition, the workgroup included representatives from four of the largest PBMs in the nation and four insurers – two commercial insurers, a workers' compensation insurer, and a self-insured entity.

The department's main objective for the PBM workgroup process was to meet the directives of the budget note. In order to answer the question of what it meant to ensure "compliance" with current statute, the department also considered: 1) how to ensure that all parties, the department and the private market actors alike, know and understand how to apply the current statutory framework; 2) how to foster transparency in PBM contracting and claims reimbursement within the context of the law and clarify the conduct by parties to achieve these goals; 3) identifying the issues in the complaints filed with the department to ensure they received a full and fair examination; and 4) how to protect the insurance-buying public through appropriate application of the Insurance Code. The workgroup met four times from May through August 2016.

While the charge of the Senate Bill 5701 budget note emphasized the department's enforcement authority, which was thoroughly examined in the workgroup process, the department's foremost goal is to foster voluntary compliance with the law among the entities it regulates and obtain corrective action well before pursuing enforcement action. Furthermore, creating a regulatory framework that promotes voluntary compliance also ensures more efficient and prudent use of department resources. The department aims to provide regulated entities with the information and guidance necessary to stay abreast of changing regulatory requirements, expectations, and industry practices, and, when these measures do not adequately result in parties abiding by the law, the department may pursue enforcement action.

The department is committed to continuing development of its expertise in order to be an effective regulator in the complex and dynamic arena of prescription drug benefit management. The department will continue to work with pharmacies, pharmacy benefit managers, other state agencies, state and federal partners, the National Association of Insurance Commissioners, and other stakeholders who are confronting issues related to pharmacy benefit management. Ultimately, the department is committed to upholding its consumer protection mission by protecting Oregonians' access to fair products and services through education, regulation, and customer assistance.

RECOMMENDATIONS

The department recommends a combination of minor statutory changes, as well as a more comprehensive set of rule changes that address definitions for key terms referred to in statute for which ambiguity and diverging interpretations among parties was expressed, as well as those pertaining to PBM registration and the appeals process. For recommended rules changes, see Appendix A. Proposed Pharmacy Benefit Manager Rules. Recommendations that include statutory changes are described below.

Registration – The registration fee in statute reflects a limited role for the department in acting as a registrar of active PBMs in the state. The registration fee should be commensurate with actual program costs that are consistent with expenses involved in conducting investigations and enforcement actions. The department recommends the registration and renewal fee be set by rule after a robust public process, which would require a statutory change.

Enforcement – The department recommends minimal rule and legislative changes regarding enforcement. The workgroup expressed that it was clear the department has the tools under existing law to pursue enforcement of PBMs and preferred the department retain its flexibility and discretion in taking enforcement action. However, a statutory change would be necessary to grant the director the power to suspend or revoke a PBM's registration with respect to violations of the statute or of rules implementing the statute.

OTHER CONSIDERATIONS

It is important to note that the report and workgroup process did not address key issues outside the scope of the budget note. Such key issues include the legal and contractual relationship of PBMs and health insurers, and the role of PBMs in contributing to the costs or savings of prescription drug administration and overall prescription drug costs, and how these costs are translated to consumers in the form of premiums and out-of pocket expenses.

Table of Contents

Introduction

In the 2016 Regular Session, the Legislature Assembly introduced Senate Bill 1505, which was intended to strengthen and clarify aspects of prior legislation regulating certain activities of pharmacy benefit managers. The bill did not pass in the short session as further exploration and discussion was needed to address concerns and questions related to the bill. Consequently, the Legislature included a **budget note to Senate Bill 5701**, which directed the Department of Consumer and Business Services (DCBS) to convene a workgroup to develop recommendations for rulemaking regarding pharmacy benefit manager (PBM) compliance. Based on the budget note, the department was charged with drafting rules, as well as recommending any suggested statutory changes or clarifications necessary to fully implement the draft rules, and report to the Legislature by November 1, 2016.

This report provides background on the history of PBM legislation and regulations in Oregon, an overview of the PBM regulatory landscape, the PBM workgroup selection and recommendations development processes per the budget note to Senate Bill 5701, and the recommendations for draft rules and statutory changes necessary to implement the draft rules.

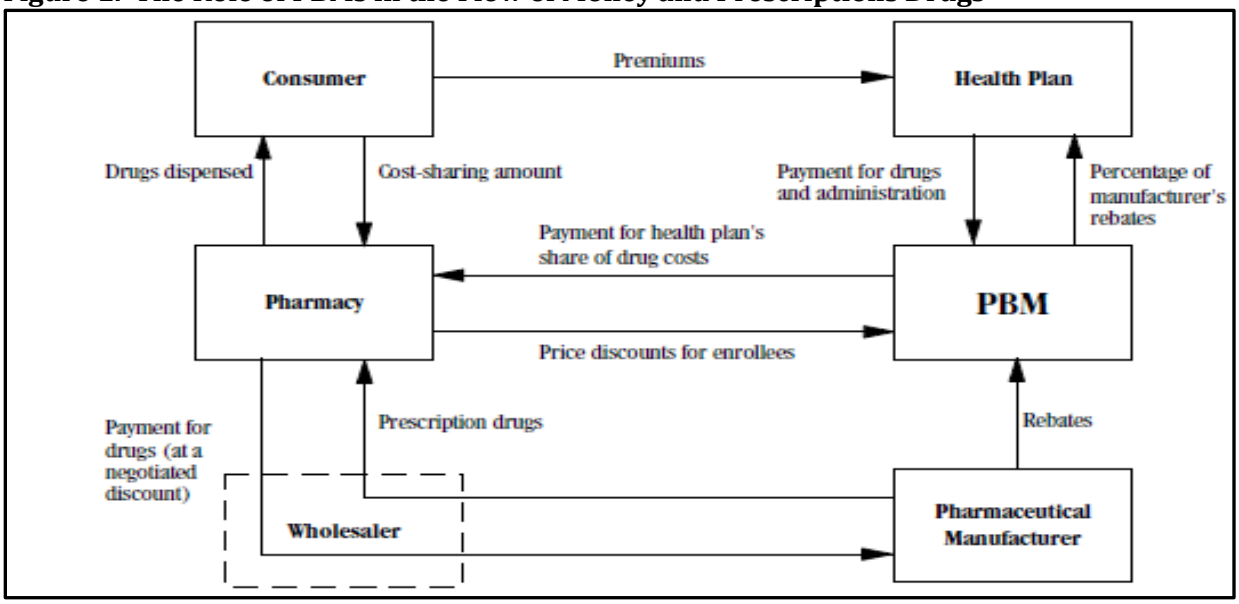
Background

Pharmacy benefit managers (PBMs) are intermediaries in a contractual relationship between wholesalers and manufacturers and health insurers or employers to administer drug benefit programs. Some services that PBMs provide include processing and analyzing prescription claims, contracting with a network of pharmacies, and developing and managing formularies and prior authorization programs. Currently, there are more than 40 entities registered as a PBM to do business in Oregon. Nationally, PBMs manage the drug benefits for an estimated 95 percent of all patients with drug coverage.[1] Figure 1 illustrates the role of PBMs in the flow of money and prescriptions drugs.[2]

[1] Kanwit, Stephanie. The Role of Pharmacy Benefit Management (PBM) Enterprises in Transforming the Pharmaceutical Marketplace, Pharmaceutical Care Management Association presentation (2004). (Available at www.ehcca.com/presentations/pharmacolloquium1/kanwit.pdf.)

[2] *See* Congressional Budget Office, *Prescription Drug Pricing in the Private Sector* 11 (January 2007) (Available at https://www.cbo.gov/publication/18275).

Figure 1. The Role of PBMs in the Flow of Money and Prescriptions Drugs



In 2013, the Oregon Legislature enacted House Bill 2123, making Oregon one of the early adopter states placing requirements on certain PBM related practices, including generic drug pricing and reimbursement. During deliberations at the Capitol of this novel law, the legislative record indicates various parties cited concerns of conflict of interest if the State Board of Pharmacy was given oversight of a counterparty in the prescription supply chain. As such, the bill was amended to substitute the Department of Consumer and Business Services as the entity to receive that authority.

Specifically, HB 2123 required PBMs to register with the department and annually renew their registration in order to conduct business in the state. The legislation also granted the department the authority to regulate specific practices of PBMs and established requirements for:

- PBM reimbursement of a pharmacy for generic drugs using a maximum allowable cost (MAC) pricing methodology
- The process for a network pharmacy to make an appeal for reimbursement of a drug subject to MAC pricing when the pharmacy is reimbursed below the net amount the pharmacy paid for the drug
- Entities or their third-party contractors that audit the claims of pharmacies

Rule authority was also granted to the department to establish a process for PBM registration. Temporary rules were adopted in December 2013 and permanent rules were adopted in June 2014.

What is Maximum Allowable Cost or MAC Pricing?

Health plans and PBMs use a variety of payment methodologies and pricing benchmarks to reimburse for pharmaceuticals, depending if the drug is covered under the medical benefit (typically drugs administered in a medical office or clinic setting, or administered through home health) vs. pharmacy benefit (typically drugs dispensed by a retail, mail order, or specialty pharmacy), covered under a public vs. private plan; if a specialty, brand name, or generic; accessed via mail order vs. retail; etc.

