

Prescription Drug Price Transparency and Purchasing

State Strategy Recommendations

Engrossed Second Substitute House Bill 1224; Chapter 334; Laws of 2019;
Section 12

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Prescription Drug Price Transparency and Purchasing

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Executive Summary

Costs for new and existing prescription drugs continue to create access and affordability challenges for patients. Prescription drug payers, including the Health Care Authority (HCA) and other state agencies, have few opportunities to control prescription drug spending effectively. Their strategies focus primarily on managing or influencing one of the two components that determine prescription drug expenditures:

- Drug utilization (the number of drug units that payers purchase for patients); and
- Drug pricing (the purchase price per unit of drug).

To manage prescription drug utilization, payers and governments historically have used formulary (preferred drug list) management and prior authorization. However, payers and governments continue to seek effective methods to influence prescription drug pricing; only a few strategies have produced encouraging results over time. More recently, Washington State and other state governments have pursued new strategies to address drug pricing, including efforts to:

- Pass legislation related to prescription drug price transparency; and
- Expand prescription drug bulk purchasing among payers jointly with other states.

Engrossed Second Substitute House Bill (E2SHB) 1224 (2019) required the Health Care Authority (HCA) to contact state agencies in Oregon and California about prescription drug strategies and make recommendations about joint state transparency and purchasing strategies. From our discussions with state agency representatives in Oregon and California and additional research, we learned that:

- Compared to prescription drug price transparency reporting in Oregon and California, HCA's reporting provides less opportunity to increase transparency about the impact that prescription drugs have on health care premiums.
- Legislative and programmatic differences between the states' transparency and purchasing efforts are barriers to Washington engaging in joint transparency efforts with Oregon and both joint transparency and purchasing efforts with California; and
- Current resources for Washington's Prescription Drug Price Transparency program appear to be insufficient, compared to programs that Oregon and California have successfully implemented.

Consequentially, HCA's recommendations to the Washington State Legislature relate to:

- Providing more resources to HCA for its prescription drug price transparency efforts;
- Amending current legislation to allow HCA to report prescription drug price information at the drug and drug class levels in its annual report to the public and Legislature;
- Amending current legislation to allow HCA to report wholesale acquisition cost (WAC) increases and provide advance notice of price increases to purchasers; and



- Continuing support for Washington’s successful joint purchasing relationship with Oregon.

The Legislature should also consider all the options available to Washington State and determine which option best serves the needs of the state. These options relate to:

- Aligning Washington’s prescription drug price transparency legislation to model legislation from NASHP; and
- Reviewing strategies with Oregon and California legislatures to amend current legislation and create coordinated programs.

By acting on these recommendations and considering these options, Washington will continue to progress toward the goal to manage prescription drug pricing more effectively and benefit both drug payers and patients.

Background

Costs for new and existing prescription drugs continue to create access and affordability challenges for patients. Prescription drug payers, including the Health Care Authority (HCA) and other state agencies, have few opportunities to control prescription drug costs effectively. Their strategies focus primarily on managing or influencing one of the two components that determine prescription drug expenditures:

- Drug utilization (the number of drug units that payers purchase for patients); and
- Drug pricing (the purchase price per unit of drug).

To manage prescription drug utilization, payers and governments historically have used formulary (preferred drug list) management and prior authorization:

- Formulary management is a process that promotes the use of the highest value (safest and most cost-effective) prescription drugs by setting the lowest cost-shares (the portion of the drug cost patients pay) on those preferred drugs compared to other, non-preferred drugs. This creates financial incentives for patients to use the highest value drugs.
- Prior authorization for prescription drugs is a process that uses evidence-based policies to review prescriber requests to ensure safe and cost-effective prescription drug use. This creates a system that ensures appropriate use of drugs to maximize value.

However, payers and governments continue to seek effective methods to influence prescription drug pricing; only a few strategies have produced encouraging results over time. Below are three examples:

1. **Contracting for prescription drug rebates** – Payers contract with drug manufacturers for rebates that reduce the net price of the prescription drugs. In the United States, many



payers do this indirectly by contracting with pharmacy benefit managers,¹ which manage drug rebates by contracting directly with the manufacturers.

2. **Leveraging cost-effectiveness analyses** – Health technology assessment entities, such as the Institute for Clinical and Economic Review (ICER),² publish cost-effectiveness analyses to determine fair pricing for prescription drugs. Payers can leverage this information to negotiate for better prescription drug rebate agreements by aligning the net price of prescription drugs with their value per the cost-effectiveness analyses.
3. **Negotiating prescription drug prices directly with manufacturers** – Public payers, such as national health systems in Europe, negotiate prices directly with prescription drug manufacturers. Often public payers leverage prescription drug cost-effectiveness analyses from their nation’s health technology assessment entities to set drug prices in their negotiations.
 - Similarly, HCA contracted with drug manufacturer AbbVie US LLC to purchase medications for the treatment of hepatitis C virus through a modified subscription model.³

More recently, Washington State and other state governments have pursued new strategies to address drug pricing, including efforts to:

- Pass legislation related to prescription drug price transparency; and
- Expand prescription drug bulk purchasing among payers within their states and jointly with other states.

¹ In the United States, a pharmacy benefit manager (PBM) is a third-party administrator of prescription drug programs for health plans. PBMs are primarily responsible for developing and maintaining the formulary, contracting with pharmacies, negotiating discounts and rebates with drug manufacturers, and processing and paying prescription drug claims. For the most part, they work to maintain or reduce the pharmacy expenditures of the plan and to improve health care outcomes.

² Institute for Clinical and Economic Review, from <https://icer-review.org/>, accessed on September 21, 2019.

³ HCA finalizes contract with AbbVie to eliminate HCV in Washington State, from <https://www.hca.wa.gov/about-hca/hca-finalizes-contract-abbvie-eliminate-hcv-washington-state>, accessed on October 24, 2019.



Washington State's Current Prescription Drug Price Transparency and Joint Purchasing Efforts

Price Transparency

In 2019, the Washington State Legislature passed Engrossed Second Substitute House Bill (E2SHB) 1224⁴ (codified in Chapter 43.71C RCW),⁵ which created the first prescription drug price transparency program in the state. Appendix A contains the full text of E2SHB 1224 (2019), which includes sections about:

- Health carrier⁶ reporting (section 3);
- Pharmacy benefit manager (PBM)⁷ reporting and compliance (sections 4 and 5);
- Manufacturer⁸ reporting and notifications about new drug applications and price increases (sections 6 through 8);
- Pharmacy services administrative organization (PSAO)⁹ reporting (section 9);
- Data collection and reporting (sections 10 and 12); and
- Enforcement and rulemaking (sections 11 and 13).

⁴ Engrossed Second Substitute House Bill 1224, from <http://lawfilesextra.leg.wa.gov/biennium/2019-20/Pdf/Bills/Session%20Laws/House/1224-S2.SL.pdf>, accessed on October 2, 2019.

⁵ Chapter 43.71C RCW PRESCRIPTION DRUG COSTS, from <https://app.leg.wa.gov/RCW/default.aspx?cite=43.71C&full=true>, accessed on October 11, 2019.

⁶ A “health carrier” is a disability insurer regulated under chapter [48.20](#) or [48.21](#) RCW, a health care service contractor as defined in RCW [48.44.010](#), or a health maintenance organization as defined in RCW [48.46.020](#), and includes “issuers” as that term is used in the patient protection and affordable care act (P.L. 111-148). See RCW 48.43.005 Definitions., from <https://app.leg.wa.gov/RCW/default.aspx?cite=48.43.005>, accessed on October 11, 2019.

⁷ A “pharmacy benefits manager” (PBM) is an entity that contracts with pharmacies on behalf of an insurer, a third-party payor, or the Consortium to: (1) Process claims for prescription drugs or medical supplies or provide retail network management for pharmacies or pharmacists; (2) Pay pharmacies or pharmacists for prescription drugs or medical supplies; or (3) Negotiate rebates with manufacturers for drugs paid for or procured. See RCW 19.340.010 Definitions., from <https://app.leg.wa.gov/RCW/default.aspx?cite=19.340.010>, accessed on October 11, 2019.

⁸ A “covered manufacturer” is an entity engaged in the manufacture of prescription drugs sold in or into Washington State. “Covered manufacturer” does not include a private label distributor or retail pharmacy that sells a drug under the retail pharmacy’s store, or a prescription drug repackager. See Engrossed Second Substitute House Bill 1224, Section 2(3), from <http://lawfilesextra.leg.wa.gov/biennium/2019-20/Pdf/Bills/Session%20Laws/House/1224-S2.SL.pdf>, accessed on October 11, 2019.

⁹ A “pharmacy services administrative organization” (PSAO) is an entity that contracts with a pharmacy to act as the pharmacy’s agent with respect to matters involving a pharmacy benefit manager, third-party payor, or other entities, including negotiating, executing, or administering contracts with the pharmacy benefit manager, third party payor, or other entities and provides administrative services to pharmacies. See Engrossed Second Substitute House Bill 1224, Section 2(6), from <http://lawfilesextra.leg.wa.gov/biennium/2019-20/Pdf/Bills/Session%20Laws/House/1224-S2.SL.pdf>, accessed on October 11, 2019.



HCA's drug price transparency program will collect relevant information on drug pricing from various sources and publish an annual report. Section 10 of E2SHB 1224 indicates that the data in the report should "demonstrate the overall impact that drug costs, rebates and other discounts have on health care premiums."

The data in the report must be aggregated and must not reveal information specific to individual health carriers, pharmacy benefit managers, pharmacy services administrative organizations, individual prescription drugs, individual classes of prescription drugs, individual manufacturers, or discount amounts paid in connection with individual prescription drugs.¹⁰

In the 2019-2021 state biennial operating budget, HCA received \$455,000 and 1.0 FTE (Management Analyst 4) to implement the Prescription Drug Price Transparency Program.¹¹ Currently, HCA is designing and implementing the drug price transparency program. These efforts include:

- Hiring new staff dedicated to this work; and
- Designing the systems, processes, policies, and rules that manufacturers, insurers, pharmacy benefit managers, and pharmacy services administrative organizations will use to submit data to HCA.

Joint Purchasing

In 2003, the Washington State Legislature passed Senate Bill 6088,¹² which created the evidence-based Washington Prescription Drug Program (WPDP)¹³ to:

- Identify evidence-based preferred prescription drugs;
- Develop programs to provide prescription drugs at an affordable price to those in need; and
- Increase public awareness regarding preferred prescription drugs' safe and cost-effective use.¹⁴

¹⁰ Engrossed Second Substitute House Bill 1224, Section 10(2), from <http://lawfilesexternal.wa.gov/biennium/2019-20/Pdf/Bills/Session%20Laws/House/1224-S2.SL.pdf>, accessed on October 2, 2019.

¹¹ 2019-21 Omnibus Operating Budget, Agency Detail Report, Health Care Authority, from <http://fiscal.wa.gov/BudgetOCurrAgyDetail.aspx>, PDF page 6, accessed on October 3, 2019.

¹² Senate Bill 6088, from <http://lawfilesexternal.wa.gov/biennium/2003-04/Pdf/Bills/Session%20Laws/Senate/6088.SL.pdf>, accessed on October 2, 2019.

¹³ Washington Prescription Drug Program, from <https://www.hca.wa.gov/about-hca/prescription-drug-program>, accessed on October 2, 2019.

¹⁴ Ibid., Section 1, pages 1-2.



Adding to the WPDP, the Washington State Legislature passed Substitute Senate Bill (SSB) 5471¹⁵ in 2005 (codified in RCW 70.14.050 through RCW 70.14.080), which created the Prescription Drug Consortium. Appendix B contains the full text of RCW 70.14.050 through RCW 70.14.80. That legislation requires state purchased health care programs to purchase prescription drugs through the Prescription Drug Consortium. SSB 5471 also allowed the following entities to voluntarily participate in the Prescription Drug Consortium:

- Units of local government;
- Private entities;
- Labor organizations; and
- Individuals who lack or are underinsured for prescription drug coverage.¹⁶

In 2006, WPDP joined with the Oregon Prescription Drug Program¹⁷ to create the Northwest Prescription Drug Consortium (Consortium),¹⁸ which enabled joint purchasing between both states' programs. Both states contract with Moda Health, a pharmacy benefit manager, to manage the Consortium's operations and ensure transparency in its purchasing processes and prescription drug prices for the states' drug programs. In calendar year 2018, Moda reported to HCA that the Consortium facilitates more than \$800 million in prescription drug purchases annually.

In both Washington and Oregon, health plans, hospitals and facilities, and individuals without prescription drug coverage benefit from joint purchasing through the Consortium:

- **Health plans** – In Washington, the Uniform Medical Plan¹⁹ (the self-funded health plan for both the Washington State Public Employees Benefits Board²⁰ and the School Employees Benefits Board²¹), and the Washington State Department of Labor and Industries²² participate in the Consortium. In Oregon, the Oregon Educators Benefits Board,²³ the

¹⁵ Substitute Senate Bill 5471, from <http://lawfilesexternal.wa.gov/biennium/2005-06/Pdf/Bills/Session%20Laws/Senate/5471-S.SL.pdf>, accessed on October 2, 2019.

¹⁶ Ibid., Section 1, pages 1-2.

¹⁷ Oregon Prescription Drug Program, from <https://www.oregon.gov/oha/hpa/dsi-opdp/Pages/index.aspx>, accessed on October 2, 2019.

¹⁸ Washington Prescription Drug Program (WPDP) Partners, from <https://www.hca.wa.gov/about-hca/prescription-drug-program/partners>, accessed on October 2, 2019.

¹⁹ Uniform Medical Plan (UMP), from <https://www.hca.wa.gov/ump>, accessed on October 2, 2019.

²⁰ Employee and retiree benefits – Public employees, from <https://www.hca.wa.gov/employee-retiree-benefits/public-employees>, accessed on October 2, 2019.

²¹ Employee and retiree benefits – School employees, from <https://www.hca.wa.gov/employee-retiree-benefits/school-employees>, accessed on October 2, 2019.

²² Washington State Department of Labor and Industries, Prescription Medications, from <https://www.lni.wa.gov/ClaimsIns/Claims/Benefits/PrescMeds/Default.asp>, accessed on October 10, 2019.

²³ Oregon Educators Benefits Board, from <https://www.oregon.gov/oha/oebb/Pages/index.aspx>, accessed on October 2, 2019.



Oregon Public Employees Benefits Board,²⁴ and Eastern Oregon Coordinated Care Organization²⁵ also purchase through the Consortium.

- **Hospitals and facilities** – In Washington, hospitals and other health care facilities (including Washington State Department of Corrections²⁶ facilities) purchase prescription drugs and medical supplies at discounted rates through Premier, Inc.,²⁷ the Consortium’s contracted group purchasing organization.²⁸
- **Individuals without prescription drug coverage** – Both in Washington and Oregon, individuals who do not have prescription drug health insurance coverage can purchase prescription drugs using their state’s discount card²⁹ at participating pharmacies at contracted rates. There are approximately 500,000 people enrolled in the discount card program, which is about half of the Consortium’s 1,000,000 covered lives.
- **Labor organization** – In Washington, the Inlandboatmen’s Union of the Pacific³⁰ also participates in the Consortium.

Legislative Reporting

E2SHB 1224 (2019) includes the requirement that the Health Care Authority (HCA) reach out to state agencies in Oregon and California about prescription drug strategies. Section 12 of that legislation states:

The authority must contact the California office of statewide health planning and development and the Oregon department of consumer and business services to develop strategies to reduce prescription drug costs and increase prescription drug cost transparency. The authority must make recommendations to the legislature for implementing joint state strategies, which may include a joint purchasing agreement, by January 1, 2020.

This report includes:

- Information about price transparency efforts in Oregon, California, and other states;

²⁴ Oregon Public Employees Benefits Board, from <https://www.oregon.gov/oha/pebb/pages/index.aspx>, accessed on October 2, 2019.

²⁵ EOCCO, from <https://www.eocco.com/members>, accessed on October 2, 2019.

²⁶ Washington State Department of Corrections, Health Services, from <https://www.doc.wa.gov/corrections/services/health.htm>, accessed on October 10, 2019.

²⁷ Northwest Prescription Drug Consortium, from <https://www.hca.wa.gov/assets/program/consortium-specialty-program-description.pdf>, page 2, accessed on October 2, 2019.

²⁸ In the United States, a group purchasing organization (GPO) is an entity that is created to leverage the purchasing power of a group of businesses to obtain discounts from vendors based on the collective buying power of the GPO members.

²⁹ Prescription drug Discount Card, from <https://www.hca.wa.gov/about-hca/prescription-drug-program/how-participate#prescription-drug-discount-card>, accessed on October 2, 2019.

³⁰ Inlandboatmen’s Union of Pacific, About Us, from https://members.ibu.org/index.cfm?zone=/unionactive/view_article.cfm&HomeID=762773&page=ABOUT20US, accessed on October 10, 2019.



- Information about purchasing efforts in Oregon and California; and
- Recommendations and options about prescription drug cost transparency and joint state purchasing strategies.

Price Transparency Efforts in Oregon and California, and Other States

Between July 2019, and September 2019, HCA staff engaged in preliminary conversations with representatives from state agencies in Oregon and California to discuss their prescription drug cost transparency programs. We also learned about transparency efforts in other states, including Nevada.

Oregon

On August 2, 2019, HCA staff had a conference call with representatives from the Oregon Department of Consumer and Business Services (DCBS). In the subsections below, we include information we learned from that phone call and follow-up research about Oregon's prescription drug price transparency efforts.

Oregon Legislation

The Oregon legislature passed House Bill (HB) 4005 in 2018, which created the Prescription Drug Price Transparency Program within the DCBS Division of Financial Regulation.^{31,32} Appendix C contains the text of HB 4005, and below are brief descriptions of the relevant sections of that legislation.

Section 2 (which both sections 6 and 7 amend) establishes the reporting requirements for manufacturers of prescription drugs sold in Oregon. Each manufacturer must comply with four sets of reporting requirements to DCBS, or risk being subject to a civil penalty:

1. Provide information by March 15 of each year about the manufacturer's prescription drugs for which:
 - a. The price was \$100 or more for a one-month supply or for a course of treatment lasting less than one month; and
 - b. There was a net price increase of 10 percent or more compared to the previous calendar year.
2. Provide information by March 15 of each year about the manufacturer's patient assistance program for consumers to gain access to the prescription drugs in #1 above.

³¹ Division of Financial Regulation, from <https://dfr.oregon.gov/Pages/index.aspx>, accessed on October 11, 2019.

³² Prescription Drug Price Transparency program, from <https://dfr.oregon.gov/drugtransparency/Pages/index.aspx>, accessed on October 11, 2019.



3. Provide information within 30 days after the manufacturer introduces a new prescription drug for sale in the United States at a price that exceeds the threshold that the Centers for Medicare and Medicaid Services established for specialty drugs in the Medicare Part D program.³³
4. Provide supporting documentation or additional information that DCBS requests concerning the manufacturer's reports for #1 through #3 above.

DCBS may use any appropriate prescription drug price information to verify the accuracy of manufacturers' reports in #1 above. DCBS shall also:

- Post on its website information it collected in #1 through #3 above and its written requests for additional information in #4 above;
- Make available to consumers a process for consumers to notify DCBS about prescription drug price increases; and
- Report to the Oregon State Legislature by December 15 each year the information DCBS collected in #1 through #4 above and related recommendations.

Section 3 declares that manufacturers that fail to report information that Section 2 of this act requires may be subject to civil penalties. DCBS is to adopt a schedule of civil penalties for manufactures that fail to report the required information. Civil penalties shall vary by the severity of each violation and shall not exceed \$10,000 per day of violation.

Section 5 establishes the reporting requirements for insurers that issue policies or certificates of health insurance for sale in Oregon that include a prescription drug benefit to report. Those insurers must report to DCBS the impact of prescription drugs on premium rates and the 25:

- Most frequently prescribed drugs;
- Most costly drugs as a portion of total annual spending; and
- Drugs that have caused the greatest year-over-year increase in total plan spending.

DCBS is required to conduct an annual public hearing on prescription drug prices and the information it receives per sections 2 and 5.

Section 11 establishes the Task Force on the Fair Pricing of Prescription Drugs (Task Force). Eighteen volunteer members comprise the Task Force, including:

- State legislators;
- Representatives from DCBS, the Oregon Health Authority, and the Oregon Health Policy Board; and

³³ Currently, the threshold is \$670 for a one-month supply at an in-network retail pharmacy. See: NOTE TO: Medicare Advantage Organizations, Prescription Drug Plan Sponsors, and Other Interested Parties, SUBJECT: Advance Notice of Methodological Changes for Calendar Year (CY) 2019 for Medicare Advantage (MA) Capitation Rates, Part C and Part D Payment Policies and 2019 draft Call Letter, page 201, from <https://www.cms.gov/Medicare/Health-Plans/MedicareAdvtgSpecRateStats/Downloads/Advance2019Part2.pdf>, accessed on October 16, 2019.



- Individuals representing various parts of the prescription drug supply chain.

The Task Force is responsible for developing strategy to create transparency for drug prices across the entire supply chain of pharmaceutical products. This would expand the Oregon Prescription Drug Transparency Program to include:

- PBMs;
- Distributors;
- Wholesalers; and
- Retail pharmacies.

By no later than November 1, 2018, the Task Force must submit a report³⁴ to the Oregon State Legislature that contains a cost-effective, enforceable solution to expose the cost factors that negatively impact the prices Oregonians pay for pharmaceutical products.

Section 13 requires DCBS to implement sections 2, 3, and 5 by January 1, 2019.

Section 14 establishes that the expenditures to implement sections 2, 3, and 5 may not exceed \$425,022 for the fiscal biennium ending on June 30, 2019.

How Oregon Legislation Compares to Washington Legislation

Similarities between Washington and Oregon prescription drug price transparency legislation include requirements that:

- Manufacturers must provide information to a state department about prescription drugs that meet specific criteria to create transparency about price increases; and
- Insurers must provide information to a state department about the highest impact drugs from insurers and those drugs' impacts on health plan premiums.

However, there are several differences between the two states' legislation:

- **Reporting entities** – In Oregon, neither PBMs nor PSAOs need to report information to DCBS. In 2019, the Oregon State Legislature introduced Senate Bill (SB) 872 to expand the Oregon program to include PBMs and other entities, but it did not pass. In Washington, both PBMs and PSAOs need to report information to HCA.
- **Required information** – Several differences exist between the specific data reporting entities need to provide in each state. For example, manufacturers in Oregon need to report the direct costs the manufacturers incurred for ongoing safety and effectiveness research associated with the prescription drug; Washington's program does not have that

³⁴ Joint Interim Task Force on the Fair Pricing of Prescription Drugs – Report on Transparency Strategies for the Pharmaceutical Supply Chain: Pursuant to House Bill 4005 (2018), from [https://www.oregonlegislature.gov/committees/jfprx/Reports/House%20Bill%204005%20\(2018\)%20Report%20on%20Transparency%20Strategies.pdf](https://www.oregonlegislature.gov/committees/jfprx/Reports/House%20Bill%204005%20(2018)%20Report%20on%20Transparency%20Strategies.pdf), accessed on October 14, 2019.

requirement. Manufacturers in Washington need to report the patent expiration date of the drug if it is under patent; Oregon's program does not have that requirement.

- **Report data aggregation** – The information Oregon's program must post on its website and report to the Oregon State Legislature annually identifies individual drugs and manufacturers. Washington's legislation requires HCA to aggregate all data in the report that it will post on its website and submit to the Washington State Legislature; it must not reveal information specific to individual:
 - Health carriers;
 - PBMs;
 - PSAsOs;
 - Prescription drugs or their paid discount amounts;
 - Classes of prescription drugs; or
 - Manufacturers.

Compared to Oregon's reporting, HCA's reporting provides less opportunity to increase transparency about the impact that prescription drugs have on health care premiums.

- **Program funding** – Oregon's program did not receive any state funds, but it received authority to establish rules to collect fees from reporting manufacturers to fund the program's operations. Oregon's program could spend a maximum of \$425,022 between the bill taking effect in March 2018³⁵ and the end of the fiscal biennium in June 2019. Washington's program received \$455,000 from the 2019-2021 state biennial operating budget to use between July 2019 and June 2021 (considerably less than Oregon's program).
- **Transparency strategy recommendations** – The Task Force on the Fair Pricing of Prescription Drugs is unique to the Oregon legislation. Washington's legislation does not have anything comparable, though it does include requirements for HCA to submit this legislative report.

At a high level, the principles of the Oregon and Washington prescription drug transparency programs are similar. However, the differences in each state's legislation result in additional variation in program implementation.

Oregon Implementation

During our conference call with DCBS staff, we discussed the Oregon program's funding, rules, operations staffing, and prescription drug information technology system.

To fund the Oregon program, staff developed a manufacturer fee schedule (established in administrative rule) to collect sufficient revenue for the program's \$425,022 expenditure budget. DCBS estimates that about 200 manufacturers sell prescription drugs in Oregon. After performing some research and consulting with stakeholders through a rulemaking advisory committee, DCBS determined that it could:

- Impose a \$400 annual fee on each manufacturer (totaling about \$80,000 per year); and

³⁵ 2018 Regular Session, HB 4005 Enrolled, Overview, from <https://olis.leg.state.or.us/liz/2018R1/Measures/Overview/HB4005>, accessed on October 15, 2019.



- Fund the remaining expenses from fees per report manufacturers submit.

DCBS is monitoring this funding method and intends to adjust these fee schedule if the funding is insufficient after its first year of operation.

To establish administrative rules for the program, DCBS sought guidance from California’s Office of Statewide Planning and Development (OSHPD), which had established its prescription drug price transparency program first.

To operate the program, DCBS hired three full-time positions during the first quarter of 2019, including:

- A program manager, who is responsible for program oversight;
- A research analyst, who is responsible for cleaning and analyzing drug manufacturer data; and
- An administrative analyst, who is responsible for facilitating program operations and performing consumer outreach.

To develop the program’s information technology (IT) systems that would allow for collection, storing, and analyzing prescription drug data, DCBS worked with its internal IT team to:

- Develop a standard data reporting template for manufacturers to use by entering data into fields on a web page or uploading files with the required data;
- Build into the data reporting template a data validation function to ensure manufacturers submit consistent and appropriate data, which facilitates the process by which program staff develop reports and provide information to the public;
- Create an online portal for manufacturers to submit data to DCBS;
- Dedicate a server for securely storing manufacturer prescription drug data; and
- Provide ongoing technical support.

How Oregon Implementation Compares to Washington Implementation

HCA is working to implement its prescription drug price transparency program. Similarities between what HCA plans to do in Washington and what Oregon has already implemented include:

- Administering the program in-house instead of contracting with a third-party vendor to administer the program; and
- Developing an IT system to collect, store, and analyze prescription drug data.

However, there are several differences between the implementation of the two states’ programs:

- **Funding structure** – Oregon’s program only receives funding from manufacturers. Washington’s program only receives funding from General Fund – State.
- **Staffing resources** – Oregon’s program has sufficient resources to hire three full-time positions. Currently, HCA only has one new full-time position to implement the entire Washington State Prescription Drug Price Transparency Program.



Based on the similarities between Oregon’s program and Washington’s program, HCA anticipates the need to hire additional staff to implement our state’s program successfully.

Early Successes of the Oregon Transparency Program

The Oregon Prescription Drug Price Transparency program has already experienced several successes during its initial implementation, which may inform Washington’s implementation:

- **Outreach efforts** – Prior to implementing Oregon’s program, DCBS had not worked directly with prescription drug manufacturers. To develop those relationships, DCBS contacted the Oregon Board of Pharmacy³⁶ to identify the manufacturers and learn how to contact them about the program, processes, and annual fees. DCBS engaged in concerted outreach efforts, including the development of educational materials that they tailored to the specific needs of their audiences. HCA will need to do the same for manufacturers, insurers, PBMs, PSAOs, and the public as it works toward implementation.
- **Standard data reporting template** – By developing a standard template for manufacturers to report data, Oregon’s program is improving the quality of the data it receives and helping to ensure that data will be consistent across different manufacturers for different drugs. HCA intends to produce similar data-entry tools for reporting entities to use.
- **Task Force report** – The Task Force on Fair Pricing of Prescription Drugs reporting process convened stakeholders from across the prescription drug supply chain to develop recommendations for the Oregon legislature. The November 2018 report³⁷ is publicly available and includes useful summaries and information about prescription drug pricing, areas of opportunity for price transparency work, and possible next steps for the future of price transparency in Oregon. HCA will likely reference the Task Force report during implementation.

Early Challenges of the Oregon Transparency Program

DCBS shared some information about the challenges they have experienced while implementing their program. Knowing about these challenges will help HCA to anticipate similar challenges if we encounter them during our implementation efforts:

- **Ensuring factually accurate reports** –The most notable challenge that Oregon’s program is facing relates to ensuring manufacturers report accurate data. Although the program is able to validate that the data is in the appropriate field and formatted correctly through the standard data reporting templates, it is a challenge for the program to verify that the data a manufacturer submitted is factually correct. Oregon’s legislation allows the program to request supporting documentation, which is one way to help verify data accuracy.

³⁶ Oregon.gov, Board of Pharmacy, from <https://www.oregon.gov/pharmacy/Pages/index.aspx>, accessed on October 16, 2019.

³⁷ Joint Interim Task Force on the Fair Pricing of Prescription Drugs – Report on Transparency Strategies for the Pharmaceutical Supply Chain: Pursuant to House Bill 4005 (2018), from [https://www.oregonlegislature.gov/committees/jfprx/Reports/House%20Bill%204005%20\(2018\)%20Report%20on%20Transparency%20Strategies.pdf](https://www.oregonlegislature.gov/committees/jfprx/Reports/House%20Bill%204005%20(2018)%20Report%20on%20Transparency%20Strategies.pdf), accessed on October 14, 2019.

- **Identifying proprietary data** – Prescription drug manufacturers may consider different reporting elements to be trade secrets when reporting information. The Oregon program must keep track of these trade secret claims, evaluate whether the information is a trade secret, and determine whether the public interest requires disclosure.

Opportunities for Alignment between States

There are several similarities and opportunities for alignment between Oregon’s Prescription Drug Price Transparency Program and Washington’s program. However, it would be necessary to change legislation in Oregon, Washington, or both to align the programs successfully. Without legislative changes, many fundamental differences in agencies’ data collection and reporting (e.g., what drugs to report) would remain incomparable between the two states. We base the recommendations in this report on our evaluation and understanding of these comparisons.

California

On August 26, 2019, HCA staff had a conference call with representatives from the California Office of Statewide Planning and Development (OSHPD).³⁸ In the subsections below, we include information we learned from that phone call and follow-up research about California’s prescription drug price transparency efforts.

California Legislation

The California legislature passed SB 17 in 2017, which created a prescription drug cost transparency program within OSHPD,³⁹ the Department of Managed Health Care (DMHC),⁴⁰ and the Department of Insurance (DOI).⁴¹ HCA’s conference call with OSHPD did not include DMHC or DOI, and we did not collect any information about implementation DMHC or DOI may have performed as part of their data collection and reporting processes.

Existing law at the time SB 17 passed required the following entities to report prescription drug information to state departments:

- Health care service plans, such as health maintenance organizations (HMOs) and the California Medicaid Program (Medi-Cal)⁴² managed care plans, must report prescription drug information to the DMHC; and
- Health insurers (group and individual fully insured plans) must report prescription drug information to DOI.

³⁸ OSHPD Cost Transparency: Prescription Drugs (CTRx), from <https://oshpd.ca.gov/data-and-reports/cost-transparency/rx/>, accessed on October 16, 2019.

³⁹ SB-17 Health care: prescription drug costs. (2017-2018), from https://leginfo.legislature.ca.gov/faces/billNavClient.xhtml?bill_id=201720180SB17, accessed on October 16, 2019.

⁴⁰ Department of Managed Health Care, from <https://www.dmhc.ca.gov/>, accessed on October 16, 2019.

⁴¹ Department of Insurance, from <https://www.insurance.ca.gov/>, accessed on October 16, 2019.

⁴² Department of Health Care Services, Medi-Cal, from <http://www.medi-cal.ca.gov/>, accessed on October 10, 2019.



Appendix E contains the text of SB 17 (2017), and below are brief descriptions of the relevant sections of that legislation.

Section 1 requires health care service plans to report to DMHC lists of the 25:

- Most frequently prescribed drugs;
- Most costly drugs by total annual plan spending; and
- Drugs with the highest year-over-year increase in total annual plan spending.

DMHC must use this information to create a report that demonstrates the overall impact of drug costs on health plan premiums and post that report to its website by January 1 each year (beginning in 2019).⁴³

Section 2 requires large group health service plans to file by October 1 each year (beginning in 2018) with DMHC:

- Average rate increases and supplemental information on factors affecting the premium base rate;
- The plan's assumptions for increases in medical costs for their population;
- A comparison of aggregate per enrollee per month costs for the previous 5 years; and
- Information on the prescription drug benefit, including the percentage of premium attributable to prescription drug costs.

Section 4 creates the Prescription Drug Pricing for Purchasers program. Manufacturers must comply with four sets of reporting requirements to OSHPD, or risk being subject to a civil penalty of \$1,000 per day:

1. Provide written notice and additional information to OSHPD and prescription drug purchasers (or other entities registered with OSHPD to receive these notifications) at least 60-days before the effective date of the manufacturer's prescription drug wholesale acquisition cost (WAC) increases of prescription drugs for which:
 - a. The price was more than \$40 for a 30-day supply or for a normal course of treatment lasting less than 30 days; and
 - b. The proposed wholesale acquisition cost (WAC) increase with the cumulative increase is greater than 16 percent within the previous two calendar years prior to the current year.
2. Provide reports to OSHPD about the WAC increases in #1 and related information on a quarterly basis (beginning January 1, 2019).

⁴³ Department of Managed Health Care, Prescription Drug Cost Transparency Report (SB 17), Measurement Year 2017, from <https://www.dmhc.ca.gov/Portals/0/Docs/DO/sb17.pdf>, accessed on October 16, 2019.



3. Provide written notice to OSHPD of a new prescription drug to market at a WAC that exceeds the threshold set for a specialty drug under the Medicare Part D program⁴⁴ within three days⁴⁵ after the release of the drug in the commercial market.
4. Provide reports to OSHPD about new prescription drugs in #3 and related information no later than 30 days after the manufacturer's notification about the new drugs.

OSHPD shall post drug-level (not aggregated) information it receives from manufacturers in #1 through #4 above on its website at least quarterly and within 60 days of receipt from a manufacturer on its website.

The California Research Bureau⁴⁶ shall submit a report to the California legislature by January 1, 2022 documenting the effectiveness of this legislation.

Section 5 requires health insurers to report to the Department of Insurance (DOI) lists of the 25:

- Most frequently prescribed drugs;
- Most costly drugs by total annual plan spending; and
- Drugs with the highest year-over-year increase in total annual plan spending.

DOI must use this information to create a report⁴⁷ by January 1 each year (beginning in 2018) that demonstrates the overall impact of drug costs on health plan premiums.

Section 6 requires large group health insurance plans to file the following with DOI

- Weighted average rate increases during the 12-month period ending January 1 of the following year;
- Supplemental information about factors affecting the premium base rate;
- The plan's assumptions for increases in medical costs for their population;
- A comparison of aggregate per enrollee per month costs for the previous five years; and
- Information about the prescription drug benefit, including the percentage of premium attributable to prescription drug costs.

⁴⁴ Currently, the threshold is \$670 for a one-month supply at an in-network retail pharmacy. See: NOTE TO: Medicare Advantage Organizations, Prescription Drug Plan Sponsors, and Other Interested Parties, SUBJECT: Advance Notice of Methodological Changes for Calendar Year (CY) 2019 for Medicare Advantage (MA) Capitation Rates, Part C and Part D Payment Policies and 2019 draft Call Letter, page 201, from <https://www.cms.gov/Medicare/Health-Plans/MedicareAdvtgSpecRateStats/Downloads/Advance2019Part2.pdf>, accessed on October 16, 2019.

⁴⁵ A manufacturer may make this notification ending approval by the federal Food and Drug Administration, if commercial availability is expected within three days of approval.

⁴⁶ California State Library, California Research Bureau, from <https://www.library.ca.gov/crb/>, accessed on October 16, 2019.

⁴⁷ Impact of Prescription Drug Costs on Health Insurance Premiums Report for Calendar Year 2017 Experience Pursuant to California Insurance Code § 10123.205(b), from <http://www.insurance.ca.gov/01-consumers/110-health/60-resources/upload/CDI-Prescription-Drug-Premium-Impact-Report-Dec-31-2018.pdf>, accessed on October 16, 2019.



How California Legislation Compares to Washington Legislation

Similarities between Washington and California prescription drug price transparency legislation include requirements for:

- Price increase notifications and the collection of drug information about how drug costs are impacting health care premiums; and
- Health insurers and health plans reporting on the impact of prescription drugs on health care premiums.

However, there are several differences between the two states' legislation:

- **Reporting entities** – California's legislation does not include PBMs and PSAs as reporting entities. Washington's legislation requires PBMs and PSAs to report information to HCA.
- **Required information** – Health insurers and health plans in California do not have a requirement to report information about rebates, discounts, and the impact of prescription drugs on health care premiums. Washington does require that information from health insurers and health plans.
- **Data analysis** – In California, OSHPD does not perform any formal data analysis or reporting beyond collecting information on drug price increases and providing that information to purchasers and other California state agencies. In the Washington legislation, HCA may use information from manufacturers in its annual report.
- **Report data aggregation** – Although the California legislation allows manufacturers to limit the information they report to OSHPD that which is publicly available, OSHPD must post that information on its website "on a per-drug basis and shall not be aggregated in a manner that would not allow identification of the drug."⁴⁸ Washington's legislation requires HCA to aggregate all data in the report that it will post on its website and submit to the Washington State Legislature; it must not reveal information specific to individual:
 - Health carriers;
 - PBMs;
 - PSAs;
 - Prescription drugs or their paid discount amounts;
 - Classes of prescription drugs; or
 - Manufacturers.

Compared to California's reporting, HCA's reporting provides less opportunity to increase transparency about the impact that prescription drugs have on health care premiums.

- **Information dissemination** – Legislation in California requires OSHPD to provide notifications about prescription drug price increases and the availability of related reports on their website to the public payers and any qualifying purchaser that registers to receive this information. Legislation in Washington requires HCA to publish an annual report on its

⁴⁸ SB-17 Health care: prescription drug costs. (2017-2018), Section 4(c), from https://leginfo.ca.gov/faces/billNavClient.xhtml?bill_id=201720180SB17, accessed on October 16, 2019.

website by December 1 each year (beginning in 2020) that includes recommendations about how to notify the public about qualifying price increases.

California Implementation

The California legislation impacts three separate state agencies related to drug pricing and purchasing: OSHPD, DMHC, and DOI.

- **OSHPD** – This agency administers California’s Prescription Drug Pricing for Purchasers program, also known as the Cost Transparency Rx (CTR_x) Program.⁴⁹ It is responsible for monitoring drug price increases and communicating these increases (and the rationale for these increases) to the purchasers and the public to facilitate drug price transparency.
- **DMHC and DOI** – These agencies have oversight responsibilities for California health plans. They are responsible for collecting drug cost information from health plans and health insurers, performing analyses on that information, and determining the overall impact of drug costs on health plan premiums.

For the purposes of this legislative report, we focus on OSHPD and its CTR_x Program.

OSHPD had previous experience collecting data from health facilities in California for the purpose of health care transparency. However, prior to SB 17, the agency did not have programs working directly with drug manufacturers and collecting information specific to drug pricing. California originally appropriated 3 FTEs for OSHPD to implement the CTR_x Program, but staffing expanded to 5.5 new FTEs after OSHPD finished scoping and detailing the implementation:

- An attorney (1.0 FTE) for levying penalties;
- An information technology (IT) specialist (0.5 FTE) for supporting the program;
- A project manager (1.0 FTE) to manage the entire program; and
- Both a working supervisor (1.0 FTE) and two staff (2.0 FTE) to manage the day-to-day operations of the program, including data collection, data clean-up, sending data to the data warehouse, and answering stakeholder questions.

OSHPD has not contracted out any of this work on the drug price transparency, but it has leveraged existing contracts and resources. For example, OSHPD leveraged existing IT resources to adapt its hospital data collection system to begin collecting data from drug manufacturers. This solution enables manufacturers to submit data by:

- Entering data directly into web fields on an online portal; or
- Downloading templates, entering information onto those forms, and submitting them to the program.

⁴⁹ Cost Transparency Rx (CTR_x) Program, from <https://oshpd.ca.gov/data-and-reports/cost-transparency/rx/#cost-transparency-rx-ctrx-program>, accessed on October 24, 2019.



OSHPD also created a registry for public and private purchasers to sign-up for 60-day advanced notices of drug price increases.

Although OSHPD does not perform any data analysis, as DMHC or DOI are doing for their public reporting, OSHPD does work to make sure the data inputs are correct and accurate to:

- Ensure compliance with the program; and
- Possibly levy fines on non-compliant manufacturers.

OSHPD verifies manufacturer data is correct and accurate by reviewing both external data sources and manufacturers' press releases.

How California Implementation Compares to Washington Implementation

HCA is working to implement its prescription drug price transparency program. Similarities between what HCA plans to do in Washington and what California has already implemented include:

- Administering the program in-house instead of contracting with a third-party vendor to administer the program; and
- Developing an IT system to collect, store, and analyze prescription drug data.

However, there are several differences between the implementation of the two states' programs:

- **Existing infrastructure** – California's program is in an agency (OSHPD) that has been responsible for collecting data from California hospitals for transparency, and already had systems and infrastructure in place to implement the CTRx Program. HCA does not have a system for receiving data from entities with which it does not directly contract for services (e.g., managed care organizations, third-party administrators, etc.); however, HCA is actively exploring options to set up a system for collecting data from drug manufacturers and other entities related to E2SHB 1224.
- **Staffing resources** – California's program has sufficient resources to hire 5.5 full-time positions. Currently, HCA only has one new full-time position to implement the entire Washington State Prescription Drug Price Transparency Program.

Among the positions the California program has is an attorney that supports the program by levying penalties on manufacturers that are non-compliant with the legislation. This is something HCA will need to consider, given the potentially high non-compliance with E2SHB 1224 data reporting requirements.

Early Successes of the California Transparency Program

California's CTRx Program has already experienced several successes during its initial implementation, which may inform Washington's implementation:

- **Outreach efforts** – When SB 17 passed, OSHPD did not have existing relationships with drug manufacturers, which required the program to determine the:



- Number of manufacturers;
- Number of drugs;
- Type of drug data;
- Available drug data vendors; and
- Scale of the program with limited experience in the pharmaceutical field.

OSHPD also needed to contact all these manufacturers to engage them in the program. It was challenging for OSHPD to find and reach out to the small manufacturers, due to their lack of engagement in the legislative and stakeholder processes. However, California was one of the first states to enact legislation on drug price transparency reporting; outreach to manufacturers may be easier for other states who are now implementing their programs.

- **Data collection** – OSHPD created multiple methods for manufacturers to report data to the CTRx Program. By allowing different methods:
 - Manufacturers with few price increases can use web fields to manually enter their data; and
 - Manufacturers with many price increases can upload a data file.
- **Data validation** – To validate manufacturers’ data, OSHPD created identifications for manufacturers and their users for tracking data uploading and editing processes. Within about one week, OSHPD staff can review data and work with manufacturers as necessary to correct the data before accepting it into the system. After OSHPD finalizes accepts a final version of the data, manufacturers are not able to make any edits without receiving special permission from OSHPD. By creating a flexible, efficient system to review and correct data, OSHPD is able to ensure that their system contains accurate, high-quality data for reporting purposes.
- **Data consistency** – OSHPD works with DMHC and DOI to ensure each agency uses similar data definitions and collects similar data. This enables the public to compare between the agencies’ different drug reports and perform analyses related to drug price transparency.

Early Challenges of the California Transparency Program

OSHPD shared some information about the challenges they have experienced while implementing their program. Knowing about these challenges will help HCA to anticipate similar challenges if we encounter them during our implementation efforts:

- **Stakeholder engagement** – It took OSHPD about a year to engage successfully with the drug manufacturer stakeholder community. This included holding meetings with public consumers (e.g., researchers, payers, etc.), legal representation from manufacturers, data teams from manufacturers, and other entities. As a result, OSHPD was able to:
 - Incorporate this information into its program; and
 - Build new relationships with manufacturers; and
 - Promote compliance among manufacturers with the program’s reporting requirements.



- **Ensuring compliance** –Not all manufacturers are complying with the CTRx Program’s reporting requirements, which requires OSHPD to enforce penalties on manufacturers for not satisfying their legal obligations.

Opportunities for Alignment between States

There are several similarities and opportunities for alignment between California’s Prescription Drug Price Transparency Program and Washington’s program. However, it would be necessary to change legislation in California, Washington, or both to align the programs successfully. Without legislative changes, many fundamental differences in agencies’ data collection and reporting (e.g., notifying purchasers and others vs. publishing reports to the Legislature) would remain incomparable between the two states. We base the recommendations in this report on our evaluation and understanding of these comparisons.

Other States

In addition to Washington, Oregon, and California, other states have been exploring opportunities to establish prescription drug price transparency programs. One example is Nevada.

Nevada passed Senate Bill (SB) 539 in 2017,⁵⁰ which directed the Nevada Department of Health and Human Services to:

- Create a list of essential medications to treat diabetes; and
- Collect and report to the public information about those drugs’ price increases and other relevant changes.

Appendix G contains the text of SB 539. Although Nevada’s drug price transparency program is more narrowly focused than other states’ programs, it is also among the more robust. In its reporting, the program provides analyses on drug classes and the information that manufacturers provide as part of their rationale for prescription drug price increases.⁵¹

In an effort to promote prescription drug price transparency across the United States, the National Academy of State Health Policy (NASHP) is working⁵² with state agencies to develop model price transparency legislation⁵³ for consistency between states. Appendix H contains the current NASHP

⁵⁰ SB539, from

[http://dhhs.nv.gov/uploadedFiles/dhhsnv.gov/content/HCPWD/DHHS%202019%20Drug%20Transparency%20Report%205-31-2019\(1\).pdf](http://dhhs.nv.gov/uploadedFiles/dhhsnv.gov/content/HCPWD/DHHS%202019%20Drug%20Transparency%20Report%205-31-2019(1).pdf), accessed on October 10, 2019.

⁵¹ Drug Transparency Report – 2019 Essential Diabetes Drugs, from

[http://dhhs.nv.gov/uploadedFiles/dhhsnv.gov/content/HCPWD/DHHS%202019%20Drug%20Transparency%20Report%205-31-2019\(1\).pdf](http://dhhs.nv.gov/uploadedFiles/dhhsnv.gov/content/HCPWD/DHHS%202019%20Drug%20Transparency%20Report%205-31-2019(1).pdf), accessed on October 10, 2019.

⁵² NASHP National Academy for State Health Policy, Center for State Rx Drug Pricing, Drug Price Transparency Model Legislation and Resources, from <https://nashp.org/drug-price-transparency/>, accessed on October 10, 2019.

⁵³ NASHP National Academy for State Health Policy, DRAFT DRUG TRANSPARENCY MODEL LEGISLATION AN ACT TO PROMOTE PRESCRIPTION DRUG PRICE TRANSPARENCY AND COST CONTROL, from <https://nashp.org/wp-content/uploads/2019/05/Revised-comprehensive-Model-Legislation-5.24.19.pdf>, accessed on October 10, 2019.



comprehensive transparency model legislation, which includes reporting requirements from the following entities:

- Manufacturers;
- PBMs;
- Wholesale drug distributors; and
- Insurance issuers.

This model legislation could provide an opportunity for states to align drug price transparency programs in the future.

Purchasing Efforts in Oregon and California

Between July 2019, and September 2019, HCA staff engaged in preliminary conversations with representatives from state agencies in Oregon and California to discuss their prescription drug purchasing efforts.

Oregon

On July 11, 2019, HCA staff had a conference call with representatives from the Oregon Health Authority's Oregon Prescription Drug Program, with which HCA participates in the Consortium. Appendix D contains the text from Oregon Revised Statutes (ORS) 412.312 through 414.320, which is Oregon's state law that governs their program.⁵⁴ Oregon's program is similar to Washington's program, per RCW 70.14.050 through 70.14.080.⁵⁵ For example, through the Consortium, both programs:

- Purchase prescription drugs through the Consortium, either directly or by reimbursing pharmacies;
- Include state purchased health care programs — either on a voluntary basis in Oregon, or on a mandatory basis with the option to be exempt if those programs can prove they can realize more cost savings outside the Consortium;
- May include, on a voluntary basis, local government units, private entities, labor organizations, or individuals who lack or are underinsured for prescription drug coverage;
- Work together currently to engage in joint state purchasing of prescription drugs; and
- Have the ability to expand the Consortium to include additional states through intergovernmental agreement and other entities through contractual agreements with the Consortium as a participating entity.

⁵⁴ Statute - Oregon Prescription Drug Program – ORS 414.312 to 414.320, from <https://www.oregon.gov/oha/HPA/dsi-opdp/Pages/Statute.aspx>, accessed on October 3, 2019.

⁵⁵ Chapter 70.14 RCW HEALTH CARE SERVICES PURCHASED BY STATE AGENCIES, from <https://app.leg.wa.gov/RCW/default.aspx?cite=70.14&full=true>, accessed on October 14, 2019.



The Consortium is working to add more participating entities and improve its strategic alignment through cross-state purchasing. Recent legislative efforts in Oregon targeted joint purchasing efforts with California, confirming that Consortium states are interested in pursuing partnerships with other states. HCA's conference call with representatives from Oregon's program focused on how the Consortium's business might change if additional states or other entities participate in the future.

California

On September 16, 2019, HCA staff had a conference call with representatives from the California Department of General Services (DGS). During the call, we learned about California's Statewide Pharmaceutical Program⁵⁶ and how it might align with the Consortium.

Appendix F contains the text from California's Government Code 14799 through 14982, which is California's state law that governs their program.⁵⁷ The kind of participants in California's Statewide Pharmaceutical Program differ from Consortium participants:

- In California's program, all state departments that must participate in the program administer hospitals or facilities (e.g., the Department of Corrections, also known as the California Department of Corrections and Rehabilitation).^{58,59} None of the participating state departments administer health plans. Neither the California Public Employees' Retirement System (CalPERS, which includes both active employees and retirees),⁶⁰ nor the California Medicaid Program (Medi-Cal)⁶¹ participate.
- In the Consortium, both state departments that administer health plans (e.g., Labor and Industries) and departments that administer facilities (e.g., Department of Corrections) participate in the program. In Washington and Oregon, health plans for public employees, school employees, and public and school retirees participate in the Consortium. However, as with California's Medi-Cal program, neither the Oregon Health Plan⁶² (with the exception of

⁵⁶ DGS Procurement Division, Statewide Pharmaceutical Program, from <https://www.dgs.ca.gov/PD/About/Page-Content/PD-Branch-Intro-Accordion-List/Acquisitions/Statewide-Pharmaceutical-Program>, accessed on October 10, 2019.