Maximum allowable cost (MAC) is typically a reimbursement limit per individual multiple-source pharmaceutical (generic, strength, and dosage form). MAC price lists are established by health plans and PBMs for private-sector clients and by many states for generic pharmaceuticals paid for by Medicaid and other state-funded programs. PBMs claim the purpose of MAC pricing is to provide equitable reimbursement to pharmacies for generic drugs overall in an environment in which market pricing for individual products may fluctuate with some frequency. However, without a better understanding of the data sources and MAC methodologies used by PBMs, this claim is difficult to confirm. This is because the PBMs usually consider private-sector MACs to be proprietary and confidential. While clearly defined for Medicaid, there is no standardized private-sector definition, methodology, update timing, or market application for MAC.

Compared with public payers, there is less transparency in the payment methods used by private payers to pay for prescription drugs. For example, private payers use MAC price lists for generic drugs; however, prices contained in these MAC lists, the methodology by which these lists are constructed, the frequency with which they are updated, and network pharmacies at which they apply are not publicly disclosed.

Source: Academy of Managed Care Pharmacy (AMCP) Guide to Pharmaceutical Payment Methods, 2013.

Since the enactment of the HB 2123, the department has gained considerable knowledge and experience in understanding the interactions between pharmacies and PBMs, particularly as the department handled consumer complaints and held ongoing discussions with stakeholders. The workgroup process helped further these strides in understanding the role of PBMs in the health care system. The department appreciates the ongoing discussions with stakeholders the robust discussions in the PBM workgroup meetings, and the information provided to the department by workgroup members.

While the charge of the SB 5701 budget note emphasized the department's enforcement authority, which was thoroughly examined in the workgroup process, the department's foremost goal is to foster voluntary compliance with the law among the entities it regulates and obtain corrective action well before pursuing enforcement action. Furthermore, creating a regulatory framework that promotes voluntary compliance also ensures more efficient and prudent use of department resources.

Ultimately, the department aims to provide regulated entities with the information and guidance necessary to stay abreast of changing regulatory requirements, expectations, and industry

practices, and, when these measures do not adequately result in parties abiding by the law, the department may pursue enforcement action.

History of Complaints against PBMs Operating in Oregon

To date, the department has received more than 68,000 alleged instances of violations of statute by 25 PBMs. The majority of complaints were received in batches and the number reflects each claims transaction as a separate alleged violation. Of the total alleged violations, nearly 24,000 were received in 2015, and all but 145 complaints were from an entity that represents many independent pharmacies in Oregon. Approximately one-third of these complaints were determined to be related to Medicare Part D claims, for which federal law pre-empts state regulatory authority.[3] Similarly, in 2016, more than 44,000 complaints were received, and all but 10 were from the same entity. Again, more than one-third of these complaints were indicated to be related to Medicare Part D claims. The remaining complainants were comprised of four independent pharmacists in Oregon. The vast majority of the complaints were not accompanied by supporting documentation.

The majority of complaints pertain to the appeal process for pharmacy claims paid by a PBM using a maximum allowable cost (MAC) methodology. Generally, alleged PBM violations fell into several common areas:

- PBM failed to respond to an appeal in regard to MAC within seven days.
- PBM failed to provide an alternate national drug code (NDC) with the denial of a MAC appeal.
- PBM provided an NDC that is not available to the pharmacy at all or is not available at or below the MAC.
- PBM increased the MAC, but did not reprocess claims back to the date of initial adjudication.
- PBM denied the MAC appeal because the loss is less than $1.50.
- PBM refused to provide the telephone number of a person who could discuss an appeal.
- PBM told the pharmacy to appeal through their Pharmacy Services Administrative Organization (PSAO).

To expand on the bulleted list, one of the frequent subjects of complaint concerns the NDC that PBMs are required to provide with a denial of a MAC appeal. The complainants contended that, in some cases, they either could not find a drug with the NDC provided by the PBM at all or could not find it for a price at or below the MAC. The NDC identifies the manufacturer of the drug in question, but not the wholesalers that the PBM has determined will sell the drug at or below MAC.

In regard to another issue, although it appears most insurers contract with a PBM to handle appeals concerning the MAC, some insurers handle such appeals themselves. Oregon law does exempt health care service contractors (HCSCs) from regulation as a PBM. Therefore, MAC appeals handled by an HCSC are not covered by the statutory appeals process. This may be

[3] *See* 42 CFR § 423.440 (preemption of state law on Medicare Part D plans.).

creating confusion among pharmacists trying to determine the appropriate entity with whom to file an appeal.

In regard to some of the alleged violations, the PBM acknowledged that a violation had occurred and provided information on corrective actions taken. However, in most cases, the PBM indicated one of the following:

- Oregon's PBM statutes do not apply to the plan in question. For example, the plan is a Medicaid, Medicare Part D, TriCare, or a self-insured ERISA plan.[4]
- The alleged violation did not occur. For example, the PBM did respond within seven days or did provide an NDC that was available for purchase at or below MAC with the denial of the appeal.
- The PBM did not have record of even receiving the appeal in question.

To date, the department has encountered challenges verifying information between the parties due to the following:

- Different interpretations of what is required by the law.
- Lack of supporting documentation provided.
- The complexity and limited transparency in the MAC reimbursement process used by PBMs to reimburse pharmacy claims.

PBM Regulatory Landscape

Oregon was one of the first states in the country to enact legislation that required PBMs to register with the state, provided for increased transparency of generic drug pricing and reimbursement, and reformed the practice of pharmacy audits. Today, more than 30 states have adopted at least some type of legislation regulating PBM activity. In preparation for and throughout the workgroup process, the department consulted with and reviewed the laws of other states with similar legislation to enhance its understanding of approaches being taken to regulate PBMs.

Updates to NAIC Prescription Drug Benefit Model Act

The National Association of Insurance Commissioners (NAIC)[5] is reviewing and considering revisions to the Health Carrier Prescription Drug Benefit Management Model Act (Model #22).[6] The purpose of model laws is to provide a uniform basis from which all states can manage regulatory issues. As with other model laws, the legislation that is ultimately enacted can be customized to fit the needs of individual states.

---

[4] Employee Retirement Income Security Act of 1974 (ERISA, Pub. L. 93-406) places the regulation of employee benefit plans (including health plans) primarily under federal jurisdiction.

[5] The NAIC is the U.S. standard-setting and regulatory support organization created and governed by the chief insurance regulators from the 50 states, the District of Columbia, and five U.S. territories. Through the NAIC, state insurance regulators establish standards and best practices, conduct peer review, and coordinate their regulatory oversight. NAIC staff supports these efforts and represents the collective views of state regulators domestically and internationally. NAIC members, together with the central resources of the NAIC, form the national system of state-based insurance regulation in the U.S.

[6] The model was last updated in July 2003.

Model #22 aims to address issues related to: a) transparency, accuracy, and disclosure regarding prescription drug formularies and formulary changes during a policy year; b) accessibility of prescription drug benefits using a variety of pharmacy options; and c) tiered prescription drug formularies and discriminatory benefit design. Across the model, NAIC is considering the direct or indirect regulation of PBMs. At least 25 organizations/entities provided initial comments about updates to Model #22. There were many proponents in favor of greater regulation of PBMs by state departments of insurance to foster transparency in drug pricing, increase access to pharmaceuticals by consumers, and strengthen states' enforcement capabilities over PBMs. This work will likely not conclude until mid-to-late 2017.

Medicare Part D

Effective January 1, 2016, Medicare began requiring drug pricing based on MAC to be subject to the regulations governing the disclosure and updating of prescription drug pricing standards,[7] which included:

- Updating pricing standards based on the cost of the drug used for reimbursement of network pharmacies on January 1 of each contract year and at least once every seven days thereafter.
- Indicating the source used for making any such updates.
- Disclosing all individual drug prices to be updated to the applicable pharmacies in advance of their use for reimbursement of claims, if the source for any prescription drug pricing standard is not publicly available.

The Centers for Medicare and Medicaid Services (CMS) explained in the preamble to the final rule (4159-F) that these changes mean that Part D sponsors will have to convey to network pharmacies the actual MAC prices to be updated in advance, but did not specify a certain timeframe.[8] In the final rule, CMS further stated that the site or other delivery method to convey MAC prices needs to be in a manner usable by network pharmacies to enable the pharmacies to connect a claim to the correct drug price at the appropriate point in time in order to validate the price.[9]

MAC Transparency Act of 2015

In January 2015, the Congress introduced H.R. 244, a bipartisan bill with sponsorship from 48 representatives that would ensure federal health plan reimbursements to pharmacies keep pace with generic drug prices. The MAC Transparency Act of 2015 was introduced by Rep. Doug Collins (R-GA-09) and Rep. Dave Loebsack (D-IA-02). The MAC Transparency Act of 2015 aimed to:

- Increase transparency of generic drug payment rates in Medicare Part D, the Federal Employees Health Benefits program (FEHB), and TRICARE pharmacy programs, by placing requirements on PBMs, similar to states' legislation.
- Expand the definition of a drug pricing standard to include MAC.
- Protect patient privacy and choice of pharmacy in Medicare Part D and FEHB pharmacy programs.

The bill's last action was its referral to the Subcommittee on Military Personnel on June 5, 2015.

---

[7] *See* 42 CFR §§423.501; 423.505(b)(21); and 423.505(i)(3)(vii).
[8] *See* 70 Fed. Reg. 29883, May 24, 2014.
[9] *See* 70 Fed. Reg. 29884, May 24, 2014.

Pharmacy Benefit Manager Rulemaking Workgroup

Workgroup Selection

The department used a comprehensive communication strategy to announce its search for diverse, knowledgeable, and collaborative participants to serve on the workgroup. The announcement described the charge of the workgroup and included an interest form that captured identifying information of the submitter, as well as their stakeholder type (e.g., consumer, pharmacist, insurer, and PBM). The announcement was emailed to subscribers of the department's electronic mailing list, as well as interested parties that were identified through past participation in PBM-related legislative activity in Oregon.