⁵⁷ CHAPTER 12. Purchase of Prescription Drugs for Government Agencies [14977 - 14982], from http://leginfo.legislature.ca.gov/faces/codes_displayText.xhtml?lawCode=GOV&division=3.&title=2.&part=5.5.&chapter=12.&article, accessed on October 10, 2019.

⁵⁸ DGS Procurement Division, Statewide Pharmaceutical Program, from <https://www.dgs.ca.gov/PD/About/Page-Content/PD-Branch-Intro-Accordion-List/Acquisitions/Statewide-Pharmaceutical-Program>, accessed on October 10, 2019.

⁵⁹ CHAPTER 12. Purchase of Prescription Drugs for Government Agencies [14977 - 14982], from http://leginfo.legislature.ca.gov/faces/codes_displayText.xhtml?lawCode=GOV&division=3.&title=2.&part=5.5.&chapter=12.&article, accessed on October 10, 2019.

⁶⁰ CalPERS, from <https://www.calpers.ca.gov/>, accessed on October 10, 2019.

⁶¹ CA.gov Department of Health Care Services, Medi-Cal, from <http://www.medi-cal.ca.gov/>, accessed on October 10, 2019.

⁶² Oregon Health Plan, from <https://www.oregon.gov/oha/HSD/OHP/pages/index.aspx>, accessed on October 14, 2019.



the Eastern Oregon Coordinated Care Organization⁶³) nor Washington’s Apple Health Plan⁶⁴ currently participate in the Consortium.

Current program participation is relevant, because health plans do not typically purchase drugs directly from manufacturers, as hospitals and facilities do. Instead, health plans reimburse pharmacies for prescription drugs that the pharmacies purchase and dispense to health plan members. Although California’s legislation⁶⁵ allows other states to join their prescription drug bulk purchasing program, its considerably different business model might make it challenging for Washington to partner with California for bulk prescription drug purchasing.

Recommendations and Options

Price Transparency

Based on what we learned from our discussions with state agency representatives in Oregon and California, HCA has prepared a list of recommendations and a list of options for the Washington State Legislature to consider how to change the Washington Prescription Drug Price Transparency Program. The Legislature will need to consider which options would best serve the needs of the state and which other states may be potential partners in alignment should they also adopt aligned legislation. Below are the lists of HCA’s recommendations and options for the Washington State Legislature on the Prescription Drug Price Transparency Program.

Recommendations

1. HCA recommends that the Washington State Legislature allocate additional staffing and financial resources for HCA to have program support that is comparable to similar programs that operate in Oregon and California. Without additional resources, the Washington Prescription Drug Price Transparency Program will not be able to function as successfully as programs in Oregon and California, and may have challenges in meeting its requirements.
2. HCA recommends that the Washington State Legislature update E2SHB 1224, Section 10(2), and RCW 43.71C.100,⁶⁶ to allow HCA to include in its annual report information at an individual drug level and a drug class level, in relation to the impact on health care premiums. Allowing HCA to report at the drug and drug class levels in its annual report would greatly improve the report’s utility to the Legislature and the public by increasing

⁶³ EOCCO, from <https://www.eocco.com/members>, accessed on October 2, 2019.

⁶⁴ Apple Health (Medicaid) coverage, from <https://www.hca.wa.gov/health-care-services-supports/apple-health-medicaid-coverage>, accessed on October 14, 2019.

⁶⁵ CHAPTER 12. Purchase of Prescription Drugs for Government Agencies [14977 - 14982], 14977.5(b), from http://leginfo.ca.gov/faces/codes_displayText.xhtml?lawCode=GOV&division=3.&title=2.&part=5.5.&chapter=12.&article, accessed on October 10, 2019.

⁶⁶ RCW 43.71C.100 Annual report—Data confidentiality., from <https://app.leg.wa.gov/RCW/default.aspx?cite=43.71C.100>, accessed on October 25, 2019.



transparency and insight about the impact that prescription drugs have on health care premiums.

3. HCA recommends that the Washington State Legislature update E2SHB 1224, Section 8(3) and RCW 43.71C.070,⁶⁷ to allow HCA to report wholesale acquisition cost (WAC) increases to the public. Allowing HCA to report WAC increases to the public would help the public understand the frequency and nature of drug price increases. WAC is also not proprietary pricing information. This would also enable HCA to provide advance notice of price increases to purchasers, per Section 8(4).

Options

1. If the Washington State Legislature wants the state to align Washington's price transparency reporting with multiple states' reporting and enable partnerships with multiple states, then we recommend that the Washington State Legislature pursue model legislation from the National Academy for State Health Policy (NASHP). If Oregon or California pursued NASHP, then that is another strategy for alignment.
2. If the Washington State Legislature wants the state to have a drug transparency program that achieves similar objectives to Oregon's drug price transparency program, then the Washington State Legislature should consider reviewing strategies with the Oregon State Legislature to create coordinated programs by amending legislation in both states.
3. If the Washington State Legislature wants the state to have a drug transparency program that achieves similar objectives to California's drug price transparency program, then the Washington State Legislature should consider reviewing strategies with the California State Legislature to create coordinated programs by amending legislation in both states.

Joint State Purchasing

Based on what we learned from our discussions with state agency representatives in Oregon and California, HCA has prepared one recommendation and one option for the Washington State Legislature to consider about joint state purchasing strategies:

Recommendation

1. HCA recommends that the Washington State Legislature continue to support and advance the Consortium and our state's joint purchasing relationship with Oregon, which has worked successfully since it began in 2004.

Option

1. If the Washington State Legislature is interested in joint state purchasing agreements with California, then the Washington State Legislature should consider reaching out to the California State Legislature and, if they are willing to participate, explore whether any California agencies and local governments may benefit from joining the Consortium.

⁶⁷ RCW 43.71C.070 Manufacturers—Notice of price increases., from <https://app.leg.wa.gov/RCW/default.aspx?cite=43.71C.070>, accessed on October 25, 2019.

Conclusion

Washington is committed to addressing concerns about rising drug costs by exploring strategies on improving drug spending through drug price transparency and pooled purchasing power. In response to E2SHB 1224 (2019), HCA reached out to representatives of Oregon and California to learn more about their legislation and prescription drug programs and assess opportunities to align our states' efforts.

From our discussions with state agency representatives in Oregon and California and additional research, we learned that:

- Compared to prescription drug price transparency reporting in Oregon and California, HCA's reporting provides less opportunity to increase transparency about the impact that prescription drugs have on health care premiums.
- Legislative differences between the states' transparency and purchasing efforts are barriers to Washington engaging in joint transparency efforts with Oregon and both joint transparency and purchasing efforts with California; and
- Current resources for Washington's Prescription Drug Price Transparency program operations appear to be insufficient, compared to programs that Oregon and California have successfully implemented.

HCA's recommendations to the Washington State Legislature relate to:

- Providing more resources to HCA for its prescription drug price transparency efforts;
- Amending current legislation to allow HCA to report prescription drug price information at the drug and drug class levels;
- Amending current legislation to allow HCA to report wholesale acquisition cost (WAC) increases and provide advance notice of price increases to purchasers; and
- Continuing support for Washington's successful joint purchasing relationship with Oregon.

The Legislature should also consider all the options available to Washington State and determine which option best serves the needs of the state. These options relate to:

- Aligning Washington's prescription drug price transparency legislation to model legislation from NASHP; and
- Reviewing strategies with Oregon and California legislatures to amend current legislation and create coordinated programs.

By acting on these recommendations and considering these options, Washington will continue to progress toward the goal to manage prescription drug pricing more effectively and benefit both drug payers and patients.



Appendix A: Washington Prescription Drug Price Transparency Legislation



CERTIFICATION OF ENROLLMENT

ENGROSSED SECOND SUBSTITUTE HOUSE BILL 1224

Chapter 334, Laws of 2019

66th Legislature
2019 Regular Session

PRESCRIPTION DRUG PRICING

EFFECTIVE DATE: July 28, 2019

Passed by the House April 25, 2019
Yeas 92 Nays 5

FRANK CHOPP

Speaker of the House of Representatives

Passed by the Senate April 25, 2019
Yeas 48 Nays 0

CYRUS HABIB

President of the Senate

Approved May 9, 2019 2:44 PM

JAY INSLEE

Governor of the State of Washington

CERTIFICATE

I, Bernard Dean, Chief Clerk of the House of Representatives of the State of Washington, do hereby certify that the attached is **ENGROSSED SECOND SUBSTITUTE HOUSE BILL 1224** as passed by the House of Representatives and the Senate on the dates hereon set forth.

BERNARD DEAN

Chief Clerk

FILED

May 13, 2019

**Secretary of State
State of Washington**

ENGROSSED SECOND SUBSTITUTE HOUSE BILL 1224

AS AMENDED BY THE CONFERENCE COMMITTEE

Passed Legislature - 2019 Regular Session

State of Washington 66th Legislature 2019 Regular Session

By House Appropriations (originally sponsored by Representatives Robinson, Macri, Ryu, Peterson, Frame, Tharinger, Bergquist, Gregerson, Jinkins, Ortiz-Self, Lovick, Doglio, Stanford, Appleton, Slatter, and Wylie)

READ FIRST TIME 03/01/19.

1 AN ACT Relating to prescription drug cost transparency;
2 reenacting and amending RCW 74.09.215; adding a new chapter to Title
3 43 RCW; and prescribing penalties.

4 BE IT ENACTED BY THE LEGISLATURE OF THE STATE OF WASHINGTON:

5 NEW SECTION. **Sec. 1.** FINDINGS. The legislature finds that the
6 state of Washington has substantial public interest in the following:

7 (1) The price and cost of prescription drugs. Washington state is
8 a major purchaser through the department of corrections, the health
9 care authority, and other entities acting on behalf of a state
10 purchaser;

11 (2) Enacting this chapter to provide notice and disclosure of
12 information relating to the cost and pricing of prescription drugs in
13 order to provide accountability to the state for prescription drug
14 pricing;

15 (3) Rising drug costs and consumer ability to access prescription
16 drugs; and

17 (4) Containing prescription drug costs. It is essential to
18 understand the drivers and impacts of these costs, as transparency is
19 typically the first step toward cost containment and greater consumer
20 access to needed prescription drugs.

1 NEW SECTION. **Sec. 2.** DEFINITIONS. The definitions in this
2 section apply throughout this chapter unless the context clearly
3 requires otherwise.

4 (1) "Authority" means the health care authority.

5 (2) "Covered drug" means any prescription drug that:

6 (a) A covered manufacturer intends to introduce to the market at
7 a wholesale acquisition cost of ten thousand dollars or more for a
8 course of treatment lasting less than one month or a thirty-day
9 supply, whichever period is longer; or

10 (b) Is currently on the market, is manufactured by a covered
11 manufacturer, and has a wholesale acquisition cost of more than one
12 hundred dollars for a course of treatment lasting less than one month
13 or a thirty-day supply, and, taking into account only price increases
14 that take effect after the effective date of this section, the
15 manufacturer increases the wholesale acquisition cost at least:

16 (i) Twenty percent, including the proposed increase and the
17 cumulative increase over one calendar year prior to the date of the
18 proposed increase; or

19 (ii) Fifty percent, including the proposed increase and the
20 cumulative increase over three calendar years prior to the date of
21 the proposed increase.

22 (3) "Covered manufacturer" means a person, corporation, or other
23 entity engaged in the manufacture of prescription drugs sold in or
24 into Washington state. "Covered manufacturer" does not include a
25 private label distributor or retail pharmacy that sells a drug under
26 the retail pharmacy's store, or a prescription drug repackager.

27 (4) "Health care provider," "health plan," "health carrier," and
28 "carrier" mean the same as in RCW 48.43.005.

29 (5) "Pharmacy benefit manager" means the same as in RCW
30 19.340.010.

31 (6) "Pharmacy services administrative organization" means an
32 entity that contracts with a pharmacy to act as the pharmacy's agent
33 with respect to matters involving a pharmacy benefit manager, third-
34 party payor, or other entities, including negotiating, executing, or
35 administering contracts with the pharmacy benefit manager, third-
36 party payor, or other entities and provides administrative services
37 to pharmacies.

38 (7) "Prescription drug" means a drug regulated under chapter
39 69.41 or 69.50 RCW, including generic, brand name, specialty drugs,

1 and biological products that are prescribed for outpatient use and
2 distributed in a retail setting.

3 (8) "Qualifying price increase" means a price increase described
4 in subsection (2)(b) of this section.

5 (9) "Wholesale acquisition cost" or "price" means, with respect
6 to a prescription drug, the manufacturer's list price for the drug to
7 wholesalers or direct purchasers in the United States, excluding any
8 discounts, rebates, or reductions in price, for the most recent month
9 for which the information is available, as reported in wholesale
10 price guides or other publications of prescription drug pricing.

11 NEW SECTION. **Sec. 3.** HEALTH CARRIER REPORTING. Beginning
12 October 1, 2019, and on a yearly basis thereafter, a health carrier
13 must submit to the authority the following prescription drug cost and
14 utilization data for the previous calendar year for each health plan
15 it offers in the state:

16 (1) The twenty-five prescription drugs most frequently prescribed
17 by health care providers participating in the plan's network;

18 (2) The twenty-five costliest prescription drugs expressed as a
19 percentage of total plan prescription drug spending, and the plan's
20 total spending for each of these prescription drugs;

21 (3) The twenty-five drugs with the highest year-over-year
22 increase in wholesale acquisition cost, excluding drugs made
23 available for the first time that plan year, and the percentages of
24 the increases for each of these prescription drugs;

25 (4) The portion of the premium that is attributable to each of
26 the following categories of covered prescription drugs, after
27 accounting for all rebates and discounts:

- 28 (a) Brand name drugs;
- 29 (b) Generic drugs; and
- 30 (c) Specialty drugs;

31 (5) The year-over-year increase, calculated on a per member, per
32 month basis and expressed as a percentage, in the total annual cost
33 of each category of covered drugs listed in subsection (4) of this
34 section, after accounting for all rebates and discounts;

35 (6) A comparison, calculated on a per member, per month basis, of
36 the year-over-year increase in the cost of covered drugs to the year-
37 over-year increase in the costs of other contributors to premiums,
38 after accounting for all rebates and discounts;

39 (7) The name of each covered specialty drug; and

1 (8) The names of the twenty-five most frequently prescribed drugs
2 for which the health plan received rebates from pharmaceutical
3 manufacturers.

4 NEW SECTION. **Sec. 4.** PHARMACY BENEFIT MANAGER REPORTING. (1) By
5 March 1st of each year, a pharmacy benefit manager must submit to the
6 authority the following data from the previous calendar year:

7 (a) All discounts, including the total dollar amount and
8 percentage discount, and all rebates received from a manufacturer for
9 each drug on the pharmacy benefit manager's formularies;

10 (b) The total dollar amount of all discounts and rebates that are
11 retained by the pharmacy benefit manager for each drug on the
12 pharmacy benefit manager's formularies;

13 (c) Actual total reimbursement amounts for each drug the pharmacy
14 benefit manager pays retail pharmacies after all direct and indirect
15 administrative and other fees that have been retrospectively charged
16 to the pharmacies are applied;

17 (d) The negotiated price health plans pay the pharmacy benefit
18 manager for each drug on the pharmacy benefit manager's formularies;

19 (e) The amount, terms, and conditions relating to copayments,
20 reimbursement options, and other payments or fees associated with a
21 prescription drug benefit plan;

22 (f) Disclosure of any ownership interest the pharmacy benefit
23 manager has in a pharmacy or health plan with which it conducts
24 business; and

25 (g) The results of any appeal filed pursuant to RCW
26 19.340.100(3).

27 (2) The information collected pursuant to this section is not
28 subject to public disclosure under chapter 42.56 RCW.

29 (3) The authority may examine or audit the financial records of a
30 pharmacy benefit manager for purposes of ensuring the information
31 submitted under this section is accurate. Information the authority
32 acquires in an examination of financial records pursuant to this
33 subsection is proprietary and confidential.

34 NEW SECTION. **Sec. 5.** PHARMACY BENEFIT MANAGER COMPLIANCE. (1)
35 No later than March 1st of each calendar year, each pharmacy benefit
36 manager must file with the authority, in the form and detail as
37 required by the authority, a report for the preceding calendar year

1 stating that the pharmacy benefit manager is in compliance with this
2 chapter.

3 (2) A pharmacy benefit manager may not cause or knowingly permit
4 the use of any advertisement, promotion, solicitation,
5 representation, proposal, or offer that is untrue, deceptive, or
6 misleading.

7 (3) An employer-sponsored self-funded health plan or a Taft-
8 Hartley trust health plan may voluntarily provide the data described
9 in subsection (1) of this section.

10 NEW SECTION. **Sec. 6.** MANUFACTURER REPORTING. (1) Beginning
11 October 1, 2019, a covered manufacturer must submit to the authority
12 the following data for each covered drug:

13 (a) A description of the specific financial and nonfinancial
14 factors used to make the decision to set or increase the wholesale
15 acquisition cost of the drug. In the event of a price increase, a
16 covered manufacturer must also submit the amount of the increase and
17 an explanation of how these factors explain the increase in the
18 wholesale acquisition cost of the drug;

19 (b) The patent expiration date of the drug if it is under patent;

20 (c) Whether the drug is a multiple source drug, an innovator
21 multiple source drug, a noninnovator multiple source drug, or a
22 single source drug;

23 (d) The itemized cost for production and sales, including the
24 annual manufacturing costs, annual marketing and advertising costs,
25 total research and development costs, total costs of clinical trials
26 and regulation, and total cost for acquisition of the drug; and

27 (e) The total financial assistance given by the manufacturer
28 through assistance programs, rebates, and coupons.

29 (2) For all qualifying price increases of existing drugs, a
30 manufacturer must submit the year the drug was introduced to market
31 and the wholesale acquisition cost of the drug at the time of
32 introduction.

33 (3) If a manufacturer increases the price of an existing drug it
34 has manufactured for the previous five years or more, it must submit
35 a schedule of wholesale acquisition cost increases for the drug for
36 the previous five years.

37 (4) If a manufacturer acquired the drug within the previous five
38 years, it must submit:

1 (a) The wholesale acquisition cost of the drug at the time of
2 acquisition and in the calendar year prior to acquisition; and

3 (b) The name of the company from which the drug was acquired, the
4 date acquired, and the purchase price.

5 (5) Except as provided in subsection (6) of this section, a
6 covered manufacturer must submit the information required by this
7 section:

8 (a) At least sixty days in advance of a qualifying price increase
9 for a covered drug; and

10 (b) Within thirty days of release of a new covered drug to the
11 market.

12 (6) For any drug approved under section 505(j) of the federal
13 food, drug, and cosmetic act, as it existed on the effective date of
14 this section, or a biosimilar approved under section 351(k) of the
15 federal public health service act, as it existed on the effective
16 date of this section, if submitting data in accordance with
17 subsection (5)(a) of this section is not possible sixty days before
18 the price increase, that submission must be made as soon as known but
19 not later than the date of the price increase.

20 (7) The information submitted pursuant to this section is not
21 subject to public disclosure under chapter 42.56 RCW.

22 NEW SECTION. **Sec. 7.** MANUFACTURER NOTICE OF NEW DRUG
23 APPLICATIONS. (1) Beginning October 1, 2019, a manufacturer must
24 submit written notice, in a form and manner specified by the
25 authority, informing the authority that the manufacturer has filed
26 with the FDA:

27 (a) A new drug application or biologics license application for a
28 pipeline drug; or

29 (b) A biologics license application for a biological product.

30 (2) The notice must be filed within sixty days of the
31 manufacturer receiving the applicable FDA approval date.

32 (3) Upon receipt of the notice, the authority may request from
33 the manufacturer the following information if it believes the drug
34 will have a significant impact on state expenditures:

35 (a) The primary disease, condition, or therapeutic area studied
36 in connection with the new drug, and whether the drug is
37 therapeutically indicated for such disease, condition, or therapeutic
38 area;

39 (b) Each route of administration studied for the drug;

1 (c) Clinical trial comparators for the drug;

2 (d) The date at which the FDA must complete its review of the
3 drug application pursuant to the federal prescription drug user fee
4 act of 1992 (106 Stat. 4491; P.L. 102-571);

5 (e) Whether the FDA has designated the drug an orphan drug, a
6 fast track product, or a breakthrough therapy; and

7 (f) Whether the FDA has designated the drug for accelerated
8 approval, priority review, or if the drug contains a new molecular
9 entity.

10 (4) A manufacturer may limit the information reported pursuant to
11 this section to that which is otherwise in the public domain or
12 publicly reported.

13 (5) The information collected pursuant to this section is not
14 subject to public disclosure under chapter 42.56 RCW.

15 NEW SECTION. **Sec. 8.** MANUFACTURER NOTICE OF PRICE INCREASES.

16 (1) Beginning October 1, 2019, a manufacturer of a covered drug must
17 notify the authority of a qualifying price increase in writing at
18 least sixty days prior to the planned effective date of the increase.
19 The notice must include:

20 (a) The date of the increase, the current wholesale acquisition
21 cost of the prescription drug, and the dollar amount of the future
22 increase in the wholesale acquisition cost of the prescription drug;
23 and

24 (b) A statement regarding whether a change or improvement in the
25 drug necessitates the price increase. If so, the manufacturer shall
26 describe the change or improvement.

27 (2) For any drug approved under section 505(j) of the federal
28 food, drug, and cosmetic act, as it existed on the effective date of
29 this section, or a biosimilar approved under section 351(k) of the
30 federal public health service act, as it existed on the effective
31 date of this section, if notification is not possible sixty days
32 before the price increase, that submission must be made as soon as
33 known but not later than the date of the price increase.

34 (3) The information submitted pursuant to this section is not
35 subject to public disclosure under chapter 42.56 RCW.

36 (4) By December 1, 2020, the authority must provide
37 recommendations on how to provide advance notice of price increases
38 to purchasers consistent with state and federal law.

1 NEW SECTION. **Sec. 9.** PHARMACY SERVICES ADMINISTRATIVE
2 ORGANIZATION REPORTING. (1) Beginning October 1, 2019, and on a
3 yearly basis thereafter, a pharmacy services administrative
4 organization representing a pharmacy or pharmacy chain in the state
5 must submit to the authority the following data from the previous
6 calendar year:

7 (a) The negotiated reimbursement rate of the twenty-five
8 prescription drugs with the highest reimbursement rate;

9 (b) The twenty-five prescription drugs with the largest year-to-
10 year change in reimbursement rate, expressed as a percentage and
11 dollar amount; and

12 (c) The schedule of fees charged to pharmacies for the services
13 provided by the pharmacy services administrative organization.

14 (2) Any pharmacy services administrative organization whose
15 revenue is generated from flat service fees not connected to drug
16 prices or volume, and paid by the pharmacy, is exempt from reporting.

17 NEW SECTION. **Sec. 10.** DATA COLLECTION AND ANNUAL REPORT. (1)
18 The authority shall compile and analyze the data submitted by health
19 carriers, pharmacy benefit managers, manufacturers, and pharmacy
20 services administrative organizations pursuant to this chapter and
21 prepare an annual report for the public and the legislature
22 synthesizing the data to demonstrate the overall impact that drug
23 costs, rebates, and other discounts have on health care premiums.

24 (2) The data in the report must be aggregated and must not reveal
25 information specific to individual health carriers, pharmacy benefit
26 managers, pharmacy services administrative organizations, individual
27 prescription drugs, individual classes of prescription drugs,
28 individual manufacturers, or discount amounts paid in connection with
29 individual prescription drugs.

30 (3) Beginning January 1, 2021, and by each January 1st
31 thereafter, the authority must publish the report on its web site.

32 (4) Except for the report, and as provided in subsection (5) of
33 this section, the authority shall keep confidential all data
34 submitted pursuant to sections 3 through 9 of this act.

35 (5) For purposes of public policy, upon request of a legislator,
36 the authority must provide all data provided pursuant to sections 3
37 through 9 of this act and any analysis prepared by the authority. Any
38 information provided pursuant to this subsection must be kept
39 confidential within the legislature and may not be publicly released.

1 (6) The data collected pursuant to this chapter is not subject to
2 public disclosure under chapter 42.56 RCW.

3 NEW SECTION. **Sec. 11.** ENFORCEMENT. The authority may assess a
4 fine of up to one thousand dollars per day for failure to comply with
5 the requirements of sections 3 through 9 of this act. The assessment
6 of a fine under this section is subject to review under the
7 administrative procedure act, chapter 34.05 RCW. Fines collected
8 under this section must be deposited in the medicaid fraud penalty
9 account created in RCW 74.09.215.

10 NEW SECTION. **Sec. 12.** The authority must contact the California
11 office of statewide health planning and development and the Oregon
12 department of consumer and business services to develop strategies to
13 reduce prescription drug costs and increase prescription drug cost
14 transparency. The authority must make recommendations to the
15 legislature for implementing joint state strategies, which may
16 include a joint purchasing agreement, by January 1, 2020.

17 NEW SECTION. **Sec. 13.** RULE MAKING. The authority may adopt any
18 rules necessary to implement the requirements of this chapter.

19 **Sec. 14.** RCW 74.09.215 and 2013 2nd sp.s. c 4 s 1902, 2013 2nd
20 sp.s. c 4 s 997, and 2013 2nd sp.s. c 4 s 995 are each reenacted and
21 amended to read as follows:

22 The medicaid fraud penalty account is created in the state
23 treasury. All receipts from civil penalties collected under RCW
24 74.09.210, all receipts received under judgments or settlements that
25 originated under a filing under the federal false claims act, all
26 receipts from fines received pursuant to section 11 of this act, and
27 all receipts received under judgments or settlements that originated
28 under the state medicaid fraud false claims act, chapter 74.66 RCW,
29 must be deposited into the account. Moneys in the account may be
30 spent only after appropriation and must be used only for medicaid
31 services, fraud detection and prevention activities, recovery of
32 improper payments, for other medicaid fraud enforcement activities,
33 and the prescription monitoring program established in chapter 70.225
34 RCW. For the 2013-2015 fiscal biennium, moneys in the account may be
35 spent on inpatient and outpatient rebasing and conversion to the
36 tenth version of the international classification of diseases. For

1 the 2011-2013 fiscal biennium, moneys in the account may be spent on
2 inpatient and outpatient rebasing.

3 NEW SECTION. **Sec. 15.** Sections 1 through 13 of this act
4 constitute a new chapter in Title 43 RCW.

Passed by the House April 25, 2019.

Passed by the Senate April 25, 2019.

Approved by the Governor May 9, 2019.

Filed in Office of Secretary of State May 13, 2019.

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Appendix B: Washington Prescription Drug Joint Purchasing Legislation

Chapter 70.14 RCW HEALTH CARE SERVICES PURCHASED BY STATE AGENCIES⁶⁸ (Excerpts)

RCW [70.14.050](#)

Drug purchasing cost controls—Establishment of evidence-based prescription drug program.

(1) Each agency administering a state purchased health care program as defined in *RCW [41.05.011](#)(2) shall, in cooperation with other agencies, take any necessary actions to control costs without reducing the quality of care when reimbursing for or purchasing drugs. To accomplish this purpose, participating agencies may establish an evidence-based prescription drug program.

(2) In developing the evidence-based prescription drug program authorized by this section, agencies:

(a) Shall prohibit reimbursement for drugs that are determined to be ineffective by the United States food and drug administration;

(b) Shall adopt rules in order to ensure that less expensive generic drugs will be substituted for brand name drugs in those instances where the quality of care is not diminished;

(c) Where possible, may authorize reimbursement for drugs only in economical quantities;

(d) May limit the prices paid for drugs by such means as negotiated discounts from pharmaceutical manufacturers, central purchasing, volume contracting, or setting maximum prices to be paid;

(e) Shall consider the approval of drugs with lower abuse potential in substitution for drugs with significant abuse potential;

(f) May take other necessary measures to control costs of drugs without reducing the quality of care; and

(g) Shall adopt rules governing practitioner endorsement and use of any list developed as part of the program authorized by this section.

(3) Agencies shall provide for reasonable exceptions, consistent with RCW [69.41.190](#), to any list developed as part of the program authorized by this section.

⁶⁸ Chapter 70.14 RCW HEALTH CARE SERVICES PURCHASED BY STATE AGENCIES, from <https://app.leg.wa.gov/RCW/default.aspx?cite=70.14&full=true>, accessed on October 3, 2019.



(4) Agencies shall establish an independent pharmacy and therapeutics committee to evaluate the effectiveness of prescription drugs in the development of the program authorized by this section.

[[2003 1st sp.s. c 29 § 9](#); [1986 c 303 § 10](#).]

NOTES:

***Reviser's note:** RCW [41.05.011](#) was alphabetized pursuant to RCW [1.08.015](#)(2)(k), changing subsection (2) to subsection (21). RCW [41.05.011](#) was subsequently alphabetized pursuant to RCW [1.08.015](#)(2)(k), changing subsection (21) to subsection (22). RCW [41.05.011](#) was subsequently amended by 2017 3rd sp.s. c 13 § 802, changing subsection (22) to subsection (25). RCW [41.05.011](#) was subsequently amended by 2018 c 260 § 4, changing subsection (25) to subsection (26).

Finding—Intent—Severability—Conflict with federal requirements—Effective date—2003 1st sp.s. c 29: See notes following RCW [74.09.650](#).

RCW [70.14.060](#)

Prescription drug purchasing consortium—Participation—Exceptions—Rules.

(1) The administrator of the state health care authority shall, directly or by contract, adopt policies necessary for establishment of a prescription drug purchasing consortium. The consortium's purchasing activities shall be based upon the evidence-based prescription drug program established under RCW [70.14.050](#). State purchased health care programs as defined in RCW [41.05.011](#) shall purchase prescription drugs through the consortium for those prescription drugs that are purchased directly by the state and those that are purchased through reimbursement of pharmacies, unless exempted under this section. The administrator shall not require any supplemental rebate offered to the department of social and health services by a pharmaceutical manufacturer for prescription drugs purchased for medical assistance program clients under chapter [74.09](#) RCW be extended to any other state purchased health care program, or to any other individuals or entities participating in the consortium. The administrator shall explore joint purchasing opportunities with other states.

(2) Participation in the purchasing consortium shall be offered as an option beginning January 1, 2006. Participation in the consortium is purely voluntary for units of local government, private entities, labor organizations, and for individuals who lack or are underinsured for prescription drug coverage. The administrator may set reasonable fees, including enrollment fees, to cover administrative costs attributable to participation in the prescription drug consortium.

(3) This section does not apply to state purchased health care services that are purchased from or through health carriers as defined in RCW [48.43.005](#), or group model health maintenance organizations that are accredited by the national committee for quality assurance.

(4) The state health care authority is authorized to adopt rules implementing chapter 129, Laws of 2005.

(5) State purchased health care programs are exempt from the requirements of this section if they can demonstrate to the administrator that, as a result of the availability of federal programs or other purchasing arrangements, their other purchasing mechanisms will result in greater discounts and aggregate cost savings than would be realized through participation in the consortium.

[[2009 c 560 § 13](#); [2005 c 129 § 1](#).]

NOTES:

Intent—Effective date—Disposition of property and funds—Assignment/delegation of contractual rights or duties—2009 c 560: See notes following RCW [18.06.080](#).

Performance audit—2005 c 129 § 1: "By December 1, 2008, the joint legislative audit and review committee shall conduct a performance audit on the operation of the consortium created in section 1 of this act. The audit shall review the operations and outcomes associated with the implementation of this consortium and identify the net savings, if any, to the members of the consortium, the percentage of targeted populations participating, and changes in the health outcomes of participants." [[2005 c 129 § 3](#).]

Severability—2005 c 129: "If any provision of this act or its application to any person or circumstance is held invalid, the remainder of the act or the application of the provision to other persons or circumstances is not affected." [[2005 c 129 § 4](#).]

Conflict with federal requirements—2005 c 129: "If any part of this act is found to be in conflict with federal requirements that are a prescribed condition to the allocation of federal funds to the state, the conflicting part of this act is inoperative solely to the extent of the conflict and with respect to the agencies directly affected, and this finding does not affect the operation of the remainder of this act in its application to the agencies concerned. Rules adopted under this act must meet federal requirements that are a necessary condition to the receipt of federal funds by the state." [[2005 c 129 § 5](#).]

RCW [70.14.070](#)

Prescription drug consortium account.

The prescription drug consortium account is created in the custody of the state treasurer. All receipts from activities related to administration of the state drug purchasing consortium on behalf of participating individuals and organizations, other than state purchased health care programs, shall be deposited into the account. The receipts include but are not limited to rebates from manufacturers, and the fees established under RCW [70.14.060](#)(2). Expenditures from the

account may be used only for the purposes of RCW [70.14.060](#). Only the administrator of the state health care authority or the administrator's designee may authorize expenditures from the account. The account is subject to allotment procedures under chapter [43.88](#) RCW, but an appropriation is not required for expenditures.

[[2005 c 129 § 2.](#)]

NOTES:

Severability—Conflict with federal requirements—2005 c 129: See notes following RCW [70.14.060](#).

RCW [70.14.080](#)

Definitions.

The definitions in this section apply throughout RCW [70.14.090](#) through [70.14.130](#) unless the context clearly requires otherwise.

(1) "Administrator" means the administrator of the Washington state health care authority under chapter [41.05](#) RCW.

(2) "Advisory group" means a group established under RCW [70.14.110](#)(2)(c).

(3) "Committee" means the health technology clinical committee established under RCW [70.14.090](#).

(4) "Coverage determination" means a determination of the circumstances, if any, under which a health technology will be included as a covered benefit in a state purchased health care program.

(5) "Health technology" means medical and surgical devices and procedures, medical equipment, and diagnostic tests. Health technologies does not include prescription drugs governed by RCW [70.14.050](#).

(6) "Participating agency" means the department of social and health services, the state health care authority, and the department of labor and industries.

(7) "Reimbursement determination" means a determination to provide or deny reimbursement for a health technology included as a covered benefit in a specific circumstance for an individual patient who is eligible to receive health care services from the state purchased health care program making the determination.

[[2006 c 307 § 1.](#)]

NOTES:



Captions not law—2006 c 307: "Captions used in this act are not any part of the law." [[2006 c 307 § 10.](#)]

Conflict with federal requirements—2006 c 307: "If any part of this act is found to be in conflict with federal requirements that are a prescribed condition to the allocation of federal funds to the state, the conflicting part of this act is inoperative solely to the extent of the conflict and with respect to the agencies directly affected, and this finding does not affect the operation of the remainder of this act in its application to the agencies concerned. Rules adopted under this act must meet federal requirements that are a necessary condition to the receipt of federal funds by the state." [[2006 c 307 § 11.](#)]



Appendix C: Oregon Prescription Drug Price Transparency Legislation



Enrolled House Bill 4005

Sponsored by Representatives NOSSE, NOBLE, Senators BEYER, LINTHICUM, STEINER HAYWARD; Representatives ALONSO LEON, BARNHART, FAHEY, HOLVEY, KENY-GUYER, KOTEK, LIVELY, MARSH, MCKEOWN, MCLAIN, MEEK, POWER, SALINAS, SMITH DB, SOLLMAN, Senators BOQUIST, JOHNSON, MONNES ANDERSON, TAYLOR (Pre-session filed.)

CHAPTER

AN ACT

Relating to the price of prescription drugs; creating new provisions; amending ORS 743.018 and 750.055; and declaring an emergency.

Whereas the state has a substantial public interest in the price and cost of prescription drugs; and

Whereas the state is a major purchaser of prescription drugs through the Public Employees' Benefit Board, the Oregon Health Authority, the Department of Human Services and the Department of Corrections; and

Whereas the state also provides major tax expenditures for health care through the tax exclusion of employer-sponsored health insurance coverage and the deductibility of the excess medical costs of individuals and families; and

Whereas the Legislative Assembly intends by sections 2, 3 and 5 of this 2018 Act to provide notice and disclosure of information relating to the cost and pricing of prescription drugs in order to provide accountability for prescription drug pricing; and

Whereas the Legislative Assembly intends by this 2018 Act to permit a manufacturer of a prescription drug to voluntarily make pricing decisions regarding a prescription drug, including decisions that result in price increases; and

Whereas the Legislative Assembly intends by this 2018 Act to permit purchasers, both public and private, as well as pharmacy benefit managers, to negotiate discounts and rebates for prescription drugs consistent with existing state and federal law; now, therefore,

Be It Enacted by the People of the State of Oregon:

SECTION 1. Sections 2 and 3 of this 2018 Act shall be known and may be cited as the Prescription Drug Price Transparency Act.

SECTION 2. (1) As used in this section:

- (a) "Drug" has the meaning given that term in ORS 689.005.**
- (b) "Health care facility" has the meaning given that term in ORS 442.015.**
- (c) "Health care service contractor" has the meaning given that term in ORS 750.005.**
- (d)(A) "Manufacture" means:**

(i) The production, preparation, propagation, compounding, conversion or processing of a drug, either directly or indirectly by extraction from substances of natural origin or inde-

pendently by means of chemical synthesis, or by a combination of extraction and chemical synthesis; and

(ii) The packaging or repackaging of a drug or labeling or relabeling of a drug container.

(B) "Manufacture" does not include the preparation or compounding of a drug by an individual for the individual's own use or the preparation, compounding, packaging or labeling of a drug:

(i) By a health care practitioner incidental to administering or dispensing a drug in the course of professional practice;

(ii) By a health care practitioner or at the practitioner's authorization and supervision for the purpose of or incidental to research, teaching or chemical analysis activities and not for sale;

(iii) By a health care service contractor for dispensing to a subscriber or delivery to a health care facility or outpatient clinic owned or operated by the health care service contractor or an affiliate of the health care service contractor;

(iv) By a centralized repackaging operation for distribution to subscribers of health care service contractors or to pharmacies, health care facilities or outpatient clinics operated by or affiliated with a health care service contractor; or

(v) By a health care facility for dispensing to a patient or other person.

(e) "Manufacturer" means a person that manufactures a prescription drug that is sold in this state.

(f) "New prescription drug" has the meaning prescribed by the Department of Consumer and Business Services by rule.

(g) "Patient assistance program" means a program that a manufacturer offers to the general public in which a consumer may reduce the consumer's out-of-pocket costs for prescription drugs by using coupons or discount cards, receiving copayment assistance or by other means.

(h) "Prescription drug" means a drug that must:

(A) Under federal law, be labeled "Caution: Federal law prohibits dispensing without prescription" prior to being dispensed or delivered; or

(B) Under any applicable federal or state law or regulation, be dispensed only by prescription or restricted to use only by health care practitioners.

(i) "Price" means the wholesale acquisition cost as defined in 42 U.S.C. 1395w-3a(c)(6)(B).

(2) No later than July 1, 2019, a manufacturer shall report the information described in subsection (3) of this section to the department regarding each prescription drug for which:

(a) The price was \$100 or more for a one-month supply or for a course of treatment lasting less than one month; and

(b) There was a net increase of 10 percent or more in the price of the prescription drug described in paragraph (a) of this subsection over the course of the previous calendar year.

(3) For each prescription drug described in subsection (2) of this section, a manufacturer shall report to the department, in the form and manner prescribed by the department:

(a) The name and price of the prescription drug and the net increase, expressed as a percentage, in the price of the drug over the course of the previous calendar year;

(b) The length of time the prescription drug has been on the market;

(c) The factors that contributed to the price increase;

(d) The name of any generic version of the prescription drug available on the market;

(e) The research and development costs associated with the prescription drug that were paid using public funds;

(f) The direct costs incurred by the manufacturer:

(A) To manufacture the prescription drug;

(B) To market the prescription drug;

(C) To distribute the prescription drug; and

(D) For ongoing safety and effectiveness research associated with the prescription drug;

(g) The total sales revenue for the prescription drug during the previous calendar year;
(h) The manufacturer's profit attributable to the prescription drug during the previous calendar year;

(i) The introductory price of the prescription drug when it was approved for marketing by the United States Food and Drug Administration and the net yearly increase, by calendar year, in the price of the prescription drug during the previous five years;

(j) The 10 highest prices paid for the prescription drug during the previous calendar year in any country other than the United States;

(k) Any other information that the manufacturer deems relevant to the price increase described in subsection (2)(b) of this section; and

(L) The documentation necessary to support the information reported under this subsection.

(4) The department may use any prescription drug price information the department deems appropriate to verify that manufacturers have properly reported price increases as required by subsections (2) and (3) of this section.

(5) A manufacturer shall accompany the report provided under subsection (2) of this section with the following information about each patient assistance program offered by the manufacturer to consumers residing in this state for the prescription drugs described in subsection (2) of this section:

(a) The number of consumers who participated in the program;

(b) The total value of the coupons, discounts, copayment assistance or other reduction in costs provided to consumers in this state who participated in the program;

(c) For each drug, the number of refills that qualify for the program, if applicable;

(d) If the program expires after a specified period of time, the period of time that the program is available to each consumer; and

(e) The eligibility criteria for the program and how eligibility is verified for accuracy.

(6) Beginning March 15, 2019, 30 days or less after a manufacturer introduces a new prescription drug for sale in the United States at a price that exceeds the threshold established by the Centers for Medicare and Medicaid Services for specialty drugs in the Medicare Part D program, the manufacturer shall notify the department, in the form and manner prescribed by the department, of all the following information:

(a) A description of the marketing used in the introduction of the new prescription drug;

(b) The methodology used to establish the price of the new prescription drug;

(c) Whether the United States Food and Drug Administration granted the new prescription drug a breakthrough therapy designation or a priority review;

(d) If the new prescription drug was not developed by the manufacturer, the date of and the price paid for acquisition of the new prescription drug by the manufacturer;

(e) The manufacturer's estimate of the average number of patients who will be prescribed the new prescription drug each month; and

(f) The research and development costs associated with the new prescription drug that were paid using public funds.

(7)(a) After receiving the report or information described in subsections (2), (3), (5) or (6) of this section, the department may make a written request to the manufacturer for supporting documentation or additional information concerning the report. The department shall prescribe by rule the periods:

(A) Following the receipt of the report or information during which the department may request additional information; and

(B) Following a request by the department for additional information during which a manufacturer may respond to the request.

(b) The department may extend the period prescribed under paragraph (a)(B) of this subsection, as necessary, on a case-by-case basis.

(8) A manufacturer may be subject to a civil penalty, as provided in section 3 of this 2018 Act, for:

- (a) Failing to submit timely reports or notices as required by this section;
- (b) Failing to provide information required under this section;
- (c) Failing to respond in a timely manner to a written request by the department for additional information under subsection (7) of this section; or
- (d) Providing inaccurate or incomplete information under this section.

(9) Except as provided in subsection (10) of this section, the department shall post to its website all of the following information:

(a) A list of the prescription drugs reported under subsection (2) of this section and the manufacturers of those prescription drugs;

(b) Information reported to the department under subsections (3) and (5) to (7) of this section; and

(c) Written requests by the department for additional information under subsection (7) of this section.

(10)(a) The department may not post to its website any information described in subsection (9) of this section if:

(A) The information is conditionally exempt from disclosure under ORS 192.345 as a trade secret; and

(B) The public interest does not require disclosure of the information.

(b) If the department withholds any information from public disclosure pursuant to this subsection, the department shall post to its website a report describing the nature of the information and the department's basis for withholding the information from disclosure.

(c) A person may petition the Attorney General, as provided in ORS 192.411, to review a decision by the department to withhold information pursuant to paragraph (a) of this subsection.

(11) The department shall make available to consumers, online and by telephone, a process for consumers to notify the department about an increase in the price of a prescription drug.

(12) The department may adopt rules as necessary for carrying out the provisions of this section, including but not limited to rules establishing fees to be paid by manufacturers to be used solely to pay the costs of the department in carrying out the provisions of this section.

(13) No later than December 15 of each year, the department shall compile and report the information collected by the department under this section to the interim committees of the Legislative Assembly related to health. The report shall include recommendations for legislative changes, if any, to contain the cost of prescription drugs and reduce the impact of price increases on consumers, the Department of Corrections, the Public Employees' Benefit Board, the Oregon Health Authority, the Department of Human Services, the Oregon Educators Benefit Board and health insurance premiums in the commercial market.

SECTION 3. (1) A manufacturer that fails to report or provide information as required by section 2 of this 2018 Act may be subject to a civil penalty as provided in this section.

(2) The Department of Consumer and Business Services shall adopt a schedule of penalties, not to exceed \$10,000 per day of violation, based on the severity of each violation.

(3) The department shall impose civil penalties under this section as provided in ORS 183.745.

(4) The department may remit or mitigate civil penalties under this section upon terms and conditions the department considers proper and consistent with the public health and safety.

(5) Civil penalties collected under this section shall be paid over to the State Treasurer and deposited in the General Fund to be made available for general governmental expenses.

SECTION 4. Section 5 of this 2018 Act is added to and made a part of the Insurance Code.

SECTION 5. (1) An insurer shall include with any filing under ORS 743.018 the following information regarding drugs reimbursed by the insurer under policies or certificates issued in this state:

- (a) The 25 most frequently prescribed drugs;**
- (b) The 25 most costly drugs as a portion of total annual spending;**
- (c) The 25 drugs that have caused the greatest increase in total plan spending from one year to the next; and**
- (d) The impact of the costs of prescription drugs on premium rates.**

(2) The Department of Consumer and Business Services shall conduct a public hearing annually on prescription drug prices, information reported to the department under section 2 of this 2018 Act and information described in subsection (1) of this section.

(3) The department shall regularly update the interim committees of the Legislative Assembly related to health on the information described in subsection (1) of this section.

(4) Subsection (1) of this section applies to an insurer that issues policies or certificates of health insurance for sale in this state that include a prescription drug benefit.

SECTION 6. Section 2 of this 2018 Act is amended to read:

Sec. 2. (1) As used in this section:

- (a) “Drug” has the meaning given that term in ORS 689.005.**
- (b) “Health care facility” has the meaning given that term in ORS 442.015.**
- (c) “Health care service contractor” has the meaning given that term in ORS 750.005.**
- (d)(A) “Manufacture” means:**
 - (i) The production, preparation, propagation, compounding, conversion or processing of a drug, either directly or indirectly by extraction from substances of natural origin or independently by means of chemical synthesis, or by a combination of extraction and chemical synthesis; and**
 - (ii) The packaging or repackaging of a drug or labeling or relabeling of a drug container.**
- (B) “Manufacture” does not include the preparation or compounding of a drug by an individual for the individual’s own use or the preparation, compounding, packaging or labeling of a drug:**
 - (i) By a health care practitioner incidental to administering or dispensing a drug in the course of professional practice;**
 - (ii) By a health care practitioner or at the practitioner’s authorization and supervision for the purpose of or incidental to research, teaching or chemical analysis activities and not for sale;**
 - (iii) By a health care service contractor for dispensing to a subscriber or delivery to a health care facility or outpatient clinic owned or operated by the health care service contractor or an affiliate of the health care service contractor;**
 - (iv) By a centralized repackaging operation for distribution to subscribers of health care service contractors or to pharmacies, health care facilities or outpatient clinics operated by or affiliated with a health care service contractor; or**
 - (v) By a health care facility for dispensing to a patient or other person.**
- (e) “Manufacturer” means a person that manufactures a prescription drug that is sold in this state.**
- (f) “New prescription drug” has the meaning prescribed by the Department of Consumer and Business Services by rule.**
- (g) “Patient assistance program” means a program that a manufacturer offers to the general public in which a consumer may reduce the consumer’s out-of-pocket costs for prescription drugs by using coupons or discount cards, receiving copayment assistance or by other means.**
- (h) “Prescription drug” means a drug that must:**
 - (A) Under federal law, be labeled “Caution: Federal law prohibits dispensing without prescription” prior to being dispensed or delivered; or**
 - (B) Under any applicable federal or state law or regulation, be dispensed only by prescription or restricted to use only by health care practitioners.**
- (i) “Price” means the wholesale acquisition cost as defined in 42 U.S.C. 1395w-3a(c)(6)(B).**

(2) No later than July 1, 2019, a manufacturer shall report the information described in subsection (3) of this section to the department regarding each prescription drug for which:

(a) The price was \$100 or more for a one-month supply or for a course of treatment lasting less than one month; and

(b) There was a net increase of 10 percent or more in the price of the prescription drug described in paragraph (a) of this subsection over the course of the previous calendar year.

(3) For each prescription drug described in subsection (2) of this section, a manufacturer shall report to the department, in the form and manner prescribed by the department:

(a) The name and price of the prescription drug and the net increase, expressed as a percentage, in the price of the drug over the course of the previous calendar year;

(b) The length of time the prescription drug has been on the market;

(c) The factors that contributed to the price increase;

(d) The name of any generic version of the prescription drug available on the market;

(e) The research and development costs associated with the prescription drug that were paid using public funds;

(f) The direct costs incurred by the manufacturer:

(A) To manufacture the prescription drug;

(B) To market the prescription drug;

(C) To distribute the prescription drug; and

(D) For ongoing safety and effectiveness research associated with the prescription drug;

(g) The total sales revenue for the prescription drug during the previous calendar year;

(h) The manufacturer's profit attributable to the prescription drug during the previous calendar year;

(i) The introductory price of the prescription drug when it was approved for marketing by the United States Food and Drug Administration and the net yearly increase, by calendar year, in the price of the prescription drug during the previous five years;

(j) The 10 highest prices paid for the prescription drug during the previous calendar year in any country other than the United States;

(k) Any other information that the manufacturer deems relevant to the price increase described in subsection (2)(b) of this section; and

(L) The documentation necessary to support the information reported under this subsection.

(4) The department may use any prescription drug price information the department deems appropriate to verify that manufacturers have properly reported price increases as required by subsections (2) and (3) of this section.

(5) A manufacturer shall accompany the report provided under subsection (2) of this section with the following information about each patient assistance program offered by the manufacturer to consumers residing in this state for the prescription drugs described in subsection (2) of this section:

(a) The number of consumers who participated in the program;

(b) The total value of the coupons, discounts, copayment assistance or other reduction in costs provided to consumers in this state who participated in the program;

(c) For each drug, the number of refills that qualify for the program, if applicable;

(d) If the program expires after a specified period of time, the period of time that the program is available to each consumer; and

(e) The eligibility criteria for the program and how eligibility is verified for accuracy.

(6) *[Beginning March 15, 2019, 30 days or less]* **No later than 30 days** after a manufacturer introduces a new prescription drug for sale in the United States at a price that exceeds the threshold established by the Centers for Medicare and Medicaid Services for specialty drugs in the Medicare Part D program, the manufacturer shall notify the department, in the form and manner prescribed by the department, of all the following information:

(a) A description of the marketing used in the introduction of the new prescription drug;

(b) The methodology used to establish the price of the new prescription drug;

(c) Whether the United States Food and Drug Administration granted the new prescription drug a breakthrough therapy designation or a priority review;

(d) If the new prescription drug was not developed by the manufacturer, the date of and the price paid for acquisition of the new prescription drug by the manufacturer;

(e) The manufacturer's estimate of the average number of patients who will be prescribed the new prescription drug each month; and

(f) The research and development costs associated with the new prescription drug that were paid using public funds.

(7)(a) After receiving the report or information described in subsections (2), (3), (5) or (6) of this section, the department may make a written request to the manufacturer for supporting documentation or additional information concerning the report. The department shall prescribe by rule the periods:

(A) Following the receipt of the report or information during which the department may request additional information; and

(B) Following a request by the department for additional information during which a manufacturer may respond to the request.