Ultimately, the department selected workgroup members made up of five pharmacy representatives, including an urban and rural independent pharmacy, a national chain pharmacy, a pharmacy association, and a pharmacy service organization (PSAO).[10] In addition, there were representatives from four of the largest PBMs in the nation, as well as four insurers, including two commercial insurers,[11] a workers' compensation insurer, and a self-insured entity.

Workgroup Process

The department's main objective for the PBM workgroup process was to meet the directives of the budget note. In order to answer the question of what it meant to ensure "compliance" with current law, the department also considered the following:

- How to ensure that all parties, the department and the private market actors alike, know and understand how to apply the current statutory framework
- How to foster transparency in PBM contracting and claims reimbursement within the context of the law and clarify the conduct by parties to achieve these goals
- Identify the issues in the complaints filed with the department to ensure they received a full and fair examination
- How to protect the insurance-buying public through appropriate application of the Insurance Code

The department developed a charter for the workgroup with the purpose and scope constructed directly from the charge described in the budget note:

> "DCBS is directed to convene a workgroup to develop recommendations for rulemaking regarding PBM compliance. Based on those recommendations, the agency will draft rules regarding PBM compliance and report to the appropriate legislative policy committees by Nov. 1, 2016. The report should include the draft rules, as well as any statutory changes or clarifications necessary to fully implement the draft rules, including fee recommendations for administration of the program. Draft rules must include, but are not limited to:

[10] PSAOs develop networks of member pharmacies by signing contractual agreements with individual pharmacies. These agreements set forth the duties and obligations of the PSAO to each pharmacy and vice versa and generally authorize PSAOs to interact with third-party payers on behalf of the members in their network. Among the responsibilities established between the PSAO and the pharmacy, the PSAO is frequently given the responsibility to contract on behalf of the pharmacy with third-party payers. *See* United States Government Accountability Office, PRESCRIPTION DRUGS: The Number, Role, and Ownership of Pharmacy Services Administrative Organizations. GAO-13-176: January 2013.

[11] Oregon's Health Co-op was one of the insurers and withdrew from participation midway through the process.

- Notification system that includes a method for informing PBMs of new regulations and for informing PBMs of complaints, investigations, and possible sanctions
- Investigation procedures
- Fees, fines, and resolution process that includes:
  - Overall schedule of fees and fines
  - Provisions for warnings before fines, based on circumstances
  - Possible escalation of fine for multiple occurrences, including combining multiple occurrences into a single complaint or enforcement action, or multiple claims related to a single reason or cause
  - Setting a maximum annual per PBM fine
  - Exceptions based on type of violation or other criteria
  - A reasonable time to re-enter compliance
  - Other provisions consistent with DCBS' existing enforcement authority and procedures

The department also established a website[12] dedicated to the PBM workgroup process. Meeting information and materials, and pertinent workgroup information were available on the site. Workgroup members and interested members of the public were encouraged to provide written comment throughout the process. A summary of each meeting's agenda and discussion is provided below.

Meeting No. 1 – Charter Adoption and Overview of PBM Regulations and Department's Regulatory and Enforcement Authority

In the first meeting, workgroup members adopted the charter and discussed their priority issues relating to PBMs. Common issues identified included:

- Leveling the playing field and ensuring there are fair dealings between pharmacies and PBMs
- Rural and smaller pharmacies are administratively strained by the requirements of PBMs for claims processing and reimbursement
- Concerns about managing high drug costs and ensuring that any steps taken by the workgroup do not worsen the problem of rising drug costs
- Eliminating contradictory or duplicative regulatory structures

In order to establish common understanding of the department's role and authority in regulating PBMs, the department then reviewed the history of complaints regarding PBMs and provided an overview of existing PBM statutes and rules in Oregon under ORS 735.530 to 735.552 and OAR 836-200-0401 to 836-200-0421, respectively. The department reviewed its existing tools for notifying stakeholders of new regulations. Currently, this is done through various communication channels, but the primary method is through emails sent to interested parties signed up to receive department updates and public notifications used to meet requirements under the Administrative Procedures Act, ensuring that interested parties are consulted to the greatest extent possible.[13]

[12] Available at https://www.oregon.gov/DCBS/Insurance/legal/committees-workgroups/Pages/pharmacy-benefit-manager/pbm-invitation.aspx

[13] *See* ORS 183.333

Lastly, the department reviewed its general regulatory and enforcement authority provided by the Insurance Code, and its applicability to PBMs (see Figures 2 and 3). In general, through a series of statutes in ORS Chapter 731, the director of DCBS shall enforce the provisions of the Insurance Code for the public good[14] and may institute actions or other lawful proceedings that the director deems necessary to enforce a provision of the Insurance Code.[15] See Appendix B. The Oregon Insurance Code and the Department of Consumer and Business Services' General Regulatory Authority, which was provided to the PBM workgroup detailing the department's current authority to enforce the Insurance Code.

Figure 2. Enforcement Process

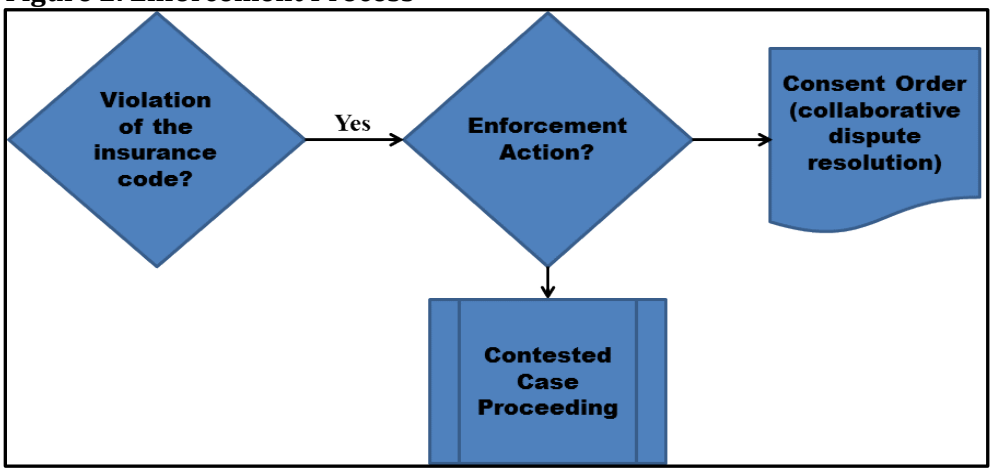
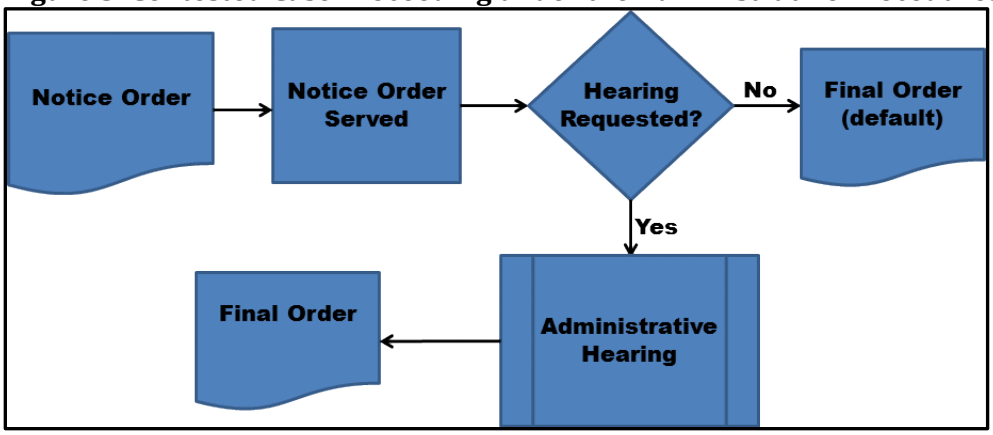


Figure 3. Contested Case Proceeding under the Administrative Procedures Act



Meeting No. 2 – Review of ORS 735.534 (Claim reimbursement; maximum allowable costs) for Potential Rulemaking

Before entering into a discussion on the process of enforcement and considerations for a penalty structure, the department prioritized seeking clarity on the conduct that would establish a violation of the Insurance Code by PBMs. The department's goal for the discussion was to ensure all stakeholders have a shared understanding as to how these laws should be

[14] *See* ORS 731.236(1)
[15] *See* ORS 731.256(1)

implemented, including the type of conduct the department would be responsible for regulating. The department considered this part of the discussion to be well within the scope of the workgroup as per the budget note in order to "… develop recommendations for rulemaking regarding PBM compliance."

It was clear in the discussion that the parties had different statutory interpretations regarding ORS 735.534 and opinions for how it should be enforced. For example, stakeholders representing PBMs stated repeatedly that a lot of work and consensus was reached when the parties originally agreed upon the 2013 legislation. PBM members expressed that even having a discussion related to assessing this statute for rulemaking opportunities was out of scope for the workgroup. A representative from the City of Portland also expressed that review of the statute was out of scope for the workgroup. Conversely, stakeholders representing pharmacies were interested in discussing issues and raising uncertainties and questions the department has encountered over the past year in its efforts to enforce the statutes.