(b) The department may extend the period prescribed under paragraph (a)(B) of this subsection, as necessary, on a case-by-case basis.

(8) A manufacturer may be subject to a civil penalty, as provided in section 3 of this 2018 Act, for:

(a) Failing to submit timely reports or notices as required by this section;

(b) Failing to provide information required under this section;

(c) Failing to respond in a timely manner to a written request by the department for additional information under subsection (7) of this section; or

(d) Providing inaccurate or incomplete information under this section.

(9) Except as provided in subsection (10) of this section, the department shall post to its website all of the following information:

(a) A list of the prescription drugs reported under subsection (2) of this section and the manufacturers of those prescription drugs;

(b) Information reported to the department under subsections (3) and (5) to (7) of this section; and

(c) Written requests by the department for additional information under subsection (7) of this section.

(10)(a) The department may not post to its website any information described in subsection (9) of this section if:

(A) The information is conditionally exempt from disclosure under ORS 192.345 as a trade secret; and

(B) The public interest does not require disclosure of the information.

(b) If the department withholds any information from public disclosure pursuant to this subsection, the department shall post to its website a report describing the nature of the information and the department's basis for withholding the information from disclosure.

(c) A person may petition the Attorney General, as provided in ORS 192.411, to review a decision by the department to withhold information pursuant to paragraph (a) of this subsection.

(11) The department shall make available to consumers, online and by telephone, a process for consumers to notify the department about an increase in the price of a prescription drug.

(12) The department may adopt rules as necessary for carrying out the provisions of this section, including but not limited to rules establishing fees to be paid by manufacturers to be used solely to pay the costs of the department in carrying out the provisions of this section.

(13) No later than December 15 of each year, the department shall compile and report the information collected by the department under this section to the interim committees of the Legislative Assembly related to health. The report shall include recommendations for legislative changes, if any, to contain the cost of prescription drugs and reduce the impact of price increases on con-

sumers, the Department of Corrections, the Public Employees' Benefit Board, the Oregon Health Authority, the Department of Human Services, the Oregon Educators Benefit Board and health insurance premiums in the commercial market.

SECTION 7. Section 2 of this 2018 Act, as amended by section 6 of this 2018 Act, is amended to read:

Sec. 2. (1) As used in this section:

(a) "Drug" has the meaning given that term in ORS 689.005.

(b) "Health care facility" has the meaning given that term in ORS 442.015.

(c) "Health care service contractor" has the meaning given that term in ORS 750.005.

(d)(A) "Manufacture" means:

(i) The production, preparation, propagation, compounding, conversion or processing of a drug, either directly or indirectly by extraction from substances of natural origin or independently by means of chemical synthesis, or by a combination of extraction and chemical synthesis; and

(ii) The packaging or repackaging of a drug or labeling or relabeling of a drug container.

(B) "Manufacture" does not include the preparation or compounding of a drug by an individual for the individual's own use or the preparation, compounding, packaging or labeling of a drug:

(i) By a health care practitioner incidental to administering or dispensing a drug in the course of professional practice;

(ii) By a health care practitioner or at the practitioner's authorization and supervision for the purpose of or incidental to research, teaching or chemical analysis activities and not for sale;

(iii) By a health care service contractor for dispensing to a subscriber or delivery to a health care facility or outpatient clinic owned or operated by the health care service contractor or an affiliate of the health care service contractor;

(iv) By a centralized repackaging operation for distribution to subscribers of health care service contractors or to pharmacies, health care facilities or outpatient clinics operated by or affiliated with a health care service contractor; or

(v) By a health care facility for dispensing to a patient or other person.

(e) "Manufacturer" means a person that manufactures a prescription drug that is sold in this state.

(f) "New prescription drug" has the meaning prescribed by the Department of Consumer and Business Services by rule.

(g) "Patient assistance program" means a program that a manufacturer offers to the general public in which a consumer may reduce the consumer's out-of-pocket costs for prescription drugs by using coupons or discount cards, receiving copayment assistance or by other means.

(h) "Prescription drug" means a drug that must:

(A) Under federal law, be labeled "Caution: Federal law prohibits dispensing without prescription" prior to being dispensed or delivered; or

(B) Under any applicable federal or state law or regulation, be dispensed only by prescription or restricted to use only by health care practitioners.

(i) "Price" means the wholesale acquisition cost as defined in 42 U.S.C. 1395w-3a(c)(6)(B).

(2) No later than [July 1, 2019] **March 15 of each year**, a manufacturer shall report the information described in subsection (3) of this section to the department regarding each prescription drug for which:

(a) The price was \$100 or more for a one-month supply or for a course of treatment lasting less than one month; and

(b) There was a net increase of 10 percent or more in the price of the prescription drug described in paragraph (a) of this subsection over the course of the previous calendar year.

(3) For each prescription drug described in subsection (2) of this section, a manufacturer shall report to the department, in the form and manner prescribed by the department:

(a) The name and price of the prescription drug and the net increase, expressed as a percentage, in the price of the drug over the course of the previous calendar year;

(b) The length of time the prescription drug has been on the market;

- (c) The factors that contributed to the price increase;
 - (d) The name of any generic version of the prescription drug available on the market;
 - (e) The research and development costs associated with the prescription drug that were paid using public funds;
 - (f) The direct costs incurred by the manufacturer:
 - (A) To manufacture the prescription drug;
 - (B) To market the prescription drug;
 - (C) To distribute the prescription drug; and
 - (D) For ongoing safety and effectiveness research associated with the prescription drug;
 - (g) The total sales revenue for the prescription drug during the previous calendar year;
 - (h) The manufacturer's profit attributable to the prescription drug during the previous calendar year;
 - (i) The introductory price of the prescription drug when it was approved for marketing by the United States Food and Drug Administration and the net yearly increase, by calendar year, in the price of the prescription drug during the previous five years;
 - (j) The 10 highest prices paid for the prescription drug during the previous calendar year in any country other than the United States;
 - (k) Any other information that the manufacturer deems relevant to the price increase described in subsection (2)(b) of this section; and
 - (L) The documentation necessary to support the information reported under this subsection.
- (4) The department may use any prescription drug price information the department deems appropriate to verify that manufacturers have properly reported price increases as required by subsections (2) and (3) of this section.
- (5) A manufacturer shall accompany the report provided under subsection (2) of this section with the following information about each patient assistance program offered by the manufacturer to consumers residing in this state for the prescription drugs described in subsection (2) of this section:
- (a) The number of consumers who participated in the program;
 - (b) The total value of the coupons, discounts, copayment assistance or other reduction in costs provided to consumers in this state who participated in the program;
 - (c) For each drug, the number of refills that qualify for the program, if applicable;
 - (d) If the program expires after a specified period of time, the period of time that the program is available to each consumer; and
 - (e) The eligibility criteria for the program and how eligibility is verified for accuracy.
- (6) No later than 30 days after a manufacturer introduces a new prescription drug for sale in the United States at a price that exceeds the threshold established by the Centers for Medicare and Medicaid Services for specialty drugs in the Medicare Part D program, the manufacturer shall notify the department, in the form and manner prescribed by the department, of all the following information:
- (a) A description of the marketing used in the introduction of the new prescription drug;
 - (b) The methodology used to establish the price of the new prescription drug;
 - (c) Whether the United States Food and Drug Administration granted the new prescription drug a breakthrough therapy designation or a priority review;
 - (d) If the new prescription drug was not developed by the manufacturer, the date of and the price paid for acquisition of the new prescription drug by the manufacturer;
 - (e) The manufacturer's estimate of the average number of patients who will be prescribed the new prescription drug each month; and
 - (f) The research and development costs associated with the new prescription drug that were paid using public funds.

(7)(a) After receiving the report or information described in subsections (2), (3), (5) or (6) of this section, the department may make a written request to the manufacturer for supporting documentation or additional information concerning the report. The department shall prescribe by rule the periods:

(A) Following the receipt of the report or information during which the department may request additional information; and

(B) Following a request by the department for additional information during which a manufacturer may respond to the request.

(b) The department may extend the period prescribed under paragraph (a)(B) of this subsection, as necessary, on a case-by-case basis.

(8) A manufacturer may be subject to a civil penalty, as provided in section 3 of this 2018 Act, for:

(a) Failing to submit timely reports or notices as required by this section;

(b) Failing to provide information required under this section;

(c) Failing to respond in a timely manner to a written request by the department for additional information under subsection (7) of this section; or

(d) Providing inaccurate or incomplete information under this section.

(9) Except as provided in subsection (10) of this section, the department shall post to its website all of the following information:

(a) A list of the prescription drugs reported under subsection (2) of this section and the manufacturers of those prescription drugs;

(b) Information reported to the department under subsections (3) and (5) to (7) of this section; and

(c) Written requests by the department for additional information under subsection (7) of this section.

(10)(a) The department may not post to its website any information described in subsection (9) of this section if:

(A) The information is conditionally exempt from disclosure under ORS 192.345 as a trade secret; and

(B) The public interest does not require disclosure of the information.

(b) If the department withholds any information from public disclosure pursuant to this subsection, the department shall post to its website a report describing the nature of the information and the department's basis for withholding the information from disclosure.

(c) A person may petition the Attorney General, as provided in ORS 192.411, to review a decision by the department to withhold information pursuant to paragraph (a) of this subsection.

(11) The department shall make available to consumers, online and by telephone, a process for consumers to notify the department about an increase in the price of a prescription drug.

(12) The department may adopt rules as necessary for carrying out the provisions of this section, including but not limited to rules establishing fees to be paid by manufacturers to be used solely to pay the costs of the department in carrying out the provisions of this section.

(13) No later than December 15 of each year, the department shall compile and report the information collected by the department under this section to the interim committees of the Legislative Assembly related to health. The report shall include recommendations for legislative changes, if any, to contain the cost of prescription drugs and reduce the impact of price increases on consumers, the Department of Corrections, the Public Employees' Benefit Board, the Oregon Health Authority, the Department of Human Services, the Oregon Educators Benefit Board and health insurance premiums in the commercial market.

SECTION 8. ORS 743.018 is amended to read:

743.018. (1) Except for group life and health insurance, and except as provided in ORS 743.015, every insurer shall file with the Director of the Department of Consumer and Business Services all schedules and tables of premium rates for life and health insurance to be used on risks in this state, and shall file any amendments to or corrections of such schedules and tables. Premium rates are subject to approval, disapproval or withdrawal of approval by the director as provided in ORS 742.003, 742.005, 742.007 and 743.019.

(2) Except as provided in ORS 743B.013 and subsection (3) of this section, a rate filing by a carrier for any of the following health benefit plans subject to ORS 743.004, 743.022, 743.535 and

743B.003 to 743B.127 shall be available for public inspection immediately upon submission of the filing to the director:

- (a) Health benefit plans for small employers.
- (b) Individual health benefit plans.
- (3) The director may by rule:
 - (a) Specify all information a carrier must submit as part of a rate filing under this section; and
 - (b) Identify the information submitted that will be exempt from disclosure under this section because the information constitutes a trade secret and would, if disclosed, harm competition.
- (4) The director, after conducting an actuarial review of the rate filing, may approve a proposed premium rate for a health benefit plan for small employers or for an individual health benefit plan if, in the director's discretion, the proposed rates are:
 - (a) Actuarially sound;
 - (b) Reasonable and not excessive, inadequate or unfairly discriminatory; and
 - (c) Based upon reasonable administrative expenses.
- (5) In order to determine whether the proposed premium rates for a health benefit plan for small employers or for an individual health benefit plan are reasonable and not excessive, inadequate or unfairly discriminatory, the director may consider:
 - (a) The insurer's financial position, including but not limited to profitability, surplus, reserves and investment savings.
 - (b) Historical and projected administrative costs and medical and hospital expenses, **including expenses for drugs reported under section 5 of this 2018 Act.**
 - (c) Historical and projected loss ratio between the amounts spent on medical services and earned premiums.
 - (d) Any anticipated change in the number of enrollees if the proposed premium rate is approved.
 - (e) Changes to covered benefits or health benefit plan design.
 - (f) Changes in the insurer's health care cost containment and quality improvement efforts since the insurer's last rate filing for the same category of health benefit plan.
 - (g) Whether the proposed change in the premium rate is necessary to maintain the insurer's solvency or to maintain rate stability and prevent excessive rate increases in the future.
 - (h) Any public comments received under ORS 743.019 pertaining to the standards set forth in subsection (4) of this section and this subsection.
- (6) The requirements of this section do not supersede other provisions of law that require insurers, health care service contractors or multiple employer welfare arrangements providing health insurance to file schedules or tables of premium rates or proposed premium rates with the director or to seek the director's approval of rates or changes to rates.

SECTION 9. ORS 750.055 is amended to read:

750.055. (1) The following provisions apply to health care service contractors to the extent not inconsistent with the express provisions of ORS 750.005 to 750.095:

- (a) ORS 705.137, 705.138 and 705.139.
- (b) ORS 731.004 to 731.150, 731.162, 731.216 to 731.362, 731.382, 731.385, 731.386, 731.390, 731.398 to 731.430, 731.428, 731.450, 731.454, 731.485, as provided in subsection (2) of this section, ORS 731.488, 731.504, 731.508, 731.509, 731.510, 731.511, 731.512, 731.574 to 731.620, 731.640 to 731.652, 731.730, 731.731, 731.735, 731.737, 731.750, 731.752, 731.804, 731.808 and 731.844 to 731.992.
- (c) ORS 732.215, 732.220, 732.230, 732.245, 732.250, 732.320, 732.325 and 732.517 to 732.596, not including ORS 732.582.
- (d) ORS 733.010 to 733.050, 733.080, 733.140 to 733.170, 733.210, 733.510 to 733.680 and 733.695 to 733.780.
- (e) ORS 734.014 to 734.440.
- (f) ORS 735.600 to 735.650.
- (g) ORS 742.001 to 742.009, 742.013, 742.016, 742.061, 742.065, 742.150 to 742.162 and 742.518 to 742.542.

(h) ORS 743.004, 743.005, 743.007, 743.008, 743.010, 743.018, 743.019, 743.020, 743.022, 743.023, 743.028, 743.029, 743.038, 743.040, 743.044, 743.050, 743.100 to 743.109, 743.402, 743.405, 743.406, 743.417, 743.472, 743.492, 743.495, 743.498, 743.522, 743.523, 743.524, 743.526, 743.535, 743.550, 743.650 to 743.656, 743.680 to 743.689, 743.788 and 743.790.

(i) ORS 743A.010, 743A.012, 743A.014, 743A.020, 743A.034, 743A.036, 743A.040, 743A.044, 743A.048, 743A.051, 743A.052, 743A.058, 743A.060, 743A.062, 743A.063, 743A.064, 743A.065, 743A.066, 743A.068, 743A.070, 743A.080, 743A.082, 743A.084, 743A.088, 743A.090, 743A.100, 743A.104, 743A.105, 743A.108, 743A.110, 743A.124, 743A.140, 743A.141, 743A.148, 743A.150, 743A.160, 743A.168, 743A.170, 743A.175, 743A.185, 743A.188, 743A.190, 743A.192, 743A.250, 743A.252 and 743A.260 and section 2, chapter 771, Oregon Laws 2013.

(j) ORS 743B.001, 743B.003 to 743B.127, 743B.128, 743B.130, 743B.195 to 743B.204, 743B.220, 743B.222, 743B.225, 743B.227, 743B.250, 743B.252, 743B.253, 743B.254, 743B.255, 743B.256, 743B.257, 743B.258, 743B.280 to 743B.285, 743B.287, 743B.300, 743B.310, 743B.320, 743B.323, 743B.330, 743B.340, 743B.341, 743B.342, 743B.343 to 743B.347, 743B.400, 743B.403, 743B.407, 743B.420, 743B.423, 743B.450, 743B.451, 743B.452, 743B.453, 743B.470, 743B.475, 743B.505, 743B.550, 743B.555, 743B.601, 743B.602 and 743B.800 **and section 5 of this 2018 Act.**

(k) The following provisions of ORS chapter 744:

(A) ORS 744.001 to 744.009, 744.011, 744.013, 744.014, 744.018, 744.022 to 744.033, 744.037, 744.052 to 744.089, 744.091 and 744.093, relating to the regulation of insurance producers;

(B) ORS 744.605, 744.609, 744.619, 744.621, 744.626, 744.631, 744.635, 744.650, 744.655 and 744.665, relating to the regulation of insurance consultants; and

(C) ORS 744.700 to 744.740, relating to the regulation of third party administrators.

(L) ORS 746.005 to 746.140, 746.160, 746.220 to 746.370, 746.600, 746.605, 746.607, 746.608, 746.610, 746.615, 746.625, 746.635, 746.650, 746.655, 746.660, 746.668, 746.670, 746.675, 746.680 and 746.690.

(2) The following provisions of the Insurance Code apply to health care service contractors except in the case of group practice health maintenance organizations that are federally qualified pursuant to Title XIII of the Public Health Service Act:

(a) ORS 731.485, if the group practice health maintenance organization wholly owns and operates an in-house drug outlet.

(b) ORS 743A.024, unless the patient is referred by a physician, physician assistant or nurse practitioner associated with a group practice health maintenance organization.

(3) For the purposes of this section, health care service contractors are insurers.

(4) Any for-profit health care service contractor organized under the laws of any other state that is not governed by the insurance laws of the other state is subject to all requirements of ORS chapter 732.

(5)(a) A health care service contractor is a domestic insurance company for the purpose of determining whether the health care service contractor is a debtor, as defined in 11 U.S.C. 109.

(b) A health care service contractor's classification as a domestic insurance company under paragraph (a) of this subsection does not subject the health care service contractor to ORS 734.510 to 734.710.

(6) The Director of the Department of Consumer and Business Services may, after notice and hearing, adopt reasonable rules not inconsistent with this section and ORS 750.003, 750.005, 750.025 and 750.045 that are necessary for the proper administration of these provisions.

SECTION 10. ORS 750.055, as amended by section 21, chapter 771, Oregon Laws 2013, section 7, chapter 25, Oregon Laws 2014, section 82, chapter 45, Oregon Laws 2014, section 9, chapter 59, Oregon Laws 2015, section 7, chapter 100, Oregon Laws 2015, section 7, chapter 224, Oregon Laws 2015, section 11, chapter 362, Oregon Laws 2015, section 10, chapter 470, Oregon Laws 2015, section 30, chapter 515, Oregon laws 2015, section 10, chapter 206, Oregon Laws 2017, section 6, chapter 417, Oregon Laws 2017, and section 22, chapter 479, Oregon Laws 2017, is amended to read:

750.055. (1) The following provisions apply to health care service contractors to the extent not inconsistent with the express provisions of ORS 750.005 to 750.095:

(a) ORS 705.137, 705.138 and 705.139.

(b) ORS 731.004 to 731.150, 731.162, 731.216 to 731.362, 731.382, 731.385, 731.386, 731.390, 731.398 to 731.430, 731.428, 731.450, 731.454, 731.485, as provided in subsection (2) of this section, ORS 731.488, 731.504, 731.508, 731.509, 731.510, 731.511, 731.512, 731.574 to 731.620, 731.640 to 731.652, 731.730, 731.731, 731.735, 731.737, 731.750, 731.752, 731.804, 731.808 and 731.844 to 731.992.

(c) ORS 732.215, 732.220, 732.230, 732.245, 732.250, 732.320, 732.325 and 732.517 to 732.596, not including ORS 732.582.

(d) ORS 733.010 to 733.050, 733.080, 733.140 to 733.170, 733.210, 733.510 to 733.680 and 733.695 to 733.780.

(e) ORS 734.014 to 734.440.

(f) ORS 735.600 to 735.650.

(g) ORS 742.001 to 742.009, 742.013, 742.016, 742.061, 742.065, 742.150 to 742.162 and 742.518 to 742.542.

(h) ORS 743.004, 743.005, 743.007, 743.008, 743.010, 743.018, 743.019, 743.020, 743.022, 743.023, 743.028, 743.029, 743.038, 743.040, 743.044, 743.050, 743.100 to 743.109, 743.402, 743.405, 743.406, 743.417, 743.472, 743.492, 743.495, 743.498, 743.522, 743.523, 743.524, 743.526, 743.535, 743.550, 743.650 to 743.656, 743.680 to 743.689, 743.788 and 743.790.

(i) ORS 743A.010, 743A.012, 743A.014, 743A.020, 743A.034, 743A.036, 743A.040, 743A.044, 743A.048, 743A.051, 743A.052, 743A.058, 743A.060, 743A.062, 743A.063, 743A.064, 743A.065, 743A.066, 743A.068, 743A.070, 743A.080, 743A.082, 743A.084, 743A.088, 743A.090, 743A.100, 743A.104, 743A.105, 743A.108, 743A.110, 743A.124, 743A.140, 743A.141, 743A.148, 743A.150, 743A.160, 743A.168, 743A.170, 743A.175, 743A.185, 743A.188, 743A.190, 743A.192, 743A.250, 743A.252 and 743A.260.

(j) ORS 743B.001, 743B.003 to 743B.127, 743B.128, 743B.130, 743B.195 to 743B.204, 743B.220, 743B.222, 743B.225, 743B.227, 743B.250, 743B.252, 743B.253, 743B.254, 743B.255, 743B.256, 743B.257, 743B.258, 743B.280 to 743B.285, 743B.287, 743B.300, 743B.310, 743B.320, 743B.323, 743B.330, 743B.340, 743B.341, 743B.342, 743B.343 to 743B.347, 743B.400, 743B.403, 743B.407, 743B.420, 743B.423, 743B.450, 743B.451, 743B.452, 743B.453, 743B.470, 743B.475, 743B.505, 743B.550, 743B.555, 743B.601, 743B.602 and 743B.800 **and section 5 of this 2018 Act.**

(k) The following provisions of ORS chapter 744:

(A) ORS 744.001 to 744.009, 744.011, 744.013, 744.014, 744.018, 744.022 to 744.033, 744.037, 744.052 to 744.089, 744.091 and 744.093, relating to the regulation of insurance producers;

(B) ORS 744.605, 744.609, 744.619, 744.621, 744.626, 744.631, 744.635, 744.650, 744.655 and 744.665, relating to the regulation of insurance consultants; and

(C) ORS 744.700 to 744.740, relating to the regulation of third party administrators.

(L) ORS 746.005 to 746.140, 746.160, 746.220 to 746.370, 746.600, 746.605, 746.607, 746.608, 746.610, 746.615, 746.625, 746.635, 746.650, 746.655, 746.660, 746.668, 746.670, 746.675, 746.680 and 746.690.

(2) The following provisions of the Insurance Code apply to health care service contractors except in the case of group practice health maintenance organizations that are federally qualified pursuant to Title XIII of the Public Health Service Act:

(a) ORS 731.485, if the group practice health maintenance organization wholly owns and operates an in-house drug outlet.

(b) ORS 743A.024, unless the patient is referred by a physician, physician assistant or nurse practitioner associated with a group practice health maintenance organization.

(3) For the purposes of this section, health care service contractors are insurers.

(4) Any for-profit health care service contractor organized under the laws of any other state that is not governed by the insurance laws of the other state is subject to all requirements of ORS chapter 732.

(5)(a) A health care service contractor is a domestic insurance company for the purpose of determining whether the health care service contractor is a debtor, as defined in 11 U.S.C. 109.

(b) A health care service contractor's classification as a domestic insurance company under paragraph (a) of this subsection does not subject the health care service contractor to ORS 734.510 to 734.710.

(6) The Director of the Department of Consumer and Business Services may, after notice and hearing, adopt reasonable rules not inconsistent with this section and ORS 750.003, 750.005, 750.025 and 750.045 that are necessary for the proper administration of these provisions.

SECTION 11. (1) The Task Force on the Fair Pricing of Prescription Drugs is established.

(2) The task force consists of 18 members appointed as follows:

(a) The President of the Senate shall appoint:

(A) One member from the Senate who is a member of the majority party.

(B) One member from the Senate who is a member of the minority party.

(b) The Speaker of the House of Representatives shall appoint:

(A) One member from the House of Representatives who is a member of the majority party.

(B) One member from the House of Representatives who is a member of the minority party.

(c) The Governor shall appoint the following members:

(A) One representative from the Department of Consumer and Business Services;

(B) One representative from the Oregon Health Authority;

(C) One representative from the Oregon Health Policy Board; and

(D) Individuals representing:

(i) Pharmaceutical manufacturers;

(ii) Insurance companies offering health insurance in this state;

(iii) Pharmacy benefit managers;

(iv) Prescription drug wholesalers;

(v) Consumers;

(vi) Independent pharmacies;

(vii) Large retail pharmacy chains;

(viii) Hospitals;

(ix) Biopharmaceutical companies based in Oregon;

(x) Coordinated care organizations; and

(xi) Medical providers.

(3) The task force shall develop a strategy to create transparency for drug prices across the entire supply chain of pharmaceutical products, including but not limited to manufacturers, insurers, pharmacy benefit managers, distributors, wholesalers and retail pharmacies.

(4) A majority of the voting members of the task force constitutes a quorum for the transaction of business.

(5) Official action by the task force requires the approval of a majority of the voting members of the task force.

(6) The task force shall elect one of its members to serve as chairperson.

(7) If there is a vacancy for any cause, the appointing authority shall make an appointment to become immediately effective.

(8) The task force shall meet at times and places specified by the call of the chairperson or of a majority of the voting members of the task force.

(9) The task force may adopt rules necessary for the operation of the task force.

(10) The task force shall submit a report in the manner provided by ORS 192.245, and may include recommendations for legislation, to the interim committees of the Legislative Assembly related to health no later than November 1, 2018. The report must contain a cost-effective and enforceable solution that exposes the cost factors that negatively impact prices paid by Oregonians for pharmaceutical products.