Meeting No. 3 – PBM Registration and Discussion of Penalty Structure

The workgroup discussed opportunities to augment the registration process, which included requiring additional contact information from the PBM. Further information would help the department work directly with the compliance departments of individual PBMs, and, if necessary, serving process upon the PBM. Other information was proposed to help pharmacists contact the most appropriate PBM personnel to appeal a decision on reimbursement and establish a fee more commensurate with the cost of regulating PBMs.

The current registration and renewal fee is $50, far less than that of any entity required to register or be licensed with the department. When establishing fees for the dozens of other programs the department administers, the department works to determine the anticipated expenditures for the program, taking into consideration the estimated number of entities to be regulated; frequency of renewal; whether the entity will be subject to investigations and exams; and number, classification, and workload of department staff necessary to effectively regulate a particular entity or program. All fee increases adopted by rule also go through a public process of advisory committee work, public hearings, and comments. Finally, fees adopted by a state agency must also be ratified by the Legislative Assembly, or the fee is ineffective.[16]

Regarding a penalty structure, the workgroup considered a range of approaches, including:

- Flexible approach – Maximum of $10,000 per offense (per ORS 731.988); each violation of the insurance code is a separate offense; department maintains greater enforcement discretion. (*Current process)*
- Penalty cap – Establishes a ceiling fine for each violation; no more than $10,000 for all violations in a given period of time.
- Penalty matrix – Establishes a penalty for a specific violations; fee may escalate during certain time period; little to no enforcement discretion.

[16] *See* ORS 291.050 – 291.060 (Agency fee restrictions). This process is sometimes termed the "333" process, in reference to the Act the adopted the original fee restrictions (1995 Or Laws ch 576 (Enrolled Senate Bill 333)).

- Penalty adjustments – Initial penalty may be adjusted based on the violator's intent in committing the infraction or the final penalty may be adjusted based on the violator's level of cooperation.

The group also considered the circumstances in which violations might be combined, and how a PBM's willingness to cooperate under an investigation and its history of compliance or noncompliance during a certain look-back period should be considered. Regarding whether and how multiple occurrences could be combined into a single complaint, there were differing viewpoints between pharmacists and PBMs. Pharmacists indicated that they are audited on an individual claim basis and, therefore, each claim should be considered a violation. PBMs expressed that it would not be appropriate as some claim reimbursements subject to violation may be due to a clerical error and the volume of complaints can be onerous.

Several workgroup members expressed concerns over using a penalty matrix, or any type of matrix that would be too rigid and remove flexibility the department may need to fully consider all factors in a case. Ultimately, the workgroup agreed that the department should retain flexibility and discretion in in determining – from the facts and circumstances of an individual matter – when a violation constituted a single violation or could be considered discrete instances of conduct, keeping in mind certain due process factors. See Table 1. DCBS Enforcement Approach in Issuing Civil Penalties under the recommendations section for more detail on the department's enforcement approach.

Meeting No. 4 – Conceptual Outline for PBM Rulemaking Recommendations

The fourth and final meeting was spent reviewing a conceptual outline for proposed statute and rule changes. The conceptual outline was used as a tool to begin to articulate the areas in statute that required additional clarity and appeared to benefit from rules that would facilitate implementation of the statute. See Appendix C. Conceptual Outline for PBM Rulemaking Recommendations. Focus was placed on registration criteria, developing definitions for terms referred to in the statute for which ambiguity and diverging interpretations among parties was expressed, and the appeals process.

Recommendations

The department recommends a combination of minor statutory changes, as well as a more comprehensive set of rule changes that address definitions, PBM registration, and the appeals process. Additionally, to fully clarify that the department may adopt rules to address matters beyond registration, the department proposes to seek more expansive rule writing authority in order to draft rules to better ensure PBM compliance. See Appendix A. Proposed Pharmacy Benefit Manager Rules.

Registration

Registration fees in statute reflect a limited role for the department in acting as a registrar of active PBMs in the state. The registration fee should be commensurate with actual program costs that are consistent with expenses involved in conducting investigations and enforcement actions. The department recommends the registration and renewal fee be set by rule after a robust public process, which would require a statutory change, as follows:

SECTION [x]. ORS 735.532 is amended to read:

735.532. (1) To conduct business in this state, a pharmacy benefit manager must register with the Department of Consumer and Business Services and annually renew the registration.

(2) To register under this section, a pharmacy benefit manager must:

(a) Submit an application to the department on a form prescribed by the department by rule.

(b) Pay a registration fee [*, not to exceed $50, adopted*] **established in rule** by the department [*by rule*].

(3) To renew a registration under this section, a pharmacy benefit manager must pay a renewal fee, [*not to exceed $50, adopted*] established **in rule** by the department [*by rule*].

(4) The department shall deposit all moneys collected under this section into the Consumer and Business Services Fund created in ORS 705.145.

Examination, Investigation & Enforcement Tools

The department recommends standard, but not extensive, rule and legislative changes regarding examination, investigation, and enforcement tools. The workgroup expressed preference for the department to retain its existing authority and discretion in investigating matters and, if necessary, take enforcement action, which are sufficient to support potential insurance law violations by PBMs. The department recommends one legislative change to grant the department authority over PBMs, which it does not currently have. That is necessary to grant the director the power to suspend or revoke a PBM's registration with respect to any violation for which an order of discontinuance has been issued. The department views suspension and revocation as an act of last resort and would only consider pursuing this course for egregious violations or if the department's continued efforts to obtain compliance with the law remained unsuccessful. Suggested language, as adapted from existing enforcement authority [17] over third-party administrators is as follows:

SECTION [x]. (1) The Director of the Department of Consumer and Business Services may suspend, revoke or refuse to renew a registration of a pharmacy benefit manager if the director finds one or more of the following with respect to a pharmacy benefit manager or an applicant for a registration as a pharmacy benefit manager:

(a) Falsification by the applicant or licensee of an application for the license or renewal thereof, or engagement in any dishonest act in relation to the application;

(b) Dishonesty, fraud or gross negligence in the transaction of insurance or in the conduct of business as a pharmacy benefit manager;

(c) Conduct resulting in a conviction of a felony under the laws of any state or of the United States, to the extent that such conduct may be considered under ORS 670.280;

[17] *See* ORS 744.718 (suspension, revocation or refusal of issuance or renewal of third party administrator license).

(d) Conviction of any crime, an essential element of which is dishonesty or fraud, under the laws of any state or of the United States;

(e) Refusal to renew or cancellation, revocation or suspension of authority to transact insurance or business as a pharmacy benefit manager or similar entity in another state;

(f) Failure to pay a civil penalty imposed by final order of the director or to carry out terms of suspension set by the director;

(g) Failure to meet the terms of a consent decree approved by a court of competent jurisdiction in this state, or a consent order made between the director and the pharmacy benefit manager;

(h) Refusal to be examined or to produce accounts, records or files for examination, refusal by any officers to give information with respect to the affairs of the pharmacy benefit manager or refusal to perform any other legal obligation as to the examination when required by the director;

(i) Violation of any rule or order of the director or any provision of the Insurance Code.

Finally, while the department recommends minimal rule and legislative changes regarding enforcement, as reference, the report describes the considerations that will be made when pursuing enforcement of PBMs in violation of the Insurance Code. See Table 1 below.

Table 1. DCBS Enforcement Approach in Issuing Civil Penalties

In accordance with ORS 731.988, any person who violates any provision of ORS 735.530 to 735.552, or any rule or final order of the director or any judgment that a court makes in response to the director's application, shall be subject to a civil penalty in an amount determined by the director that does not exceed $10,000 for each offense. Per ORS 731.988, each violation is considered a separate offense.

When pursuing enforcement actions and imposing civil penalties, the department and director are able to exercise discretion. The director has sole discretion to determine whether any instance or instances of noncompliance constitute a single or multiple violations of the law, depending upon the particular circumstances.

When determining whether enforcement action or administrative sanction is appropriate, the director may consider:

- The nature of the violation, and the number of violations, at issue;
- Whether the violation involved intentional, reckless or negligent conduct;
- Whether the person has committed the same or similar violations previously and the time frame in which they occurred;
- The nature and degree of the harm to others;
- Whether the violation was self-reported; and,
- Whether, and how, the person cooperated in the investigation or in achieving resolution.

In an effort to remedy a violation or violations of ORS 735.530 to 735.552, the director may allow submission of a plan that assures compliance with the law and protects against future instances of noncompliance. No such remedial plan shall excuse current or future non-compliance with the law.

Recommendations for Rule Changes

The department emphasizes that the recommendations for rule changes provided in this report are preliminary. If the department is charged with adopting formal rules, it will conduct its rulemaking process under the Administrative Procedures Act. This would entail convening a formal rules advisory committee broadly composed of interested stakeholders to develop final rules for PBM compliance.

Purpose, Authority and Applicability – The department recommends rules changes that directly bring in more expansive rule writing authority to implement the PBM statutes, which are already referenced under the statutory authority cited for the existing set of PBM rules. The rule recommendations also expressly authorize the department to administer and enforce the PBM statutes in accordance with the Insurance Code.

Definitions – In examination and discussion of the PBM statutes, it was concluded that the department needed further clarification for the meaning of several terms used throughout the statute. Such terms had varying interpretations both among and between the different representation segments of the workgroup (PBMs, health insurers, and pharmacies). Without clearly articulated standards – derived from the current statute – for the department, PBMs, or pharmacists to apply, any compliance efforts could be difficult to pursue at best, or a violation of due process at worst. Clarification of such terms is necessary to foster voluntary compliance for regulated entities and for the department to serve as an effective regulator. Any ambiguity or susceptibility to varying interpretations creates opportunities for noncompliance and contestation of enforcement action pursued by the department.