(11) The Legislative Policy and Research Director shall provide staff support to the task force.

(12) Members of the Legislative Assembly appointed to the task force are nonvoting members of the task force and may act in an advisory capacity only.

(13) Members of the task force who are not members of the Legislative Assembly are not entitled to compensation or reimbursement for expenses and serve as volunteers on the task force.

(14) All agencies of state government, as defined in ORS 174.111, are directed to assist the task force in the performance of the task force's duties and, to the extent permitted by laws relating to confidentiality, to furnish information and advice the members of the task force consider necessary to perform their duties.

SECTION 12. Section 11 of this 2018 Act is repealed on December 31, 2020.

SECTION 13. (1) Sections 1 to 5 of this 2018 Act and the amendments to ORS 743.018 and 750.055 by sections 8 to 10 of this 2018 Act become operative on January 1, 2019.

(2) The Department of Consumer and Business Services shall take all steps necessary before January 1, 2019, to carry out the provisions of sections 1 to 5 of this 2018 Act and the amendments to ORS 743.018 and 750.055 by sections 8 to 10 of this 2018 Act on and after January 1, 2019.

(3) The amendments to section 2 of this 2018 Act by section 6 of this 2018 Act become operative on March 15, 2019.

(4) The amendments to section 2 of this 2018 Act by section 7 of this 2018 Act become operative on July 2, 2019.

SECTION 14. Notwithstanding any other law limiting expenditures, the limitation on expenditures established by section 1 (5), chapter 372, Oregon Laws 2017, for the biennium ending June 30, 2019, as the maximum limit for payment of expenses from fees, moneys or other revenues, including Miscellaneous Receipts, but excluding lottery funds and federal funds, collected or received by the Department of Consumer and Business Services, for the Division of Financial Regulation, is increased by \$425,022 for carrying out sections 2, 3 and 5 of this 2018 Act.

SECTION 15. This 2018 Act being necessary for the immediate preservation of the public peace, health and safety, an emergency is declared to exist, and this 2018 Act takes effect on its passage.

Passed by House February 28, 2018

.....
Timothy G. Sekerak, Chief Clerk of House

.....
Tina Kotek, Speaker of House

Passed by Senate March 2, 2018

.....
Peter Courtney, President of Senate

Received by Governor:

.....M.,....., 2018

Approved:

.....M.,....., 2018

.....
Kate Brown, Governor

Filed in Office of Secretary of State:

.....M.,....., 2018

.....
Dennis Richardson, Secretary of State

Appendix D: Oregon Prescription Drug Joint Purchasing Legislation

Statute - Oregon Prescription Drug Program⁶⁹

414.312 Oregon Prescription Drug Program. (1) As used in ORS 414.312 to 414.318:

(a) “Pharmacy benefit manager” means an entity that negotiates and executes contracts with pharmacies, manages preferred drug lists, negotiates rebates with prescription drug manufacturers and serves as an intermediary between the Oregon Prescription Drug Program, prescription drug manufacturers and pharmacies.

(b) “Prescription drug claims processor” means an entity that processes and pays prescription drug claims, adjudicates pharmacy claims, transmits prescription drug prices and claims data between pharmacies and the Oregon Prescription Drug Program and processes related payments to pharmacies.

(c) “Program price” means the reimbursement rates and prescription drug prices established by the administrator of the Oregon Prescription Drug Program.

(2) The Oregon Prescription Drug Program is established in the Oregon Health Authority. The purpose of the program is to:

(a) Purchase prescription drugs, replenish prescription drugs dispensed or reimburse pharmacies for prescription drugs in order to receive discounted prices and rebates;

(b) Make prescription drugs available at the lowest possible cost to participants in the program as a means to promote health;

(c) Maintain a list of prescription drugs recommended as the most effective prescription drugs available at the best possible prices; and

(d) Promote health through the purchase and provision of discount prescription drugs and coordination of comprehensive prescription benefit services for eligible entities and members.

(3) The Director of the Oregon Health Authority shall appoint an administrator of the Oregon Prescription Drug Program. The administrator may:

(a) Negotiate price discounts and rebates on prescription drugs with prescription drug manufacturers or group purchasing organizations;

(b) Purchase prescription drugs on behalf of individuals and entities that participate in the program;

(c) Contract with a prescription drug claims processor to adjudicate pharmacy claims and transmit program prices to pharmacies;

(d) Determine program prices and reimburse or replenish pharmacies for prescription drugs dispensed or transferred;

(e) Adopt and implement a preferred drug list for the program;

(f) Develop a system for allocating and distributing the operational costs of the program and any rebates obtained to participants of the program; and

(g) Cooperate with other states or regional consortia in the bulk purchase of prescription drugs.

(4) The following individuals or entities may participate in the program:

(a) Public Employees’ Benefit Board, Oregon Educators Benefit Board and Public Employees Retirement System;

⁶⁹ Statute - Oregon Prescription Drug Program – ORS 414.312 to 414.320, from <https://www.oregon.gov/oha/HPA/dsi-opdp/Pages/Statute.aspx>, accessed on October 3, 2019.



- (b) Local governments as defined in ORS 174.116 and special government bodies as defined in ORS 174.117 that directly or indirectly purchase prescription drugs;
 - (c) Oregon Health and Science University established under ORS 353.020;
 - (d) State agencies that directly or indirectly purchase prescription drugs, including agencies that dispense prescription drugs directly to persons in state-operated facilities;
 - (e) Residents of this state who lack or are underinsured for prescription drug coverage;
 - (f) Private entities; and
 - (g) Labor organizations.
- (5) The administrator may establish different program prices for pharmacies in rural areas to maintain statewide access to the program.
- (6) The administrator may establish the terms and conditions for a pharmacy to enroll in the program. A licensed pharmacy that is willing to accept the terms and conditions established by the administrator may apply to enroll in the program.
- (7) Except as provided in subsection (8) of this section, the administrator may not:
- (a) Contract with a pharmacy benefit manager;
 - (b) Establish a state-managed wholesale or retail drug distribution or dispensing system; or
 - (c) Require pharmacies to maintain or allocate separate inventories for prescription drugs dispensed through the program.
- (8) The administrator shall contract with one or more entities to perform any of the functions of the program, including but not limited to:
- (a) Contracting with a pharmacy benefit manager and directly or indirectly with such pharmacy networks as the administrator considers necessary to maintain statewide access to the program.
 - (b) Negotiating with prescription drug manufacturers on behalf of the administrator.
- (9) Notwithstanding subsection (4)(e) of this section, individuals who are eligible for Medicare Part D prescription drug coverage may participate in the program.
- (10) The program may contract with vendors as necessary to utilize discount purchasing programs, including but not limited to group purchasing organizations established to meet the criteria of the Nonprofit Institutions Act, 15 U.S.C. 13c, or that are exempt under the Robinson-Patman Act, 15 U.S.C. 13. [2003 c.714 §1; 2007 c.2 §1; 2007 c.67 §1; 2007 c.697 §17; 2009 c.263 §2; 2009 c.466 §1; 2009 c.595 §291; 2011 c.720 §136; 2013 c.14 §6; 2015 c.551 §1]

Note: 414.312 to 414.320 were enacted into law by the Legislative Assembly but were not added to or made a part of ORS chapter 414 or any series therein by legislative action. See Preface to Oregon Revised Statutes for further explanation.

414.314 Application and participation in Oregon Prescription Drug Program; prescription drug charges; fees. (1) An individual or entity described in ORS 414.312 (4) may apply to participate in the Oregon Prescription Drug Program. Participants shall apply on an application provided by the Oregon Health Authority. The authority may charge participants a nominal fee to participate in the program. The authority shall issue a prescription drug identification card to participants of the program.

(2) The authority shall provide a mechanism to calculate and transmit the program prices for prescription drugs to a pharmacy. The pharmacy shall charge the participant the program price for a prescription drug.

(3) A pharmacy may charge the participant the professional dispensing fee set by the authority.

(4) Prescription drug identification cards issued under this section must contain the information necessary for proper claims adjudication or transmission of price data. [2003 c.714 §2; 2007 c.67 §2; 2007 c.697 §18; 2009 c.595 §292]



Note: See note under 414.312.

414.316 [2003 c.714 §3; 2007 c.697 §19; 2009 c.595 §293; repealed by 2015 c.318 §56]

414.318 Prescription Drug Purchasing Fund. The Prescription Drug Purchasing Fund is established separate and distinct from the General Fund. The Prescription Drug Purchasing Fund shall consist of moneys appropriated to the fund by the Legislative Assembly and moneys received by the Oregon Health Authority for the purposes established in this section in the form of gifts, grants, bequests, endowments or donations. The moneys in the Prescription Drug Purchasing Fund are continuously appropriated to the authority and shall be used to purchase prescription drugs, reimburse pharmacies for prescription drugs and reimburse the authority for the costs of administering the Oregon Prescription Drug Program, including contracted services costs, computer costs, professional dispensing fees paid to retail pharmacies and other reasonable program costs. Interest earned on the fund shall be credited to the fund. [2003 c.714 §4; 2007 c.697 §20; 2009 c.595 §294]

Note: See note under 414.312.

414.320 Rules. The Oregon Health Authority shall adopt rules to implement and administer ORS 414.312 to 414.318. The rules shall include but are not limited to establishing procedures for:

(1) Issuing prescription drug identification cards to individuals and entities that participate in the Oregon Prescription Drug Program; and

(2) Enrolling pharmacies in the program. [2003 c.714 §5; 2007 c.697 §21; 2009 c.595 §295]

Note: See note under 414.312.



Appendix E: California Prescription Drug Price Transparency Legislation



Senate Bill No. 17

CHAPTER 603

An act to amend Sections 1385.045 and 127280 of, to add Section 1367.243 to, to add Chapter 9 (commencing with Section 127675) to Part 2 of Division 107 of, and to repeal Section 127686 of, the Health and Safety Code, and to amend Section 10181.45 of, and to add Section 10123.205 to, the Insurance Code, relating to health care.

[Approved by Governor October 9, 2017. Filed with
Secretary of State October 9, 2017.]

LEGISLATIVE COUNSEL'S DIGEST

SB 17, Hernandez. Health care: prescription drug costs.

Existing law, the Knox-Keene Health Care Service Plan Act of 1975, provides for the licensure and regulation of health care service plans by the Department of Managed Health Care (DMHC) and makes a willful violation of the act a crime. Existing law also provides for the regulation of health insurers by the Department of Insurance (DOI). Existing law requires health care service plans and health insurers to file specified rate information with DMHC or DOI, as applicable, for health care service plan contracts or health insurance policies in the individual or small group markets and for health care service plan contracts and health insurance policies in the large group market. Existing law requires health care service plans and health insurers to also disclose specified supporting information for the rate information described above. Existing law requires the DMHC and DOI, as applicable, to conduct an annual public meeting regarding large group rates within 3 months of posting that information.

This bill would require health care service plans or health insurers that file the above-described rate information to report to DMHC or DOI, on a date no later than the reporting of the rate information, specified cost information regarding covered prescription drugs, including generic drugs, brand name drugs, and specialty drugs, dispensed as provided. DMHC and DOI would be required to compile the reported information into a report for the public and legislators that demonstrates the overall impact of drug costs on health care premiums and publish the reports on their Internet Web sites by January 1 of each year. Except for the report, DMHC and DOI would be required to keep confidential all information provided pursuant to these provisions. The bill would also require health care service plans or health insurers that file the above-described rate information to disclose to DMHC and DOI with the rate information specified information regarding the relation of prescription drug costs to plan or insurer spending and premium charges. The bill would instead require DMHC and DOI to conduct an annual public meeting within 4 months of posting the rate information

described above. Because a willful violation of these provisions by a health care service plan would be a crime, the bill would impose a state-mandated local program.

The bill would require a manufacturer of a prescription drug with a wholesale acquisition cost of more than \$40 that is purchased or reimbursed by specified purchasers, including state agencies, health care service plans, health insurers, and pharmacy benefit managers, to notify the purchaser of an increase in the wholesale acquisition cost of a prescription drug if the increase in the wholesale acquisition cost for a course of therapy, as defined, exceeds a specified threshold. The bill would require that notice to be given at least 60 days prior to the planned effective date of the increase. Commencing no earlier than January 1, 2019, the bill would require the manufacturer to notify the Office of Statewide Health Planning and Development (OSHPD) of specified information relating to that increase in wholesale acquisition cost on a quarterly basis at a time and in a format prescribed by the office. The bill would require the manufacturer to notify OSHPD of specified information relating to the wholesale acquisition cost, marketing, and usage of a new prescription drug if the cost exceeds a specified threshold, and would require OSHPD to publish that information on its Internet Web site, as specified. The bill would require OSHPD to enforce the provisions requiring manufacturer reporting to OSHPD and would subject a manufacturer to liability for a civil penalty if the information described above is not reported. The bill would authorize OSHPD to adopt regulations or issue guidance for the implementation of these provisions. The bill would require the California Research Bureau to report to the Legislature on the implementation of these provisions, and would subject these provisions to review by the appropriate policy committees of the Legislature, as specified.

Existing law establishes the California Health Data and Planning Fund within the office for the purpose of receiving and expending certain fee revenues. Existing law establishes the Managed Care Fund for the purpose of supporting the administration of DMHC. Existing law establishes the Insurance Fund for, among other things, the support of DOI as authorized in the annual Budget Act.

This bill would prohibit the use of any moneys in the fund from being used for the implementation of these provisions. The bill would provide that funding for the office to conduct the activities described above shall be provided, subject to appropriation by the Legislature, from transfers of moneys from the Managed Care Fund and the Insurance Fund, as specified.

This bill would provide that the above-described provisions are severable.

Existing constitutional provisions require that a statute that limits the right of access to the meetings of public bodies or the writings of public officials and agencies be adopted with findings demonstrating the interest protected by the limitation and the need for protecting that interest.

This bill would make legislative findings to that effect.

The California Constitution requires the state to reimburse local agencies and school districts for certain costs mandated by the state. Statutory provisions establish procedures for making that reimbursement.

This bill would provide that no reimbursement is required by this act for a specified reason.

The people of the State of California do enact as follows:

SECTION 1. Section 1367.243 is added to the Health and Safety Code, to read:

1367.243. (a) (1) A health care service plan that reports rate information pursuant to Section 1385.03 or 1385.045 shall report the information described in paragraph (2) to the department no later than October 1 of each year, beginning October 1, 2018.

(2) For all covered prescription drugs, including generic drugs, brand name drugs, and specialty drugs dispensed at a plan pharmacy, network pharmacy, or mail order pharmacy for outpatient use, all of the following shall be reported:

(A) The 25 most frequently prescribed drugs.

(B) The 25 most costly drugs by total annual plan spending.

(C) The 25 drugs with the highest year-over-year increase in total annual plan spending.

(b) The department shall compile the information reported pursuant to subdivision (a) into a report for the public and legislators that demonstrates the overall impact of drug costs on health care premiums. The data in the report shall be aggregated and shall not reveal information specific to individual health care service plans.

(c) For the purposes of this section, a “specialty drug” is one that exceeds the threshold for a specialty drug under the Medicare Part D program (Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (Public Law 108-173)).

(d) By January 1 of each year, beginning January 1, 2019, the department shall publish on its Internet Web site the report required pursuant to subdivision (b).

(e) After the report required in subdivision (b) is released, the department shall include the report as part of the public meeting required pursuant to subdivision (b) of Section 1385.045.

(f) Except for the report required pursuant to subdivision (b), the department shall keep confidential all of the information provided to the department pursuant to this section, and the information shall be protected from public disclosure.

SEC. 2. Section 1385.045 of the Health and Safety Code is amended to read:

1385.045. (a) For large group health care service plan contracts, each health plan shall file with the department the weighted average rate increase for all large group benefit designs during the 12-month period ending January

1 of the following calendar year. The average shall be weighted by the number of enrollees in each large group benefit design in the plan's large group market and adjusted to the most commonly sold large group benefit design by enrollment during the 12-month period. For the purposes of this section, the large group benefit design includes, but is not limited to, benefits such as basic health care services and prescription drugs. The large group benefit design shall not include cost sharing, including, but not limited to, deductibles, copays, and coinsurance.

(b) (1) A plan shall also submit any other information required pursuant to any regulation adopted by the department to comply with this article.

(2) The department shall conduct an annual public meeting regarding large group rates within four months of posting the aggregate information described in this section in order to permit a public discussion of the reasons for the changes in the rates, benefits, and cost sharing in the large group market. The meeting shall be held in either the Los Angeles area or the San Francisco Bay area.

(c) A health care service plan subject to subdivision (a) shall also disclose the following for the aggregate rate information for the large group market submitted under this section:

(1) For rates effective during the 12-month period ending January 1 of the following year, number and percentage of rate changes reviewed by the following:

(A) Plan year.

(B) Segment type, including whether the rate is community rated, in whole or in part.

(C) Product type.

(D) Number of enrollees.

(E) The number of products sold that have materially different benefits, cost sharing, or other elements of benefit design.

(2) For rates effective during the 12-month period ending January 1 of the following year, any factors affecting the base rate, and the actuarial basis for those factors, including all of the following:

(A) Geographic region.

(B) Age, including age rating factors.

(C) Occupation.

(D) Industry.

(E) Health status factors, including, but not limited to, experience and utilization.

(F) Employee, and employee and dependents, including a description of the family composition used.

(G) Enrollees' share of premiums.

(H) Enrollees' cost sharing, including cost sharing for prescription drugs.

(I) Covered benefits in addition to basic health care services, as defined in Section 1345, and other benefits mandated under this article.

(J) Which market segment, if any, is fully experience rated and which market segment, if any, is in part experience rated and in part community rated.

(K) Any other factor that affects the rate that is not otherwise specified.

(3) (A) The plan's overall annual medical trend factor assumptions for all benefits and by aggregate benefit category, including hospital inpatient, hospital outpatient, physician services, prescription drugs and other ancillary services, laboratory, and radiology for the applicable 12-month period ending January 1 of the following year. A health plan that exclusively contracts with no more than two medical groups in the state to provide or arrange for professional medical services for the enrollees of the plan shall instead disclose the amount of its actual trend experience for the prior contract year by aggregate benefit category, using benefit categories, to the maximum extent possible, that are the same as, or similar to, those used by other plans.

(B) The amount of the projected trend separately attributable to the use of services, price inflation, and fees and risk for annual plan contract trends by aggregate benefit category, including hospital inpatient, hospital outpatient, physician services, prescription drugs and other ancillary services, laboratory, and radiology. A health plan that exclusively contracts with no more than two medical groups in the state to provide or arrange for professional medical services for the enrollees of the plan shall instead disclose the amount of its actual trend experience for the prior contract year by aggregate benefit category, using benefit categories that are, to the maximum extent possible, the same or similar to those used by other plans.

(C) A comparison of the aggregate per enrollee per month costs and rate of changes over the last five years for each of the following:

- (i) Premiums.
- (ii) Claims costs, if any.
- (iii) Administrative expenses.
- (iv) Taxes and fees.

(D) Any changes in enrollee cost sharing over the prior year associated with the submitted rate information, including both of the following:

(i) Actual copays, coinsurance, deductibles, annual out of pocket maximums, and any other cost sharing by the benefit categories determined by the department.

(ii) Any aggregate changes in enrollee cost sharing over the prior years as measured by the weighted average actuarial value, weighted by the number of enrollees.

(E) Any changes in enrollee benefits over the prior year, including a description of benefits added or eliminated, as well as any aggregate changes, as measured as a percentage of the aggregate claims costs, listed by the categories determined by the department.

(F) Any cost containment and quality improvement efforts since the plan's prior year's information pursuant to this section for the same category of health benefit plan. To the extent possible, the plan shall describe any significant new health care cost containment and quality improvement efforts and provide an estimate of potential savings together with an estimated cost or savings for the projection period.

(G) The number of products covered by the information that incurred the excise tax paid by the health plan.

(4) (A) For covered prescription generic drugs excluding specialty generic drugs, prescription brand name drugs excluding specialty drugs, and prescription brand name and generic specialty drugs dispensed at a plan pharmacy, network pharmacy, or mail order pharmacy for outpatient use, all of the following shall be disclosed:

(i) The percentage of the premium attributable to prescription drug costs for the prior year for each category of prescription drugs as defined in this subparagraph.

(ii) The year-over-year increase, as a percentage, in per-member, per-month total health plan spending for each category of prescription drugs as defined in this subparagraph.

(iii) The year-over-year increase in per-member, per-month costs for drug prices compared to other components of the health care premium.

(iv) The specialty tier formulary list.

(B) The plan shall include the percentage of the premium attributable to prescription drugs administered in a doctor's office that are covered under the medical benefit as separate from the pharmacy benefit, if available.

(C) (i) The plan shall include information on its use of a pharmacy benefit manager, if any, including which components of the prescription drug coverage described in subparagraphs (A) and (B) are managed by the pharmacy benefit manager.

(ii) The plan shall also include the name or names of the pharmacy benefit manager, or managers if the plan uses more than one.

(d) The information required pursuant to this section shall be submitted to the department on or before October 1, 2018, and on or before October 1 annually thereafter. Information submitted pursuant to this section is subject to Section 1385.07.

(e) For the purposes of this section, a "specialty drug" is one that exceeds the threshold for a specialty drug under the Medicare Part D program (Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (Public Law 108-173)).

SEC. 3. Section 127280 of the Health and Safety Code is amended to read:

127280. (a) Every health facility licensed pursuant to Chapter 2 (commencing with Section 1250) of Division 2, except a health facility owned and operated by the state, shall each year be charged a fee established by the office consistent with the requirements of this section.

(b) Commencing in calendar year 2004, every freestanding ambulatory surgery clinic as defined in Section 128700, shall each year be charged a fee established by the office consistent with the requirements of this section.

(c) The fee structure shall be established each year by the office to produce revenues equal to the appropriation made in the annual Budget Act or another statute to pay for the functions required to be performed by the office pursuant to this chapter, Article 2 (commencing with Section 127340) of Chapter 2, or Chapter 1 (commencing with Section 128675) of Part 5, and to pay for any other health-related programs administered by the office. The fee shall be due on July 1 and delinquent on July 31 of each year.

(d) The fee for a health facility that is not a hospital, as defined in subdivision (c) of Section 128700, shall be not more than 0.035 percent of the gross operating cost of the facility for the provision of health care services for its last fiscal year that ended on or before June 30 of the preceding calendar year.

(e) The fee for a hospital, as defined in subdivision (c) of Section 128700, shall be not more than 0.035 percent of the gross operating cost of the facility for the provision of health care services for its last fiscal year that ended on or before June 30 of the preceding calendar year.

(f) (1) The fee for a freestanding ambulatory surgery clinic shall be established at an amount equal to the number of ambulatory surgery data records submitted to the office pursuant to Section 128737 for encounters in the preceding calendar year multiplied by not more than fifty cents (\$0.50).

(2) (A) For the calendar year 2004 only, a freestanding ambulatory surgery clinic shall estimate the number of records it will file pursuant to Section 128737 for the calendar year 2004 and shall report that number to the office by March 12, 2004. The estimate shall be as accurate as possible. The fee in the calendar year 2004 shall be established initially at an amount equal to the estimated number of records reported multiplied by fifty cents (\$0.50) and shall be due on July 1 and delinquent on July 31, 2004.

(B) The office shall compare the actual number of records filed by each freestanding clinic for the calendar year 2004 pursuant to Section 128737 with the estimated number of records reported pursuant to subparagraph (A). If the actual number reported is less than the estimated number reported, the office shall reduce the fee of the clinic for calendar year 2005 by the amount of the difference multiplied by fifty cents (\$0.50). If the actual number reported exceeds the estimated number reported, the office shall increase the fee of the clinic for calendar year 2005 by the amount of the difference multiplied by fifty cents (\$0.50) unless the actual number reported is greater than 120 percent of the estimated number reported, in which case the office shall increase the fee of the clinic for calendar year 2005 by the amount of the difference, up to and including 120 percent of the estimated number, multiplied by fifty cents (\$0.50), and by the amount of the difference in excess of 120 percent of the estimated number multiplied by one dollar (\$1).

(g) There is hereby established the California Health Data and Planning Fund within the office for the purpose of receiving and expending fee revenues collected pursuant to this chapter.

(h) Any amounts raised by the collection of the special fees provided for by subdivisions (d), (e), and (f) that are not required to meet appropriations in the Budget Act for the current fiscal year shall remain in the California Health Data and Planning Fund and shall be available to the office in succeeding years when appropriated by the Legislature in the annual Budget Act or another statute, for expenditure under the provisions of this chapter, Article 2 (commencing with Section 127340) of Chapter 2, and Chapter 1 (commencing with Section 128675) of Part 5, or for any other health-related programs administered by the office, and shall reduce the amount of the

special fees that the office is authorized to establish and charge. In no event, however, shall those amounts be used for programs administered by the office pursuant to Sections 127676, 127679, 127681, 127683, and 127685, that become effective on or after January 1, 2019.

(i) (1) No health facility liable for the payment of fees required by this section shall be issued a license or have an existing license renewed unless the fees are paid. A new, previously unlicensed, health facility shall be charged a pro rata fee to be established by the office during the first year of operation.

(2) The license of any health facility, against which the fees required by this section are charged, shall be revoked, after notice and hearing, if it is determined by the office that the fees required were not paid within the time prescribed by subdivision (c).

(j) This section shall become operative on January 1, 2002.