Registration – In addition to recommending the registration and renewal fee be set by rule, the department calls for the telephone number and email of the PBM and person directly responsible for the processing on appeals to be included in the registration. This will ensure that the department has all of the necessary contact information for the PBM, which may be used to confirm the contact information that is being made available to pharmacies filing appeals with a respective PBM.

Appeals Process – Recommendations pertaining to the appeals process were intended to clarify and streamline certain aspects of the appeals process, while also providing safeguards to pharmacies filing appeals to ensure they were not penalized for doing so.

Public Comment

All PBM workgroup meetings were open for the public to attend and provide public comment. Individuals or groups were also invited to submit public comment electronically at any time throughout the process. All written public comments are posted to the Web at http://dfr.oregon.gov/public-resources/committees-workgroups/Pages/pbm-comments.aspx. The list of public comment received is shown below.

Draft PBM Report and Recommendations (draft) and comments to draft report:

- 10/19/16: April Alexander, Esq. (PCMA)
- 10/19/16: Ann Marie Murray R.Ph. (Murray Drugs Inc.)
- 10/16/16: Thomas Holt (Cambia Health Solutions)

All other public comment:

- 10/6/16: Patrick Bowman (Tualatin Pharmacy)
- 8/23/16: Pharmaceutical Care Management Association (PCMA)
- 7/29/16: Express Scripts
- 7/27/16: Ann Marie Murray R.Ph. (Murray Drugs Inc.)
- 7/27/16: Pharmaceutical Care Management Association (PCMA)
- 7/25/16: Oregon State Pharmacy Association (OSPA)
- 7/15/16: Cambia
- 7/6/16: Oregon State Pharmacy Association (OSPA)
- 6/29/16: Express Scripts
- 6/29/16: Walgreens Boots Alliance
- 6/28/16: City of Portland
- 6/23/16: Pharmaceutical Care Management Association (PCMA)

Additional Considerations

In addition to focusing on opportunities for rulemaking, working within the existing statutory framework, additional issues and recommendations were raised by stakeholder members that were beyond the direct scope of the workgroup, but were related to issues experienced by pharmacies and their reimbursement by PBMs. Stakeholder members were informed that while the workgroup meetings could serve as a venue for voicing related concerns beyond the charge of the budget note, the group would not focus its efforts on analyzing and addressing these issues in this process or the report, but that such issues would be noted in the report as additional considerations. These include:

- Independent pharmacy representatives raised the issue that underpayment due to MAC reimbursement put a financial strain on their business, a particularly critical issue in rural areas where access to a physical pharmacy may already be a challenge. Conversely, payers indicated that pharmacies might also earn profits on other individual drugs.
- Pharmacy representatives also expressed that if a MAC appeal is upheld, the PBM should make an adjustment for the pharmacy that requested the appeal, and all other similarly situated pharmacies, from the date of initial adjudication forward. This approach would be consistent with the department's broader regulatory approach, which is to ensure that when one party is found to be in violation of the Insurance Code, to work to ensure that all affected individuals or groups, not only those that submit complaints, receive the same protections under the law.
- Use of more generic pharmacy claims reimbursement language as opposed to exclusively reimbursement subject to MAC, for a broader applicability of the law and the types of cases that would be eligible for appeal by pharmacies.
- Broaden the applicability of the law to include pharmacy claims reimbursement in the Medicaid program, which is currently excluded in statute, and also the Medicare Part D program, which the department understands is that federal law preempts state regulatory authority.
- Rule changes to address audit issues raised in public comments.
- PBM representatives recommended "the department ask the legislature for authority to levy a fine or take other administrative action against an organization that files frivolous appeals."

Conclusion

The department is committed to continue developing its expertise and being an effective regulator in the complex and dynamic arena of pharmacy benefit drug management. This includes working to ensure that health insurers and their contracted pharmacy benefit managers are on a level playing field with network pharmacies by fostering transparency in maximum allowable cost (MAC) pricing practices and claims reimbursement. The department will continue to work with other state agencies, state and federal partners, the National Association of Insurance Commissioners, and other stakeholders who are confronting issues related to pharmacy benefits management. Ultimately, the department is committed to upholding its consumer protection mission by protecting Oregonians' access to fair products and services through education, regulation, and customer assistance.

Appendix A. Proposed Pharmacy Benefit Manager Rules

Pharmacy Benefit Managers

836-200-0401

Statement of Purpose; Authority; Applicability

(1) OAR 836-200-[*0*]0401 to 836-200-0421 are adopted under the authority of section **1** [*3*], chapter 570, Oregon Laws 2013**, and ORS 731.244 and 735.532**, for the purpose of implementing **ORS 735.530 to 735.552 [***sections 2 and 3, chapter 570, Oregon Laws 2013*].

(2) [*For any registration completed between January 2, 2014 and August 31, 2015 the first annual renewal of the registration shall be September 1, 2015.*] **Under the authority of section 1, chapter 570, Oregon Laws 2013, ORS 735.530 to 735.552 shall be administered and enforced in accordance with the Insurance Code.**

Stat. Auth.: 2013 OL Ch. 570, Sec. 1; ORS 731.004, 731.244, 735.532
Stats. Implemented: ORS 735.530 to 735.552[, 735.532]
Hist.: ID 12-2014, f. & cert. ef. 7-21-14

836-200-0403

Definitions

As used in ORS 735.534:

(1) "Generally available" means that a drug is available for purchase in this state by the pharmacy from a national or regional wholesaler at the time of claim submission. A drug shall not be deemed "generally available" if the drug is:

(a) Restricted to hospital or institutional dispensing;

(b) Unavailable due to product or ingredient shortage;

(c) Only available to the pharmacy at or below the maximum allowable cost price if purchased in substantial quantities not consistent with the business needs of the pharmacy;

(d) Being sold at a discount due to being short dated; or

(e) Subject to an active or pending drug recall.

(2) "Readily accessible to and usable" and "readily accessible and useable" means an electronic, computer accessible and searchable format that lists all drugs for which maximum allowable costs have been established and, for each drug, includes:

(a) Fee schedule reference code (name of network schedule);

(b) Generic product identifier and/or national drug code;

(c) Maximum allowable cost price; and.

(d) Price effective date and time.

(3) "Similarly situated pharmacies" means all other pharmacies in this state that:

(a) Are part of the same class of trade, which include, but are not limited to independent, retail, chain, grocery, mass merchandiser, mail order, or specialty; and

(b) Are contracted with a pharmacy benefit manager under the same network agreement.

(4) "Sources utilized" means an identification of the all specific, non-proprietary authoritative industry sources from which the pharmacy benefit manager obtains information, or with which the pharmacy benefit manager conducts research, to determine maximum allowable cost pricing for a drug.

(5) "Net amount" is the price of the drug paid by the pharmacy as reflected on the invoice from the supplier of the drug.

Stat. Auth.: ORS 731.244, 735.532
Stats. Implemented: ORS 735.530, 735.534
Hist.: New.

836-200-0406

Application Requirements for Pharmacy Benefit Manager Registration

(1) Each pharmacy benefit manager conducting business in Oregon must register with the Department of Consumer and Business Services. To register as a pharmacy benefit manager, the entity must complete a Pharmacy Benefit Manager Application, [*Exhibit 1 of this rule*] **as published on the Department's website**.

(2) An applicant for registration as a pharmacy benefit manager shall include in the application:

(a) The identity of the pharmacy benefit manager;

(b) The name, business address, [*and*] contact person**, contact telephone number and contact e-mail address** for the pharmacy benefit manager: [*and*]

(c) Where applicable, the FEIN number for the entity [.]**; and**,

(d) The telephone number and e-mail address at which persons directly responsible for the processing of pharmacy maximum allowable cost claims and reimbursement appeals may be contacted.

(3) A pharmacy benefit manager shall provide information on any material modification to the information provided by the pharmacy benefit manager in its application for registration not later than 30 days after the modification.

(4) The application for registration as a pharmacy benefit manager must include a fee of [*$50*] **_____**. The fee under this section must be submitted with the filing.

Stat. Auth.: ORS 731.244, 735.532
Stats. Implemented: ORS 735.530, 735.532
Hist.: ID 12-2014, f. & cert. ef. 7-21-14

836-200-0411

Renewal of Pharmacy Benefit Registration

(1) All pharmacy benefit registrations expire on September 1 unless renewed on or before that date. A registrant must renew the registration by submitting a renewal application**, as published on the Department's website,** and renewal fee to the Director of the Department of Consumer and Business Services. The application to renew a registration as a pharmacy benefit manager must include a renewal fee of [$50] _____.

(2) A registered pharmacy benefit manager shall include with the renewal application any change in the information submitted since the registrant initially registered or last renewed the pharmacy benefit manager registration.

Stat. Auth.: ORS 731.244, 735.532
Stats. Implemented: ORS 735.530, 735.532
Hist.: ID 12-2014, f. & cert. ef. 7-21-14

836-200-0416

Registration Requirements Not Exclusive

Compliance with the filing requirements of OAR 836-200-0401 to 836-200-0421 are additional to and not in lieu of filing and other requirements established by law for the purpose of doing business in this state, including but not limited to compliance with filing requirements of the Secretary of State applicable to assumed business names and applicable to the business structure of an applicant.

Stat. Auth.: ORS 731.244, 735.532
Stats. Implemented: ORS 735.530, 735.532
Hist.: ID 12-2014, f. & cert. ef. 7-21-14

836-200-0421

Service on Registrant

The Director of the Department of Consumer and Business Services may make service on a registered pharmacy benefit manager at the address shown on the current registration of the pharmacy benefit manager on file with the director, in the manner provided in ORS 183.310 to 183.550.

Stat. Auth.: ORS 731.244, 735.532
Stats. Implemented: ORS 735.530, 735.532
Hist.: ID 12-2014, f. & cert. ef. 7-21-14

836-200-04XX

Appeals for Reimbursement for a Drug Subject To Maximum Allowable Cost Pricing

(1) A pharmacy benefit manager shall allow the submission of paper or electronic documentation by a network pharmacy for purpose of appeal.

(2) A pharmacy benefit manager shall not:

(a) Refuse to accept an appeal from a network pharmacy's designated representative;

(b) Refuse to accept an appeal for reason that it is submitted with multiple claims or within a batch of appeals; or

(c) Impose procedures or restrictions that have the effect of obstructing or unreasonably delaying the appeal process.

(3) If an appeal is upheld, the pharmacy benefit manager:

(a) Must allow the resubmission of the claim by the network pharmacy and all other similarly situated pharmacies.

(b) May not impose additional fees for making an adjustment.

(4) If an appeal is denied, the pharmacy benefit manager shall provide the pharmacy with the name of the national or regional wholesaler or wholesalers where the drug was generally available for purchase by the pharmacy in this state at a price equal to or less than the maximum allowable cost at the time of claim submission.

Stat. Auth.: ORS 731.244, 735.532
Stats. Implemented: ORS 735.530, 735.534
Hist.: New.

Appendix B. The Oregon Insurance Code and the Department of Consumer and Business Services' General Regulatory Authority

SHORT TITLE; PURPOSE AND CONSTRUCTION

731.004 Short title. ORS chapters 731, 732, 733, 734, 735, 737, 742, 743, 743A, 743B, 744, 746, 748 and 750 may be cited as the Insurance Code. [1967 c.359 §1; 1973 c.97 §1; 1975 c.769 §1]

731.008 Purpose of Insurance Code. The Legislative Assembly declares that the Insurance Code is for the protection of the insurance-buying public. [Formerly 736.003]

731.016 Construction of Insurance Code. The Insurance Code shall be liberally construed and shall be administered and enforced by the Director of the Department of Consumer and Business Services to give effect to the policy stated in ORS 731.008. [1967 c.359 §4]

731.232 Subpoena power. (1) For the purpose of an investigation or proceeding under the Insurance Code, the Director of the Department of Consumer and Business Services may administer oaths and affirmations, subpoena witnesses, compel their attendance, take evidence and require the production of books, papers, correspondence, memoranda, agreements or other documents or records which the director considers relevant or material to the inquiry. Each witness who appears before the director under a subpoena shall receive the fees and mileage provided for witnesses in ORS 44.415 (2).
(2) If a person fails to comply with a subpoena so issued or a party or witness refuses to testify on any matters, the judge of the circuit court for any county, on the application of the director, shall compel obedience by proceedings for contempt as in the case of disobedience of the requirements of a subpoena issued from such court or a refusal to testify therein. [1967 c.359 §51; 1989 c.980 §22]

731.236 General powers and duties. (1) The Director of the Department of Consumer and Business Services shall enforce the provisions of the Insurance Code for the public good, and shall execute the duties imposed by the code.
(2) The director has the powers and authority expressly conferred by or reasonably implied from the provisions of the Insurance Code.
(3) The director may conduct such examinations and investigations of insurance matters, in addition to examinations and investigations expressly authorized, as the director considers proper to determine whether any person has violated any provision of the Insurance Code or to secure information useful in the lawful administration of any such provision. The cost of such additional examinations and investigations shall be borne by the state.
(4) The director has such additional powers and duties as may be provided by other laws of this state. [1967 c.359 §52]

731.252 Cease and desist orders. (1) Whenever the Director of the Department of Consumer and Business Services has reason to believe that any person has been engaged or is engaging or is about to engage in any violation of the Insurance Code, the director may issue an order, directed to such person, to discontinue or desist from such violation or threatened violation. The copy of the order forwarded to the person involved shall set forth a statement of the specific

charges and the fact that the person may request a hearing within 20 days of the date of mailing. Where a hearing is requested, the director shall set a date for the hearing to be held within 30 days after receipt of the request, and shall give the person involved written notice of the hearing date at least seven days prior thereto. The person requesting the hearing must establish to the satisfaction of the director that such order should not be complied with. The order shall become final 20 days after the date of mailing unless within such 20-day period the person to whom it is directed files with the director a written request for a hearing. To the extent applicable and not inconsistent with the foregoing, the provisions of ORS chapter 183 shall govern the hearing procedure and any judicial review thereof. Where the hearing has been requested, the director's order shall become final at such time as the right to further hearing or review has expired or been exhausted.
(2) No order of the director under this section or order of a court to enforce the same shall in any way relieve or absolve any person affected by such order from any liability under any other laws of this state.
(3) The powers vested in the director pursuant to this section are supplementary and not in lieu of any other powers to suspend or revoke certificates of authority or licenses or to enforce any penalties, fines or forfeitures, authorized by law with respect to any violation for which an order of discontinuance has been issued. [Formerly 736.835]

731.256 Enforcement generally; restitution. (1) The Director of the Department of Consumer and Business Services may institute actions or other lawful proceedings that the director deems necessary to enforce a provision of the Insurance Code or any order or action the director makes or takes in pursuance of law.
(2) As part of or in addition to any action or proceeding the director institutes against an insurer under subsection (1) of this section, the director may:
(a) Seek restitution on a consumer's behalf for actual damages the consumer suffers as a result of the insurer's violation of a provision of the Insurance Code or applicable federal law or the insurer's breach of an insurance contract or policy the insurer has with the consumer; and
(b) Seek other equitable relief the director deems appropriate under the circumstances.
(3) If the director has reason to believe that a person has violated a provision of the Insurance Code or another law that applies to insurance operations, and if the violation is subject to criminal prosecution and in the opinion of the director criminal prosecution is warranted, the director shall give the information about the violation to the Attorney General or district attorney that has jurisdiction over the violation. The Attorney General or district attorney promptly shall institute an action or a proceeding against the person as the information requires or justifies.
(4) An action or proceeding that the director institutes under subsection (1) of this section is an exercise of the director's regulatory authority and, except as otherwise provided in subsection (3) of this section, does not create a cause of action for any other person. [1967 c.359 §57; 2013 c.618 §1]

731.296 Director's inquiries. The Director of the Department of Consumer and Business Services may address any proper inquiries to any insurer, licensee or its officers in relation to its activities or condition or any other matter connected with its transactions. Any such person so addressed shall promptly and truthfully reply to such inquiries using the form of communication requested by the director. The reply shall be verified by an officer of such person, if the director

so requires. A reply is subject to the provisions of ORS 731.260. [Formerly 736.542; 1975 c.298 §1]

731.300 Examination of insurers; when required. (1) The Director of the Department of Consumer and Business Services shall examine every authorized insurer, including an audit of the financial affairs of such insurer, as often as the director determines an examination to be necessary but at least once each five years. An examination shall be conducted for the purpose of determining the financial condition of the insurer, its ability to fulfill its obligations and its manner of fulfillment, the nature of its operations and its compliance with the Insurance Code. The director may also make such an examination of any surplus lines insurance producer or any person holding the capital stock of an authorized insurer or surplus lines insurance producer for the purpose of controlling the management thereof as a voting trustee or otherwise, or both.
(2) Instead of conducting an examination of an authorized foreign or alien insurer, the director may accept an examination report on the insurer that is prepared by the insurance department for the state of domicile or state of entry of the insurer if:
(a) At the time of the examination the insurance department of the state was accredited under the Financial Regulation Standards and Accreditation Program or successor program of the National Association of Insurance Commissioners; or
(b) The examination was performed under the supervision of an accredited insurance department or with the participation of one or more examiners who are employed by such an accredited insurance department and who, after a review of the examination work papers and report, state under oath that the examination was performed in a manner consistent with the standards and procedures required by their insurance department.
(3) Examination of an alien insurer shall be limited to its insurance transactions, assets, trust deposits and affairs in the United States except as otherwise required by the director. [Formerly 736.545; 1979 c.870 §2; 1981 c.874 §18; 1990 c.2 §46; 1993 c.447 §1; 2003 c.364 §67]

731.302 Appointment of examiners; retaining of appraisers, actuaries and others; evidentiary status of facts and conclusions. (1) When the Director of the Department of Consumer and Business Services determines that an examination should be conducted, the director shall appoint one or more examiners to perform the examination and instruct them as to the scope of the examination. In conducting the examination, each examiner shall consider the guidelines and procedures in the examiner handbook, or its successor publication, adopted by the National Association of Insurance Commissioners. The director may prescribe the examiner handbook or its successor publication and employ other guidelines and procedures that the director determines to be appropriate.
(2) When making an examination, the director may retain appraisers, independent actuaries, independent certified public accountants or other professionals and specialists as needed. The cost of retaining such professionals and specialists shall be borne by the person that is the subject of the examination.
(3) At any time during the course of an examination, the director may take other action pursuant to the Insurance Code.
(4) Facts determined and conclusions made pursuant to an examination shall be presumptive evidence of the relevant facts and conclusions in any judicial or administrative action. [1993 c.447 §2]

731.316 Expenses of examination of insurer. Any person examined under ORS 731.300 shall pay to the Director of the Department of Consumer and Business Services the just and legitimate costs of the examination as determined by the director, including actual necessary transportation and traveling expenses. [Formerly 736.565; 1969 c.336 §6]

PENALTIES

731.988 Civil penalties. (1) A person that violates any provision of the Insurance Code, any lawful rule or final order of the Director of the Department of Consumer and Business Services or any judgment that a court makes in response to the director's application, shall forfeit and pay to the General Fund of the State Treasury a civil penalty in an amount determined by the director that does not exceed $10,000 for each offense. The civil penalty for individual insurance producers, adjusters or insurance consultants may not exceed $1,000 for each offense. Each violation is a separate offense.