SEC. 4. Chapter 9 (commencing with Section 127675) is added to Part 2 of Division 107 of the Health and Safety Code, to read:

CHAPTER 9. PRESCRIPTION DRUG PRICING FOR PURCHASERS

127675. (a) This chapter shall apply to a manufacturer of a prescription drug that is purchased or reimbursed by any of the following:

(1) A state purchaser in California, including, but not limited to, the Public Employees' Retirement System, the State Department of Health Care Services, the Department of General Services, and the Department of Corrections and Rehabilitation, or an entity acting on behalf of a state purchaser.

(2) A licensed health care service plan.

(3) A health insurer holding a valid outstanding certificate of authority from the Insurance Commissioner.

(4) A pharmacy benefit manager as defined in subdivision (j) of Section 4430 of the Business and Professions Code.

(b) For the purposes of this chapter, the term "office" shall mean the Office of Statewide Health Planning and Development.

127676. (a) The Legislature finds and declares that the State of California has a substantial public interest in the price and cost of prescription drugs. California is a major purchaser through the Public Employees' Retirement System, the State Department of Health Care Services, the Department of General Services, the Department of Corrections and Rehabilitation, and other entities acting on behalf of a state purchaser. California also provides major tax expenditures through the tax exclusion of employer sponsored coverage and tax deductibility of coverage purchased by individuals, as well as tax deductibility of excess health care costs for individuals and families.

(b) (1) It is the intent of the Legislature in enacting this chapter to provide notice and disclosure of information relating to the cost and pricing of

prescription drugs in order to provide accountability to the state for prescription drug pricing.

(2) It is further the intent of the Legislature to permit a manufacturer of a prescription drug to voluntarily make pricing decisions regarding a prescription drug, including any price increases. It is further the intent of the Legislature to permit purchasers, both public and private, as well as pharmacy benefit managers, to negotiate discounts and rebates consistent with existing state and federal law.

127677. (a) A manufacturer of a prescription drug with a wholesale acquisition cost of more than forty dollars (\$40) for a course of therapy shall notify each purchaser described in Section 127675 if the increase in the wholesale acquisition cost of a prescription drug is more than 16 percent, including the proposed increase and the cumulative increases that occurred within the previous two calendar years prior to the current year. For purposes of this section, a “course of therapy” is defined as either of the following:

(1) The recommended daily dosage units of a prescription drug pursuant to its prescribing label as approved by the federal Food and Drug Administration for 30 days.

(2) The recommended daily dosage units of a prescription drug pursuant to its prescribing label as approved by the federal Food and Drug Administration for a normal course of treatment that is less than 30 days.

(b) The notice required by subdivision (a) shall be provided in writing at least 60 days prior to the planned effective date of the increase.

(c) (1) The notice required by subdivision (a) shall include the date of the increase, the current wholesale acquisition cost of the prescription drug, and the dollar amount of the future increase in the wholesale acquisition cost of the prescription drug.

(2) The notice required by subdivision (a) shall include a statement regarding whether a change or improvement in the drug necessitates the price increase. If so, the manufacturer shall describe the change or improvement.

(d) The notice required by subdivision (a) shall be provided to each state purchaser and other purchasers described in paragraphs (2) to (4), inclusive, of subdivision (a) of Section 127675 if a purchaser registers with the office for the purpose of this notification. The office shall make available to manufacturers a list of registered purchasers for the purpose of this notification.

(e) If a pharmacy benefit manager receives a notice of an increase in wholesale acquisition cost consistent with subdivision (a), it shall notify its large contracting public and private purchasers of the increase. For the purposes of this section, a “large purchaser” means a purchaser that provides coverage to more than 500 covered lives.

127679. (a) On a quarterly basis at a time prescribed by the office and in a format prescribed by the office, commencing no earlier than January 1, 2019, a manufacturer shall report to the office all of the following information for each drug for which an increase in wholesale acquisition cost is described in Section 127677:

(1) A description of the specific financial and nonfinancial factors used to make the decision to increase the wholesale acquisition cost of the drug and the amount of the increase, including, but not limited to, an explanation of how these factors explain the increase in the wholesale acquisition cost of the drug.

(2) A schedule of wholesale acquisition cost increases for the drug for the previous five years if the drug was manufactured by the company.

(3) If the drug was acquired by the manufacturer within the previous five years, all of the following information:

(A) The wholesale acquisition cost of the drug at the time of acquisition and in the calendar year prior to acquisition.

(B) The name of the company from which the drug was acquired, the date acquired, and the purchase price.

(C) The year the drug was introduced to market and the wholesale acquisition cost of the drug at the time of introduction.

(4) The patent expiration date of the drug if it is under patent.

(5) If the drug is a multiple source drug, an innovator multiple source drug, a noninnovator multiple source drug, or a single source drug, as defined in subparagraph (A) of paragraph (7) of subdivision (k) of Section 1396r-8 of Title 42 of the United States Code.

(6) A description of the change or improvement in the drug, if any, that necessitates the price increase.

(7) Volume of sales of the manufacturer's drug in the United States for the previous year.

(b) The manufacturer may limit the information reported pursuant to subdivision (a) to that which is otherwise in the public domain or publicly available.

(c) The office shall publish the information provided to it pursuant to this section on its Internet Web site on no less than a quarterly basis. The information shall be published within 60 days of receipt from a manufacturer. The information shall be published in a manner that identifies the information that is disclosed on a per-drug basis and shall not be aggregated in a manner that would not allow identification of the drug.

(d) The office shall be responsible for the enforcement of this section.

(e) A manufacturer of a prescription drug subject to this chapter that does not report the information required pursuant to this section is liable for a civil penalty of one thousand dollars (\$1,000) per day for every day after the reporting period described in this section that the required information is not reported.

(f) A civil penalty shall be assessed and recovered in a civil action brought by the office in the name of the people of the State of California. Assessment of a civil penalty may, at the request of any manufacturer of a prescription drug subject to this section, be reviewed on appeal, and the penalty may be reduced or waived for good cause.

(g) Any money received by the office pursuant to this section shall be paid into the Managed Care Fund.

127681. (a) A manufacturer of a prescription drug shall notify the office in writing if it is introducing a new prescription drug to market at a wholesale acquisition cost that exceeds the threshold set for a specialty drug under the Medicare Part D program (Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (Public Law 108-173)). The notice shall be provided in writing within three days after the release of the drug in the commercial market. A manufacturer may make this notification pending approval by the federal Food and Drug Administration, if commercial availability is expected within three days of approval.

(b) No later than 30 days after notification pursuant to this section, a manufacturer shall report all of the following information to the office in a format prescribed by the office:

(1) A description of the marketing and pricing plans used in the launch of the new drug in the United States and internationally.

(2) The estimated volume of patients that may be prescribed the drug.

(3) If the drug was granted breakthrough therapy designation or priority review by the federal Food and Drug Administration prior to final approval.

(4) The date and price of acquisition if the drug was not developed by the manufacturer.

(c) The manufacturer may limit the information reported pursuant to subdivision (b) to that which is otherwise in the public domain or publicly available.

(d) The office shall publish the information provided to it pursuant to this section on its Internet Web site on no less than a quarterly basis. The information shall be published in a manner that identifies the information that is disclosed on a per-drug basis and shall not be aggregated in a manner that would not allow identification of the drug.

(e) The office shall be responsible for the enforcement of this section.

(f) A manufacturer of a prescription drug subject to this chapter that does not report the information required pursuant to this section is liable for a civil penalty of one thousand dollars (\$1,000) per day for every day after the notification period described in this section that the required information is not reported.

(g) A civil penalty shall be assessed and recovered in a civil action brought by the office in the name of the people of the State of California. Assessment of a civil penalty may, at the request of any manufacturer of a prescription drug subject to this section, be reviewed on appeal, and the penalty may be reduced or waived for good cause.

(h) Any money received by the office pursuant to this section shall be paid into the Managed Care Fund.

127683. (a) Funding for the actual and necessary expenses of the office to conduct the activities described in this section and in Sections 127676, 127679, 127681, and 127685, shall be provided, subject to appropriation by the Legislature, from transfers of moneys from the Managed Care Fund and the Insurance Fund.

(b) The share of funding from the Managed Care Fund shall be based on the number of covered lives in the state that are covered under plans

regulated by the Department of Managed Health Care, including covered lives under Medi-Cal managed care, as determined by the Department of Managed Health Care, in proportion to the total number of all covered lives in the state.

(c) The share of funding to be provided from the Insurance Fund shall be based on the number of covered lives in the state that are covered under health insurance policies and benefit plans regulated by the Department of Insurance, including covered lives under Medicare supplement plans, as determined by the Department of Insurance, in proportion to the total number of all covered lives in the state.

127685. (a) The office may adopt regulations or issue guidance for the implementation of this chapter. All information that is required to be reported to the office pursuant to this chapter shall be reported in a form prescribed by the office, commencing in the first calendar quarter of 2019.

(b) The office may consult with the Department of Managed Health Care, the Department of Insurance, the California State Board of Pharmacy, and any state purchaser of prescription drugs, or an entity acting on behalf of a state purchaser, in issuing guidance or adopting necessary regulations pursuant to subdivision (a), in posting information on its Internet Web site pursuant to this chapter, and in taking any other action for the purpose of implementing this chapter.

127686. (a) By January 1, 2022, the California Research Bureau shall report to the Legislature on the implementation of this chapter, including, but not limited to, this chapter's effectiveness in addressing the following goals:

(1) Promoting transparency in pharmaceutical pricing for the state and other payers.

(2) Enhancing understanding about pharmaceutical spending trends.

(3) Assisting the state and other payers in management of pharmaceutical drug costs.

(b) A report submitted pursuant to subdivision (a) shall be submitted in compliance with Section 9795 of the Government Code.

(c) Notwithstanding any other law, implementation of this chapter shall be subject to review by the appropriate policy committees of the Legislature. The review shall be performed as if this chapter were scheduled to be repealed on January 1, 2023.

(d) This section shall remain in effect only until January 1, 2024, and as of that date is repealed.

SEC. 5. Section 10123.205 is added to the Insurance Code, to read:

10123.205. (a) (1) A health insurer that reports rate information pursuant to Section 10181.3 or 10181.45 shall report the information described in paragraph (2) to the department no later than October 1 of each year, beginning October 1, 2018.

(2) For all covered prescription drugs, including generic drugs, brand name drugs, and specialty drugs dispensed at a plan pharmacy, network pharmacy, or mail order pharmacy for outpatient use, all of the following shall be reported:

- (A) The 25 most frequently prescribed drugs.
- (B) The 25 most costly drugs by total annual plan spending.
- (C) The 25 drugs with the highest year-over-year increase in total annual plan spending.

(b) The department shall compile the information reported pursuant to subdivision (a) into a report for the public and legislators that demonstrates the overall impact of drug costs on health care premiums. The data in the report shall be aggregated and shall not reveal information specific to individual health insurers.

(c) For the purposes of this section, a “specialty drug” is one that exceeds the threshold for a specialty drug under the Medicare Part D program (Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (Public Law 108-173)).

(d) By January 1 of each year, beginning January 1, 2018, the department shall publish on its Internet Web site the report required pursuant to subdivision (b).

(e) After the report required in subdivision (b) is released, the department shall include the report as part of the public meeting required pursuant to subdivision (b) of Section 10181.45.

(f) Except for the report required pursuant to subdivision (b), the department shall keep confidential all of the information provided to the department pursuant to this section, and the information shall be protected from public disclosure.

SEC. 6. Section 10181.45 of the Insurance Code is amended to read:

10181.45. (a) For large group health insurance policies, each health insurer shall file with the department the weighted average rate increase for all large group benefit designs during the 12-month period ending January 1 of the following calendar year. The average shall be weighted by the number of insureds in each large group benefit design in the insurer’s large group market and adjusted to the most commonly sold large group benefit design by enrollment during the 12-month period. For the purposes of this section, the large group benefit design includes, but is not limited to, benefits such as basic health care services and prescription drugs. The large group benefit design shall not include cost sharing, including, but not limited to, deductibles, copays, and coinsurance.

(b) (1) A health insurer shall also submit any other information required pursuant to any regulation adopted by the department to comply with this article.

(2) The department shall conduct an annual public meeting regarding large group rates within four months of posting the aggregate information described in this section in order to permit a public discussion of the reasons for the changes in the rates, benefits, and cost sharing in the large group market. The meeting shall be held in either the Los Angeles area or the San Francisco Bay area.

(c) A health insurer subject to subdivision (a) shall also disclose the following for the aggregate rate information for the large group market submitted under this section:

(1) For rates effective during the 12-month period ending January 1 of the following year, number and percentage of rate changes reviewed by the following:

- (A) Plan year.
- (B) Segment type, including whether the rate is community rated, in whole or in part.
- (C) Product type.
- (D) Number of insureds.
- (E) The number of products sold that have materially different benefits, cost sharing, or other elements of benefit design.

(2) For rates effective during the 12-month period ending January 1 of the following year, any factors affecting the base rate, and the actuarial basis for those factors, including all of the following:

- (A) Geographic region.
- (B) Age, including age rating factors.
- (C) Occupation.
- (D) Industry.
- (E) Health status factors, including, but not limited to, experience and utilization.
- (F) Employee, and employee and dependents, including a description of the family composition used.
- (G) Insureds' share of premiums.
- (H) Insureds' cost sharing, including cost sharing for prescription drugs.
- (I) Covered benefits in addition to basic health care services, as defined in Section 1345 of the Health and Safety Code, and other benefits mandated under this article.

(J) Which market segment, if any, is fully experience rated and which market segment, if any, is in part experience rated and in part community rated.

(K) Any other factor that affects the rate that is not otherwise specified.

(3) (A) The insurer's overall annual medical trend factor assumptions for all benefits and by aggregate benefit category, including hospital inpatient, hospital outpatient, physician services, prescription drugs and other ancillary services, laboratory, and radiology for the applicable 12-month period ending January 1 of the following year. A health insurer that exclusively contracts with no more than two medical groups in the state to provide or arrange for professional medical services for the health insurer's insureds shall instead disclose the amount of its actual trend experience for the prior contract year by aggregate benefit category, using benefit categories, to the maximum extent possible, that are the same or similar to those used by other insurers.

(B) The amount of the projected trend separately attributable to the use of services, price inflation, and fees and risk for annual policy trends by aggregate benefit category, including hospital inpatient, hospital outpatient, physician services, prescription drugs and other ancillary services, laboratory, and radiology. A health insurer that exclusively contracts with no more than two medical groups in the state to provide or arrange for professional medical

services for the insureds shall instead disclose the amount of its actual trend experience for the prior contract year by aggregate benefit category, using benefit categories that are, to the maximum extent possible, the same or similar to those used by other insurers.

(C) A comparison of the aggregate per insured per month costs and rate of changes over the last five years for each of the following:

- (i) Premiums.
- (ii) Claims costs, if any.
- (iii) Administrative expenses.
- (iv) Taxes and fees.

(D) Any changes in insured cost sharing over the prior year associated with the submitted rate information, including both of the following:

(i) Actual copays, coinsurance, deductibles, annual out of pocket maximums, and any other cost sharing by the benefit categories determined by the department.

(ii) Any aggregate changes in insured cost sharing over the prior years as measured by the weighted average actuarial value, weighted by the number of insureds.

(E) Any changes in insured benefits over the prior year, including a description of benefits added or eliminated as well as any aggregate changes as measured as a percentage of the aggregate claims costs, listed by the categories determined by the department.

(F) Any cost containment and quality improvement efforts made since the insurer's prior year's information pursuant to this section for the same category of health insurer. To the extent possible, the insurer shall describe any significant new health care cost containment and quality improvement efforts and provide an estimate of potential savings together with an estimated cost or savings for the projection period.

(G) The number of products covered by the information that incurred the excise tax paid by the health insurer.

(4) (A) For covered prescription generic drugs excluding specialty generic drugs, prescription brand name drugs excluding specialty drugs, and prescription brand name and generic specialty drugs dispensed at a pharmacy, network pharmacy, or mail order pharmacy for outpatient use, all of the following shall be disclosed:

(i) The percentage of the premium attributable to prescription drug costs for the prior year for each category of prescription drugs as defined in this subparagraph.

(ii) The year-over-year increase, as a percentage, in per-member, per-month total health insurer spending for each category of prescription drugs as defined in this subparagraph.

(iii) The year-over-year increase in per-member, per-month costs for drug prices compared to other components of the health care premium.

(iv) The specialty tier formulary list.

(B) The insurer shall include the percentage of the premium attributable to prescription drugs administered in a doctor's office that are covered under the medical benefit as separate from the pharmacy benefit, if available.

(C) (i) The insurer shall include information on its use of a pharmacy benefit manager, if any, including which components of the prescription drug coverage described in subparagraphs (A) and (B) are managed by the pharmacy benefit manager.

(ii) The insurer shall also include the name or names of the pharmacy benefit manager, or managers if the insurer uses more than one.

(d) The information required pursuant to this section shall be submitted to the department on or before October 1, 2016, and on or before October 1 annually thereafter. Information submitted pursuant to this section is subject to Section 10181.7.

(e) For the purposes of this section, a “specialty drug” is one that exceeds the threshold for a specialty drug under the Medicare Part D program (Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (Public Law 108-173)).

SEC. 7. The provisions of this act are severable. If any provision of this act or its application is held invalid, that invalidity shall not affect other provisions or applications that can be given effect without the invalid provision or application.

SEC. 8. The Legislature finds and declares that Sections 1 and 5 of this act, which add Section 1367.243 to the Health and Safety Code and Section 10123.205 to the Insurance Code, respectively, impose a limitation on the public’s right of access to the meetings of public bodies or the writings of public officials and agencies within the meaning of Section 3 of Article I of the California Constitution. Pursuant to that constitutional provision, the Legislature makes the following findings to demonstrate the interest protected by this limitation and the need for protecting that interest:

In order to protect proprietary, confidential information regarding health care service plan and health insurer prescription drug utilization and spending information that is specific to the plan or insurer and to protect the integrity of the competitive market, it is necessary that this act limit the public’s right of access to that information.

SEC. 9. No reimbursement is required by this act pursuant to Section 6 of Article XIII B of the California Constitution because the only costs that may be incurred by a local agency or school district will be incurred because this act creates a new crime or infraction, eliminates a crime or infraction, or changes the penalty for a crime or infraction, within the meaning of Section 17556 of the Government Code, or changes the definition of a crime within the meaning of Section 6 of Article XIII B of the California Constitution.

Appendix F: California Prescription Drug Joint Purchasing Legislation

GOVERNMENT CODE - GOV

TITLE 2. GOVERNMENT OF THE STATE OF CALIFORNIA [8000 - 22980]

(Title 2 enacted by Stats. 1943, Ch. 134.)

DIVISION 3. EXECUTIVE DEPARTMENT [11000 - 15986]

(Division 3 added by Stats. 1945, Ch. 111.)

PART 5.5. DEPARTMENT OF GENERAL SERVICES [14600 - 14985.11]

(Part 5.5 added by Stats. 1965, Ch. 371.)

CHAPTER 12. Purchase of Prescription Drugs for Government Agencies [14977 - 14982]⁷⁰

(Chapter 12 added by Stats. 2002, Ch. 483, Sec. 2.)

14977.

As used in this chapter, “department” means the Department of General Services.

(Added by Stats. 2002, Ch. 483, Sec. 2. Effective January 1, 2003.)

14977.1.

(a) Notwithstanding any other provision of law, the Department of General Services may enter into exclusive or nonexclusive contracts on a bid or negotiated basis with manufacturers and suppliers of single source or multisource drugs. The department may obtain from those manufacturers and suppliers, discounts, rebates, or refunds based on quantities purchased insofar as permissible under federal law. Contracts entered into pursuant to this chapter may include price discounts, rebates, refunds, or other strategies aimed at managing escalating prescription drug prices.

(b) Contracts under this chapter shall be exempt from Chapter 2 (commencing with Section 10290) of Part 2 of Division 2 of the Public Contract Code.

(Added by Stats. 2002, Ch. 483, Sec. 2. Effective January 1, 2003.)

14977.5.

(a) The following state agencies shall participate in the prescription drug bulk purchasing program authorized under this chapter.

(1) State Department of State Hospitals.

(2) Department of Corrections.

(3) Department of the Youth Authority.

(4) State Department of Developmental Services.

⁷⁰ CHAPTER 12. Purchase of Prescription Drugs for Government Agencies [14977 - 14982], from http://leginfo.ca.gov/faces/codes_displayText.xhtml?lawCode=GOV&division=3.&title=2.&part=5.5.&chapter=12.&article, accessed on October 3, 2019.

(b) Any state, district, county, city, municipal, or public agency governmental entity, other than a state entity specified in subdivision (a), may elect to participate in the coordinated purchasing program.

(Amended by Stats. 2012, Ch. 440, Sec. 19. (AB 1488) Effective September 22, 2012.)

14978.

The department, in consultation with the agencies listed in subdivision (a) of Section 14977.5, may investigate and implement other options and strategies to achieve the greatest savings on prescription drugs with prescription drug manufacturers and wholesalers.

(Added by Stats. 2002, Ch. 483, Sec. 2. Effective January 1, 2003.)

14979.

The department may appoint and contract with a pharmaceutical benefits manager or other entity for purposes of the prescription drugs purchased under this chapter. The pharmaceutical benefits manager or other entity may do all of the following:

(a) Negotiate price discounts, rebates, or other options that achieve the greatest savings on prescription drugs with prescription drug manufacturers and wholesalers.

(b) Purchase prescription drugs for participating state, district, county, or municipal governmental entities.

(c) Act as a consultant to the department.

(Added by Stats. 2002, Ch. 483, Sec. 2. Effective January 1, 2003.)

14980.

The department may explore additional strategies for managing the increasing costs of prescription drugs, including:

(a) Coordinating programs offered by pharmaceutical manufacturers that provide prescription drugs for free or at reduced prices.

(b) Studying the feasibility and appropriateness of including in the bulk purchasing programs entities in the private sector, including employers, providers, and individual consumers.

(c) Implementing other strategies, as permitted under state and federal law, aimed at managing escalating prescription drug prices.

(Added by Stats. 2002, Ch. 483, Sec. 2. Effective January 1, 2003.)

14982.

(a) It is the intent of the Legislature that the Department of General Services, University of California, and the Public Employees' Retirement System regularly meet and share information regarding each agency's procurement of prescription drugs in an effort to identify and implement opportunities for cost savings in connection with this procurement. It is the intent of the Legislature that the University of California and the Public Employees' Retirement System cooperate with the department in order to reduce each agency's costs for prescription drugs.

(b) The department shall do all of the following:



- (1) Share information on a regular basis with the University of California and the Public Employees' Retirement System regarding each agency's procurement of prescription drugs, including, but not limited to, prices paid for the same or similar drugs and information regarding drug effectiveness.
 - (2) Identify opportunities for the department, the University of California, and the Public Employees' Retirement System to consolidate drug procurement or engage in other joint activities that will result in cost savings in the procurement of prescription drugs.
 - (3) Participate in at least one independent association that develops information on the relative effectiveness of prescription drugs.
 - (4) Develop strategies, in consultation with the affected agencies, for the state to achieve savings through greater use of generic drugs.
 - (5) No later than January 1, 2006, and annually thereafter, develop a workplan that includes, but is not limited to, a description of the department's annual activities to reduce the state's costs for prescription drugs and an estimate of cost savings.
- (c) Nothing in this section shall be construed to require sharing of information that is prohibited by any other provision of law or contractual agreement, or the disclosure of information that may adversely affect potential drug procurement by any state agency.
- (Amended by Stats. 2009, Ch. 284, Sec. 5. (AB 1311) Effective January 1, 2010.)*



Appendix G: Nevada Prescription Drug Price Transparency Legislation



EMERGENCY REQUEST of Senate Minority Leader

Senate Bill No. 539—Senators Roberson, Gansert; Atkinson, Cancela, Cannizzaro, Denis, Farley, Ford, Goicoechea, Harris, Manendo, Parks, Ratti, Segerblom, Settlemeyer, Spearman and Woodhouse

CHAPTER.....

AN ACT relating to prescription drugs; requiring the Department of Health and Human Services to compile certain lists of certain prescription drugs that are used to treat diabetes; requiring the manufacturer of a drug included on such lists and a pharmacy benefit manager to provide certain information to the Department; requiring the Department to compile a report based on such information; requiring a manufacturer of prescription drugs to submit a list of each pharmaceutical sales representative who markets prescription drugs to certain persons in this State; prohibiting a pharmaceutical sales representative who is not included on such a list from marketing prescription drugs on behalf of a manufacturer; requiring each pharmaceutical sales representative included on such a list to report certain information to the Department; requiring certain nonprofit organizations to report to the Department certain information concerning certain contributions and benefits received from drug manufacturers, insurers and pharmacy benefit managers or trade and advocacy groups for such entities; requiring the Department to place certain information on its Internet website; authorizing the Department to impose an administrative penalty in certain circumstances; providing that certain information does not constitute a trade secret; imposing certain requirements on a pharmacy benefit manager; requiring a private school to allow a pupil to keep and self-administer certain drugs; requiring certain insurers to provide certain notice to insureds; providing penalties; and providing other matters properly relating thereto.

Legislative Counsel's Digest:

Existing law requires the organization with the largest membership in this State which represents the interests of retail merchants to prepare a list of not less than 100 prescription drugs most commonly prescribed to residents of this State. (NRS 439.905) Existing law also requires the Department of Health and Human Services to place on the Internet website maintained by the Department certain information reported by pharmacies concerning the prices charged by the pharmacies for drugs that appear on that list. (NRS 439.915) **Section 3.6** of this bill requires the Department to compile: (1) a list of prescription drugs that the Department



determines to be essential for treating diabetes in this State; and (2) a list of such prescription drugs that have been subject to a significant price increase within the immediately preceding 2 calendar years. **Section 3.8** of this bill requires the manufacturer of a prescription drug included on the list of essential diabetes drugs to submit to the Department an annual report that contains certain information concerning the cost of the drug. **Section 4** of this bill requires the manufacturer of a drug included on the list of essential diabetes drugs that have undergone a substantial cost increase to submit to the Department a report concerning the reasons for the cost increase. **Section 4.2** of this bill requires a pharmacy benefit manager to report certain information concerning essential diabetes drugs to the Department. **Section 9** of this bill provides that any information that a manufacturer of an essential diabetes drug, a pharmacy benefit manager or a pharmaceutical sales representative is required to report is not a trade secret. **Section 4.3** of this bill requires the Department to analyze the information submitted by such manufacturers and compile a report concerning the reasons for and effect of the pricing of essential diabetes drugs.