(2) In addition to the civil penalty specified in subsection (1) of this section, a person that violates any provision of the Insurance Code, any lawful rule or final order of the director or any judgment that a court makes in response to the director's application, may be required to forfeit and pay to the General Fund of the State Treasury a civil penalty in an amount determined by the director that does not exceed the amount by which the person profited in any transaction that violates the provision, rule, order or judgment.

(3) In addition to the civil penalties specified in subsections (1) and (2) of this section, an insurer that must submit a report under ORS 742.400 and that fails to do so within the specified time may be required to pay to the General Fund of the State Treasury a civil penalty in an amount determined by the director that does not exceed $10,000.

(4) In addition to the penalties specified in subsection (1), (2), (5) and (6) of this section, a director or officer of an insurance holding company system who engages in a transaction or makes an investment that has not been properly reported under, or does not otherwise comply with, ORS 732.517 to 732.592, who knowingly participates in or assents to the transaction or investment, or who permits another officer or an agent of the insurance holding company system to engage in the transaction or make the investment, shall pay, in the director or officer's individual capacity, a civil penalty in an amount determined by the director that does not exceed $10,000.

(5) In addition to the penalties specified in subsections (1), (2), (4) and (6) of this section, an insurer or other person that fails to make a required filing or demonstrate a good faith effort to comply with a filing requirement under ORS 732.527, 732.537, 732.539, 732.542 or 732.544 shall pay a civil penalty in an amount determined by the director that does not exceed $50,000.

(6) In addition to the penalties specified in subsections (1), (2), (4) and (5) of this section, an insurer or other person that violates a cease and desist order the director has issued under ORS 731.252 in connection with a violation of a provision of ORS 732.517 to 732.592 may be subject to a civil penalty in an amount determined by the director that does not exceed $10,000 for each day of the violation.

(7) A civil penalty imposed under this section may be recovered either as provided in subsection (8) of this section or in an action brought in the name of the State of Oregon in any court of appropriate jurisdiction.

(8) Civil penalties under this section must be imposed and enforced in accordance with ORS 183.745.

(9) The provisions of this section are in addition to and not in lieu of any other enforcement provisions specified in the Insurance Code. [1967 c.359 §144; 1971 c.231 §16; 1987 c.774 §65; 1989 c.701 §70; 1991 c.401 §2; 1991 c.734 §120; 1993 c.265 §6; 1997 c.131 §5; 2003 c.364 §81; 2003 c.576 §220; 2013 c.370 §15]

Appendix C. Conceptual Outline for PBM Rulemaking Recommendations

Note: This document is not final and is intended to inform further discussions with the PBM Workgroup.

DCBS Objectives for PBM Workgroup

1. Achieve the goals of the budget note by developing recommendations for rulemaking regarding PBM compliance, draft rules based on the recommendations, and statutory changes or clarifications necessary to fully implement the draft rules.
2. Foster transparency in PBM contracting and claims reimbursement and to clarify the conduct to achieve these goals.
3. Protect the insurance-buying public.[1,2]

ORS	Preliminary Rulemaking Recommendations	Outstanding Issues/Questions and Other Considerations
735.532 Registration of pharmacy benefit managers; fees; rules. (1) To conduct business in this state, a pharmacy benefit manager must register with the Department of Consumer and Business Services and annually renew the registration. (2) To register under this section, a pharmacy benefit manager must: (a)) Submit an application to the department on a form prescribed by the department by rule. (b) Pay a registration fee, not to exceed $50, adopted by the department by rule. (3) To renew a registration under this section, a pharmacy benefit manager must pay a renewal fee, not to exceed $50, adopted by the department by rule.	The application for PBM registration shall also include: • The email and contact phone number of the people or department directly responsible for processing pharmacy appeals for MAC reimbursement. • The phone number provided by the PBM may not be a general purpose number and may not be for a person that cannot address MAC appeals and decisions under this section. • Internal facing phone numbers and emails of company contact that DCBS can reach in order to investigate an appeal and ensure compliance. • Contact information for agent for service of process that includes a physical address.	• *Regarding the registration fee, the department recommends this be established in rule, which would allow for the department's Central Services Department to conduct a study on fees appropriate for the registration and regulation of PBMs and for this decision to be vetted through a public process.* • *The department bas begun to assess registration fees used for other programs it regulates, as well as the fees used by other states re registration of PBMs.*

[1] ORS 731.008 Purpose of Insurance Code. The Legislative Assembly declares that the Insurance Code is for the protection of the insurance-buying public.

[2] ORS 731.016 Construction of Insurance Code. The Insurance Code shall be liberally construed and shall be administered and enforced by the Director of the Department of Consumer and Business Services to give effect to the policy stated in ORS 731.008.

ORS	Preliminary Rulemaking Recommendations	Outstanding Issues/Questions and Other Considerations
(4) The department shall deposit all moneys collected under this section into the Consumer and Business Services Fund created in ORS 705.145. [2013 c.570 §3] **Note:** See note under 735.530.		
735.534 Claim reimbursement; maximum allowable costs. (1) As used in this section:		• *Interaction Workers' Compensation*
(a) "List" means the list of drugs for which maximum allowable costs have been established.		
(b) "Maximum allowable cost" means the maximum amount that a pharmacy benefit manager will reimburse a pharmacy for the cost of a drug.	Recommended statute change: • In addition to not being able to include dispensing fees in the MAC, PBMs shall not include pharmacy's administrative costs for submitting or processing a claim, or any fees associated with appealing the reimbursement of a claim. **Verification source:** MAC lists and the pharmacy's contracted rate with the PBM.	
(c) "Multiple source drug" means a therapeutically equivalent drug that is available from at least two manufacturers.		
(d) "Network pharmacy" means a retail drug outlet registered under ORS 689.305 that contracts with a pharmacy benefit manager.	• In rule definitions include a pharmacy licensed under ORS 689.305 or any authorized representative or agent of Network Pharmacy, including but not limited to Pharmacy Service Administrative Organizations (PSAO's). **Verification source:** Service Agreement between Network Pharmacy and authorized representative.	

ORS	Preliminary Rulemaking Recommendations	Outstanding Issues/Questions and Other Considerations
(e) "Therapeutically equivalent" has the meaning given that term in ORS 689.515. *Per ORS 689.515(1)(e)* "Therapeutically equivalent" means drugs that are approved by the United States Food and Drug Administration for interstate distribution and the Food and Drug Administration has determined that the drugs will provide essentially the same efficacy and toxicity when administered to an individual in the same dosage regimen.	**Verification source:** FDA's Approved Drug Products with Therapeutic Equivalence Evaluations (Orange Book)	
(2) A pharmacy benefit manager:		
(a) May not place a drug on a list unless there are at least two therapeutically equivalent, multiple source drugs, or at least one generic drug available from only one manufacturer, **generally available for purchase by network pharmacies from national or regional wholesalers**.	• Generally available means that a drug is available from at least three out of four of the listed national wholesalers for availability: McKesson, Cardinal, Morrison Dickson, Amerisource Bergen; and • Means that a drug is not: a) Restricted to hospital or institutional dispensing. b) Unavailable due to product or ingredient shortage. c) Subject to pharmacy volume purchase from wholesaler/manufacturer to purchase at price below MAC. d) Being sold at a discount due to being short dated or other similarly discounted products. e) Subject to an active or pending drug recall.	

ORS	Preliminary Rulemaking Recommendations	Outstanding Issues/Questions and Other Considerations
	statement from a national wholesaler or drug manufacturer	
(b) Shall ensure that all drugs on a list are **generally available for purchase by pharmacies in this state from national or regional wholesalers**.	• See recommendations for "generally available" above. **Verification source:** Information or statement from a national wholesaler or drug manufacturer	
(c) Shall ensure that all drugs on a list are not obsolete.	**Verification source:** Orange Book, Medispan/FirstData Inactive Date	
(d) Shall make available to each network pharmacy at the beginning of the term of a contract, and upon renewal of a contract, the sources utilized to determine the maximum allowable cost pricing of the pharmacy benefit manager.	• PBMs shall list the specific pricing sources used to determine MAC rates, including, but not limited to, a list of all wholesalers and data sources used to determine MAC pricing for all MAC lists that will be covered by the contract with the pharmacy. • Source information provided must not be generalized. For example, "Medispan/FirstData or other nationally recognized providers of drug information, drug wholesalers, or other sources as seen fit by PBM."	
(e) Shall make a list available to a network pharmacy upon request in a format that is **readily accessible to and usable by the network pharmacy**.	• A PBM shall provide an electronic process for providers to readily access the complete MAC lists specific to that provider that is used to pay the claims for which the appeal has been made. • "Readily accessible and usable" means that the list should be made available in database-accessible (e.g. .csv, .xls, etc.) and searchable format; and that • At a minimum, information include in the MAC list should include: Fee Schedule Reference Code (name of network schedule), Generic Product	

ORS	Preliminary Rulemaking Recommendations	Outstanding Issues/Questions and Other Considerations
	Identifier (GPI) or NDC, MAC Price, and Price Effective Date. **Verification source:** Documentation of request by pharmacy; verify lists provided by PBM	
(f) Shall update each list maintained by the pharmacy benefit manager **every seven business days** and make the updated lists, including all changes in the price of drugs, available to network pharmacies in a **readily accessible and usable format**.	• See definition for "readily accessible and usable" above. • Each updated list must include the entire history of changes, including prices for each drug and associated date and time of change, including date of last change, for the specified timeframe. • List must include all drugs subject to MAC pricing, including drugs that have not had a price change in the specified timeframe. • The PBM shall provide a secure electronic process for providers to readily access the complete MAC lists specific to that provider and used to pay claims. **Verification source:** Documentation of request by pharmacy; verify lists provided by PBM	• *How do pharmacists ensure secure handling of MAC lists?*
(g) Shall ensure that dispensing fees are not included in the calculation of maximum allowable cost.	Recommended statute change: • In addition to not being able to include dispensing fees in the MAC, PBMs shall not include pharmacy's administrative costs for submitting or processing a claim, or any fees associated with appealing the reimbursement of a claim. **Verification source:** MAC lists and the pharmacy's contracted rate with the PBM	
(3) A pharmacy benefit manager must	• The pharmacy must provide the PBM with	• *What kind of information should the*

ORS	Preliminary Rulemaking Recommendations	Outstanding Issues/Questions and Other Considerations
establish a process by which a network pharmacy may appeal its reimbursement for a drug subject to maximum allowable cost pricing. A network pharmacy may appeal a maximum allowable cost if the reimbursement for the drug is less than the net amount that the network pharmacy paid to the supplier of the drug. An appeal requested under this section must be completed within 30 calendar days of the pharmacy making the claim for which appeal has been requested.	documentation of acquisition costs for MAC reimbursement of drugs being appealed. • A PBM shall permit the submission of either paper or electronic documentation by a network pharmacy in order to establish and complete an appeal. • A PBM shall not require the submission of appeals on an individual claim or non-batch basis or refuse to accept appeals from a network pharmacy's designated representative or require procedures that have the effect of obstructing or delaying the appeal process. **Verification source:** Written appeal by pharmacy and documentation of acquisition costs for drugs being appealed	*pharmacy be required to provide the PBM when making an appeal?*
(4) A pharmacy benefit manager must provide as part of the appeals process established under subsection (3) of this section:		
(a) A telephone number at which a network pharmacy may contact the pharmacy benefit manager and speak with an individual who is responsible for processing appeals;	• At registration, a PBM must provide the email and contact phone number of the people or department directly responsible for processing pharmacy appeals for MAC reimbursement. • The phone number provided by the PBM may not be a general purpose number and may not be for a person that cannot address MAC appeals and decisions under this section. • This information would be made publicly available on a DCBS-hosted webpage.	

ORS	Preliminary Rulemaking Recommendations	Outstanding Issues/Questions and Other Considerations
	Verification source: PBM registration form	
(b) A final response to an appeal of a maximum allowable cost within seven business days; and	• The pharmacy must be able to provide written documentation that an appeal was made that includes the claims for which the appeal was made and the date of the appeal.	
(c) If the appeal is denied, the reason for the denial and the national drug code of a drug that may be purchased by **similarly situated pharmacies at a price that is equal to or less than the maximum allowable cost**.	• If a pharmacy's appeal is denied, the PBM shall provide the reason for the denial, including the National Drug Code and the name of the national or regional wholesalers from whom the drug was generally available for purchase by similarly situated pharmacies [*at the time of claim adjudication or at the time of purchase of drug?],* at or below the PBM's Maximum Allowable Cost. • Similarly situated means pharmacy: a) Is part of the same class of trade. Classes of trade are independent retail, chain, grocery, mass merchandiser, mail order, or specialty. b) Is contracted with PBM under the same Network Agreement. c) Must be licensed and registered in the state of Oregon. • See recommendations for definition of "generally available" provided earlier. **Verification source:** Written description of reason for denial form PBM, information or statement from a national wholesaler or drug manufacturer	• *How would the Department confirm class of trade designation?*
(5)(a) If an appeal is upheld under this section, the pharmacy benefit manager shall make an adjustment for the pharmacy that requested the appeal from the date of	A PBM may not: • Require the pharmacy to resubmit/reprocess the claim for which the appeal was made • Impose any additional fees associated with making	

ORS	Preliminary Rulemaking Recommendations	Outstanding Issues/Questions and Other Considerations
initial adjudication forward.	an adjustment for the pharmacy for claims related to the appeal from the date of adjudication forward. Statute change: • If a provider's appeal is upheld, the PBM shall make the adjustment from the date of adjudication forward for all similarly situated Oregon pharmacies.	
(b) If the request for an adjustment has come from a critical access pharmacy, as defined by the Oregon Health Authority by rule for purposes related to the Oregon Prescription Drug Program, the adjustment approved under paragraph (a) of this subsection shall apply only to critical access pharmacies.		
(6) This section does not apply to the state medical assistance program. [2013 c.570 §11; 2013 c.570 §13]		
Note: See note under 735.530.		
The report should include the draft rules, as well as any statutory changes or clarifications necessary to fully implement the draft rules, including fee recommendations for administration of the program. Draft rules must include, but are not limited to:		
➢ ***Notification system that includes a method for informing PBMs of new regulations, and for informing PBMs of complaints, investigations, and possible sanctions***		
• *PBMs who wish to receive notice of any proposed changes to regulations may be placed on the department's rulemaking mailing list upon written request. See ORS 183.335(8).*	• All of the general enforcement statutes and rules that exist in the insurance code shall apply to PBMs.	

ORS	Preliminary Rulemaking Recommendations	Outstanding Issues/Questions and Other Considerations
• *As a practical matter, PBMs will be asked to respond to complaints or to provide further information regarding perceived compliance issues, and therefore will receive notice of complaints or investigations in the regular course of business. If an administrative sanction is proposed, the PBM will receive notice as appropriate. See ORS 183.415.* • *ORS 731.264 (1) A complaint made to the Director of the Department of Consumer and Business Services against any person regulated by the Insurance Code, and the record thereof, shall be confidential and may not be disclosed except as provided in ORS 705.137*		
➢ ***Investigation procedures***		
• *The director's authority to administer and enforce the provisions of ORS 735.530 to 735.552 includes the authority to examine and investigate, to issue warnings, to institute actions or other lawful proceedings, to issue orders to cease and desist and to assess and impose civil penalties, as appropriate. See ORS 731.236, 731.252, 731.256, 731.260 and 731.988.* • *ORS 731.263(3) The director may conduct such examinations and investigations of insurance matters, in*	• All of the general enforcement statutes and rules that exist in the insurance code shall apply to PBMs.	

ORS	Preliminary Rulemaking Recommendations	Outstanding Issues/Questions and Other Considerations
addition to examinations and investigations expressly authorized, as the director considers proper to determine whether any person has violated any provision of the Insurance Code or to secure information useful in the lawful administration of any such provision. The cost of such additional examinations and investigations shall be borne by the state.		
➢ ***Fees, fines, and resolution process that includes:*** ○ ***Overall schedule of fees and fines*** ○ ***Provisions for warnings before fines, based on circumstances*** ○ ***Possible escalation of fine for multiple occurrences including combining multiple occurrences into a single complaint or enforcement action, or multiple claims related to a single reason or cause*** ○ ***Setting a maximum annual per PBM fine*** ○ ***Exceptions based on type of violation or other criteria*** ○ ***A reasonable time to re-enter compliance*** ○ ***Other provisions consistent with DCBS' existing enforcement authority and procedures***		
• *ORS 735.532 Registration of pharmacy benefit managers; fees; rules.* • *ORS 731.236, 731.252, 731.256, 731.260 and 731.988.*	• All of the general enforcement statutes that occur in the insurance code shall apply to PBMs. • The director has the power to suspend or revoke a PBM's registration or to enforce any penalties, fines, or forfeitures authorized by law with respect to any violation for which an order of discontinuance has been issued. Statutory change: • The department will need to be granted more expansive rule writing authority in order to draft rules to better ensure PBM compliance.	• *See next page for additional considerations.*

In accordance with ORS 731.988, any person who violates any provision of ORS 735.530 to 735.552, or any rule or final order of the director or any judgment that a court makes in response to the director's application, shall be subject to a civil penalty in an amount determined by the director that does not exceed $10,000 for each offense. Each violation shall be deemed a separate offense, provided however:

- The director may deem non-compliance that is based upon the same facts, and that occurs within the same time frame, to be a single violation for purpose of enforcement action or administrative sanction.
- The director may deem a failure to cure non-compliance, in the absence of notice to cure or further change in circumstance, to be a single violation for purpose of enforcement action or administrative sanction.

The director has sole discretion to determine whether any instance or instances of non-compliance constitute a single or multiple violations of the law, depending upon the particular circumstances.

When determining whether enforcement action or administrative sanction is appropriate, the director may consider:

- The nature of the violation, and the number of violations, in issue;
- Whether the violation involved intentional, reckless or negligent conduct;
- Whether the person has committed the same or similar violations previously and within what time frame;
- The nature and degree of the harm inflicted upon others;
- Whether the person self-reported the violation; and,
- Whether, and how, the person cooperated in the investigation or in achieving resolution.

In an effort to remedy a violation or violations of ORS 735.530 to 735.552, a person may submit a plan that assures current compliance with the law and protects against future instances of non-compliance. Any such remedial plan shall be in writing and must be fully implemented within a period not to exceed one hundred eighty (180) days following acceptance. No such remedial plan shall excuse current or future non- compliance with the law.