Section 4.9 of this bill requires a nonprofit organization that advocates for patients or funds medical research in this State to post on its Internet website or, if the nonprofit organization does not maintain an Internet website, submit to the Department certain information concerning payments, donations and anything else of value that the organization receives from manufacturers of prescription drugs, certain third parties or pharmacy benefit managers or trade or advocacy groups for such entities. **Section 6** of this bill requires the Department to place on the Internet website maintained by the Department: (1) the information and lists compiled by the Department pursuant to **sections 3.6, 4.3 and 4.6**; and (2) the information submitted to the Department pursuant to **sections 3.8 and 4.9**. **Section 6.5** of this bill provides that the Department is not liable for any act, omission, error or technical problem that results in the failure to provide information or the provision of any incorrect information placed on the Internet website of the Department. **Section 7** of this bill requires the Department to adopt any necessary regulations concerning the reporting of information by manufacturers and nonprofit organizations for inclusion on the Internet website of the Department. **Section 26.3** of this bill requires an insurer that offers or issues a policy of individual health insurance and uses a formulary to provide, during each open enrollment period, a notice of any drugs on the list of essential diabetes drugs that have been removed from the formulary or will be removed from the formulary during the current plan year or the next plan year.

Section 4.6 of this bill requires a manufacturer to provide to the Department a list of each pharmaceutical sales representative who markets prescription drugs to providers of health care, pharmacies, medical facilities and insurers in this State on behalf of the manufacturer. **Section 4.6** also prohibits a person who is not included on such a list from marketing prescription drugs on behalf of a manufacturer to providers of health care, pharmacies, medical facilities and insurers. Additionally, **section 4.6** requires each pharmaceutical sales representative who is included on such a list to submit an annual report to the Department. Finally, **section 4.6** requires the Department to compile an annual report based on the information submitted by pharmaceutical sales representatives. **Section 8** of this bill authorizes the Department to impose an administrative penalty against a manufacturer, pharmacy benefit manager, nonprofit organization or pharmaceutical sales representative who fails to provide the information required by **sections 3.8, 4, 4.2, 4.6 and 4.9**.



Upon the submission of a written request, existing law requires a public school to allow a pupil who has asthma, anaphylaxis or diabetes to carry and self-administer medication to treat his or her disorder while the pupil is on the grounds of a public school, participating in an activity sponsored by a public school or on a school bus. (NRS 392.425) Willful failure to carry out this requirement is grounds to suspend, demote, dismiss or refuse to reemploy a teacher or administrator. (NRS 391.750) **Section 8.6** of this bill: (1) imposes similar requirements for private schools; and (2) makes a willful violation of those requirements a misdemeanor. **Section 19** of this bill provides that a pharmacy benefit manager has a fiduciary duty to an insurer with which the pharmacy benefit manager has entered into a contract to manage prescription drug coverage.

Section 20 of this bill prohibits a pharmacy benefit manager from engaging in certain trade practices.

Federal law prohibits states from regulating an employee benefit plan established under the Employee Retirement Income Security Act of 1974. (29 U.S.C. § 1144) **Section 17** of this bill provides that the requirements that this bill imposes upon pharmacy benefit managers and insurers do not apply to the management or provision of prescription drug benefits included in such a plan unless the plan requires compliance with those provisions.

EXPLANATION – Matter in *bolded italics* is new; matter between brackets ~~omitted material~~ is material to be omitted.

THE PEOPLE OF THE STATE OF NEVADA, REPRESENTED IN
SENATE AND ASSEMBLY, DO ENACT AS FOLLOWS:

Section 1. Chapter 439 of NRS is hereby amended by adding thereto the provisions set forth as sections 2 to 4.9, inclusive, of this act.

Sec. 2. *“Manufacturer” has the meaning ascribed to it in NRS 639.009.*

Sec. 3. *“Pharmacy” means every store or shop licensed by the State Board of Pharmacy where drugs, controlled substances, poisons, medicines or chemicals are stored or possessed, or dispensed or sold at retail, or displayed for sale at retail, or where prescriptions are compounded or dispensed. The term does not include an institutional pharmacy as defined in NRS 639.0085.*

Sec. 3.2. *“Pharmacy benefit manager” has the meaning ascribed to it in section 14.5 of this act.*

Sec. 3.4. *“Wholesale acquisition cost” means the manufacturer’s list price for a prescription drug to wholesalers or direct purchasers in the United States, not including any discounts, rebates or reductions in price, as reported in wholesale price guides or other publications of drug pricing data.*

Sec. 3.6. *On or before February 1 of each year, the Department shall compile:*

1. A list of prescription drugs that the Department determines to be essential for treating diabetes in this State and the wholesale



acquisition cost of each such drug on the list. The list must include, without limitation, all forms of insulin and biguanides marketed for sale in this State.

2. A list of prescription drugs described in subsection 1 that have been subject to an increase in the wholesale acquisition cost of a percentage equal to or greater than:

(a) The percentage increase in the Consumer Price Index, Medical Care Component during the immediately preceding calendar year; or

(b) Twice the percentage increase in the Consumer Price Index, Medical Care Component during the immediately preceding 2 calendar years.

Sec. 3.8. *On or before April 1 of each year, the manufacturer of a prescription drug that appears on the most current list compiled by the Department pursuant to subsection 1 of section 3.6 of this act shall prepare and submit to the Department, in the form prescribed by the Department, a report which must include:*

- 1. The costs of producing the drug;*
- 2. The total administrative expenditures relating to the drug, including marketing and advertising costs;*
- 3. The profit that the manufacturer has earned from the drug and the percentage of the manufacturer's total profit for the period during which the manufacturer has marketed the drug for sale that is attributable to the drug;*
- 4. The total amount of financial assistance that the manufacturer has provided through any patient prescription assistance program;*
- 5. The cost associated with coupons provided directly to consumers and for programs to assist consumers in paying copayments, and the cost to the manufacturer attributable to the redemption of those coupons and the use of those programs;*
- 6. The wholesale acquisition cost of the drug;*
- 7. A history of any increases in the wholesale acquisition cost of the drug over the 5 years immediately preceding the date on which the report is submitted, including the amount of each such increase expressed as a percentage of the total wholesale acquisition cost of the drug, the month and year in which each increase became effective and any explanation for the increase;*
- 8. The aggregate amount of all rebates that the manufacturer has provided to pharmacy benefit managers for sales of the drug within this State; and*
- 9. Any additional information prescribed by regulation of the Department for the purpose of analyzing the cost of prescription*



drugs that appear on the list compiled pursuant to subsection 1 of section 3.6 of this act, trends in those costs and rebates available for such drugs.

Sec. 4. *On or before April 1 of a year in which a drug is included on the list compiled pursuant to subsection 2 of section 3.6 of this act, the manufacturer of the drug shall submit to the Department a report describing the reasons for the increase in the wholesale acquisition cost of the drug described in that subsection. The report must include, without limitation:*

- 1. A list of each factor that has contributed to the increase;*
- 2. The percentage of the total increase that is attributable to each factor;*
- 3. An explanation of the role of each factor in the increase; and*
- 4. Any other information prescribed by regulation by the Department.*

Sec. 4.2. *1. Except as otherwise provided in subsection 2, on or before April 1 of each year, a pharmacy benefit manager shall submit to the Department a report which includes:*

(a) The total amount of all rebates that the pharmacy benefit manager negotiated with manufacturers during the immediately preceding calendar year for prescription drugs included on the list compiled by the Department pursuant to subsection 1 of section 3.6 of this act;

(b) The total amount of all rebates described in paragraph (a) that were retained by the pharmacy benefit manager; and

(c) The total amount of all rebates described in paragraph (a) that were negotiated for purchases of such drugs for use by:

- (1) Recipients of Medicare;*
- (2) Recipients of Medicaid;*
- (3) Persons covered by third parties that are governmental entities which are not described in subparagraph (1) or (2);*
- (4) Persons covered by third parties that are not governmental entities; and*
- (5) Persons covered by a plan described in subsection 2 to the extent required by a contract entered into pursuant to subsection 3.*

2. Except as otherwise provided in subsection 3, the requirements of this section do not apply to the coverage of prescription drugs under a plan that is subject to the Employee Retirement Income Security Act of 1974 or any information relating to such coverage.



3. A plan described in subsection 2 may, by contract, require a pharmacy benefit manager that manages the coverage of prescription drugs under the plan to comply with the requirements of this section.

Sec. 4.3. On or before June 1 of each year, the Department shall analyze the information submitted pursuant to sections 3.8, 4 and 4.2 of this act and compile a report on the price of the prescription drugs that appear on the most current lists compiled by the Department pursuant to section 3.6 of this act, the reasons for any increases in those prices and the effect of those prices on overall spending on prescription drugs in this State. The report may include, without limitation, opportunities for persons and entities in this State to lower the cost of drugs for the treatment of diabetes while maintaining access to such drugs.

Sec. 4.6. 1. A manufacturer of a prescription drug shall provide to the Department a list of each pharmaceutical sales representative who markets prescription drugs on behalf of the manufacturer to providers of health care licensed, certified or registered in this State, pharmacies or employees thereof, operators or employees of medical facilities or persons licensed or certified under the provisions of title 57 of NRS and update the list at least annually.

2. The Department shall provide electronic access to the most recent list provided by each manufacturer pursuant to subsection 1 to each provider of health care licensed, certified or registered in this State, operator of a pharmacy, operator of a medical facility or person licensed or certified under the provisions of title 57 for the purposes of ensuring compliance with the requirements of subsection 3. This subsection must not be construed to impose any duty on a provider of health care, operator of a pharmacy, operator of a medical facility or person licensed or certified under the provisions of title 57 to ensure such compliance.

3. A person who is not included on a current list submitted pursuant to subsection 1 shall not market prescription drugs on behalf of a manufacturer:

(a) To any provider of health care licensed, certified or registered in this State, pharmacy or employee thereof, operator or employee of a medical facility or person licensed or certified under the provisions of title 57 of NRS; or

(b) For sale to any resident of this State.

4. On or before March 1 of each year, each person who was included on a list of pharmaceutical sales representatives submitted pursuant to subsection 1 at any time during the



immediately preceding calendar year shall submit to the Department a report, which must include, for the immediately preceding calendar year:

(a) A list of providers of health care licensed, certified or registered in this State, pharmacies and employees thereof, operators and employees of medical facilities and persons licensed or certified under the provisions of title 57 of NRS to whom the pharmaceutical sales representative provided:

(1) Any type of compensation with a value that exceeds \$10; or

(2) Total compensation with a value that exceeds \$100 in aggregate; and

(b) The name and manufacturer of each prescription drug for which the pharmaceutical sales representative provided a free sample to a provider of health care licensed, certified or registered in this State, pharmacy or employee thereof, operator or employee of a medical facility or person licensed or certified under the provisions of title 57 of NRS and the name of each such person to whom a free sample was provided.

5. The Department shall analyze annually the information submitted pursuant to subsection 4 and compile a report on the activities of pharmaceutical sales representatives in this State. Any information contained in such a report that is derived from a list provided pursuant to subsection 1 or a report submitted pursuant to subsection 3 must be reported in aggregate and in a manner that does not reveal the identity of any person or entity. On or before June 1 of each year, the Department shall:

(a) Post the report on the Internet website maintained by the Department; and

(b) Submit the report to the Governor and the Director of the Legislative Counsel Bureau for transmittal to the Legislative Committee on Health Care and, in even-numbered years, the next regular session of the Legislature.

6. As used in this section:

(a) "Medical facility" has the meaning ascribed to it in NRS 629.026.

(b) "Pharmaceutical sales representative" means a person who markets prescription drugs to providers of health care licensed, certified or registered in this State, pharmacies or employees thereof, operators or employees of medical facilities or persons licensed or certified under the provisions of title 57 of NRS.

(c) "Provider of health care" has the meaning ascribed to it in NRS 629.031.



Sec. 4.9. 1. On or before February 1 of each year, a nonprofit organization that advocates on behalf of patients or funds medical research in this State and has received a payment, donation, subsidy or anything else of value from a manufacturer, third party or pharmacy benefit manager or a trade or advocacy group for manufacturers, third parties or pharmacy benefit managers during the immediately preceding calendar year shall:

(a) Compile a report which includes:

(1) For each such contribution, the amount of the contribution and the manufacturer, third party or pharmacy benefit manager or group that provided the payment, donation, subsidy or other contribution; and

(2) The percentage of the total gross income of the organization during the immediately preceding calendar year attributable to payments, donations, subsidies or other contributions from each manufacturer, third party, pharmacy benefit manager or group; and

(b) Except as otherwise provided in this paragraph, post the report on an Internet website that is maintained by the nonprofit organization and accessible to the public. If the nonprofit organization does not maintain an Internet website that is accessible to the public, the nonprofit organization shall submit the report compiled pursuant to paragraph (a) to the Department.

2. As used in this section, "third party" means:

(a) An insurer, as that term is defined in NRS 679B.540;

(b) A health benefit plan, as that term is defined in NRS 689A.540, for employees which provides coverage for prescription drugs;

(c) A participating public agency, as that term is defined in NRS 287.04052, and any other local governmental agency of the State of Nevada which provides a system of health insurance for the benefit of its officers and employees, and the dependents of officers and employees, pursuant to chapter 287 of NRS; or

(d) Any other insurer or organization that provides health coverage or benefits in accordance with state or federal law.

↳ The term does not include an insurer that provides coverage under a policy of casualty or property insurance.

Sec. 5. NRS 439.900 is hereby amended to read as follows:

439.900 As used in NRS 439.900 to 439.940, inclusive, and sections 2 to 4.9, inclusive, of this act, unless the context otherwise requires, ~~["pharmacy" means every store or shop licensed by the State Board of Pharmacy where drugs, controlled substances, poisons, medicines or chemicals are stored or possessed, or~~



~~dispensed or sold at retail, or displayed for sale at retail, or where prescriptions are compounded or dispensed. The term does not include an institutional pharmacy as defined in NRS 639.0085.]~~ *the words and terms defined in sections 2 to 3.4, inclusive, of this act have the meanings ascribed to them in those sections.*

Sec. 6. NRS 439.915 is hereby amended to read as follows:

439.915 1. Except as otherwise provided in subsection 2 ~~§~~ *and subsection 3 of section 4.6 of this act*, the Department shall:

(a) Place or cause to be placed on the Internet website maintained by the Department ~~the~~ :

(1) The information provided by each pharmacy pursuant to NRS 439.910;

(2) The information compiled by a nonprofit organization pursuant to section 4.9 of this act if such a report is submitted pursuant to paragraph (b) of subsection 1 of that section;

(3) The lists of prescription drugs compiled by the Department pursuant to section 3.6 of this act;

(4) The wholesale acquisition cost of each prescription drug reported pursuant to section 3.8 of this act; and

(5) The reports compiled by the Department pursuant to sections 4.3 and 4.6 of this act.

(b) Ensure that the information ~~provided by each pharmacy pursuant to NRS 439.910 and~~ placed on the Internet website maintained by the Department *pursuant to paragraph (a)* is organized so that each individual pharmacy , *manufacturer and nonprofit organization* has its own separate entry on that website; and

(c) Ensure that the usual and customary price that each pharmacy charges for each prescription drug that is on the list prepared pursuant to NRS 439.905 and that is stocked by the pharmacy:

(1) Is presented on the Internet website maintained by the Department in a manner which complies with the requirements of NRS 439.920; and

(2) Is updated not less frequently than once each calendar quarter.

↳ Nothing in this subsection prohibits the Department from determining the usual and customary price that a pharmacy charges for a prescription drug by extracting or otherwise obtaining such information from claims reported by pharmacies to the Medicaid program.

2. If a pharmacy is part of a larger company or corporation or a chain of pharmacies or retail stores, the Department may present the



pricing information pertaining to such a pharmacy in such a manner that the pricing information is combined with the pricing information relative to other pharmacies that are part of the same company, corporation or chain, to the extent that the pricing information does not differ among those pharmacies.

3. The Department may establish additional or alternative procedures by which a consumer who is unable to access the Internet or is otherwise unable to receive the information described in subsection 1 in the manner in which it is presented by the Department may obtain that information:

- (a) In the form of paper records;
- (b) Through the use of a telephonic system; or
- (c) Using other methods or technologies designed specifically to assist consumers who are hearing impaired or visually impaired.

4. As used in this section, “usual and customary price” means the usual and customary charges that a ~~provider~~ **pharmacy** charges to the general public for a drug, as described in 42 C.F.R. § ~~447.331~~ **447.512**.

Sec. 6.5. NRS 439.925 is hereby amended to read as follows:

439.925 The Department and its members, officers and employees are not liable civilly or criminally for any act, omission, error or technical problem that results in:

1. The failure to provide to consumers information regarding a pharmacy, **prescription drug or nonprofit organization**, including, without limitation, the ~~prices charged by the pharmacy for the prescription drugs and generic equivalents that are on the list prepared pursuant to NRS 439.905; or~~ **information made available on the Department’s Internet website pursuant to NRS 439.915; or**

2. The providing to consumers of incorrect information regarding a pharmacy, **prescription drug or nonprofit organization**, including, without limitation, the ~~prices charged by the pharmacy for the prescription drugs and generic equivalents that are on the list prepared pursuant to NRS 439.905.~~ **information made available on the Department’s Internet website pursuant to NRS 439.915.**

Sec. 7. NRS 439.930 is hereby amended to read as follows:

439.930 The Department shall adopt such regulations as it determines to be necessary or advisable to carry out the provisions of NRS 439.900 to 439.940, inclusive ~~+~~ **, and sections 2 to 4.9, inclusive, of this act.** Such regulations must provide for, without limitation:

1. Notice to consumers stating that:
 - (a) Although the Department will strive to ensure that consumers receive accurate information regarding pharmacies,



prescription drugs and nonprofit organizations including, without limitation, the ~~{prices charged by those pharmacies for the prescription drugs and generic equivalents that are on the list prepared pursuant to NRS 439.905,}~~ *information made available on the Department's Internet website pursuant to NRS 439.915*, the Department is unable to guarantee the accuracy of such information;

(b) If a consumer follows an Internet link from the Internet website maintained by the Department to an Internet website *not* maintained by ~~{a pharmacy,}~~ *the Department*, the Department is unable to guarantee the accuracy of any information made available on ~~{the}~~ *that* Internet website ; ~~{maintained by the pharmacy;}~~ and

(c) The Department advises consumers to contact a pharmacy , *manufacturer or nonprofit organization* directly to verify the accuracy of any information regarding the pharmacy , *a prescription drug manufactured by the manufacturer or the nonprofit organization, as applicable*, which is made available to consumers pursuant to NRS 439.900 to 439.940, inclusive ~~{,}~~ , *and sections 2 to 4.9, inclusive, of this act;*

2. Procedures adopted to direct consumers who have questions regarding the program described in NRS 439.900 to 439.940, inclusive, *and sections 2 to 4.9, inclusive, of this act* to contact the Office for Consumer Health Assistance of the Department;

3. Provisions in accordance with which the Department will allow an Internet link to the information ~~{provided by each pharmacy pursuant to NRS 439.910 and}~~ made available on the Department's Internet website *pursuant to NRS 439.915* to be placed on other Internet websites managed or maintained by other persons and entities, including, without limitation, Internet websites managed or maintained by:

(a) Other governmental entities, including, without limitation, the State Board of Pharmacy and the Office of the Governor; and

(b) Nonprofit organizations and advocacy groups;

4. Procedures pursuant to which consumers , ~~{and}~~ *pharmacies , manufacturers and nonprofit organizations* may report to the Department that information made available to consumers pursuant to NRS 439.900 to 439.940, inclusive, *and sections 2 to 4.9, inclusive, of this act* is inaccurate;

5. The form and manner in which pharmacies are to provide to the Department the information described in NRS 439.910; and

6. *The form and manner in which manufacturers are to provide to the Department the information described in sections 3.8, 4 and 4.6 of this act;*



7. The form and manner in which pharmacy benefit managers are to provide to the Department the information described in section 4.2 of this act;

8. The form and manner in which pharmaceutical sales representatives are to provide to the Department the information described in section 4.6 of this act;

9. The form and manner in which nonprofit organizations are to provide to the Department the information described in section 4.9 of this act, if required; and

10. Standards and criteria pursuant to which the Department may remove from its Internet website information regarding a pharmacy or an Internet link to the Internet website maintained by a pharmacy, or both, if the Department determines that the pharmacy has:

(a) Ceased to be licensed and in good standing pursuant to chapter 639 of NRS; or

(b) Engaged in a pattern of providing to consumers information that is false or would be misleading to reasonably informed persons.

Sec. 7.5. NRS 439.935 is hereby amended to read as follows:

439.935 1. On or before July 1 of each odd-numbered year, the Department shall make a determination of whether sufficient money is available and authorized for expenditure to fund one or more components of the programs and other duties of the Department relating to NRS 439.900 to 439.940, inclusive **†**, *and sections 2 to 4.9, inclusive, of this act.*

2. The Department shall temporarily suspend any components of the program or duties of the Department for which it determines pursuant to subsection 1 that sufficient money is not available.

3. The Department may apply for and accept any available grants and may accept any bequests, devises, donations or gifts from any public or private source to carry out the provisions of NRS 439.900 to 439.940, inclusive **†**, *and sections 2 to 4.9, inclusive, of this act.*

Sec. 8. NRS 439.940 is hereby amended to read as follows:

439.940 **1.** If a pharmacy that is licensed under the provisions of chapter 639 of NRS and is located within the State of Nevada fails to provide to the Department the information required to be provided pursuant to NRS 439.910 or fails to provide such information on a timely basis, and the failure was not caused by excusable neglect, technical problems or other extenuating circumstances, the Department may impose against the pharmacy an administrative penalty of not more than \$500 for each day of such failure.



2. *If a manufacturer fails to provide to the Department the information required by section 3.8, 4 or 4.6 of this act, a pharmacy benefit manager fails to provide to the Department the information required by section 4.2 of this act, a nonprofit organization fails to post or provide to the Department, as applicable, the information required by section 4.9 of this act or a manufacturer, pharmacy benefit manager or nonprofit organization fails to post or provide, as applicable, such information on a timely basis, and the failure was not caused by excusable neglect, technical problems or other extenuating circumstances, the Department may impose against the manufacturer, pharmacy benefit manager or nonprofit organization, as applicable, an administrative penalty of not more than \$5,000 for each day of such failure.*

3. *If a pharmaceutical sales representative fails to comply with the requirements of section 4.6 of this act, the Department may impose against the pharmaceutical sales representative an administrative penalty of not more than \$500 for each day of such failure.*

4. *Any money collected as administrative penalties pursuant to this section must be accounted for separately and used by the Department to establish and carry out programs to provide education concerning diabetes and prevent diabetes.*

Sec. 8.6. Chapter 394 of NRS is hereby amended by adding thereto a new section to read as follows:

1. *The parent or legal guardian of a pupil who has asthma, anaphylaxis or diabetes may submit a written request to the principal or, if applicable, the school nurse of the private school in which the pupil is enrolled to allow the pupil to self-administer medication for the treatment of the pupil's asthma, anaphylaxis or diabetes while the pupil is on the grounds of the private school, participating in an activity sponsored by the private school or on a school bus.*

2. *A private school shall establish protocols for containing blood-borne pathogens and the handling and disposal of needles, medical devices and other medical waste and provide a copy of these protocols and procedures to the parent or guardian of a pupil who requests permission for the pupil to self-administer medication pursuant to subsection 1.*

3. *A written request made pursuant to subsection 1 must include:*



(a) A signed statement of a physician indicating that the pupil has asthma, anaphylaxis or diabetes and is capable of self-administration of the medication while the pupil is on the grounds of the private school, participating in an activity sponsored by the private school or on a school bus;

(b) A written treatment plan prepared by the physician pursuant to which the pupil will manage his or her asthma, anaphylaxis or diabetes if the pupil experiences an asthmatic attack, anaphylactic shock or diabetic episode while on the grounds of the private school, participating in an activity sponsored by the private school or on a school bus; and

(c) A signed statement of the parent or legal guardian:

(1) Indicating that the parent or legal guardian grants permission for the pupil to self-administer the medication while the pupil is on the grounds of the private school, participating in an activity sponsored by the private school or on a school bus;

(2) Acknowledging that the parent or legal guardian is aware of and understands the provisions of subsections 4 and 5;

(3) Acknowledging the receipt of the protocols provided pursuant to subsection 2;

(4) Acknowledging that the protocols established pursuant to subsection 2 have been explained to the pupil who will self-administer the medication and that he or she has agreed to comply with the protocols; and

(5) Acknowledging that authorization to self-administer medication pursuant to this section may be revoked if the pupil fails to comply with the protocols established pursuant to subsection 2.

4. The provisions of this section do not create a duty for the private school in which the pupil is enrolled, or an employee or agent thereof, that is in addition to those duties otherwise required in the course of service or employment.

5. If a pupil is granted authorization pursuant to this section to self-administer medication, the governing body of the private school in which the pupil is enrolled, the private school and any employee or agent thereof, are immune from liability for the injury to or death of:

(a) The pupil as a result of self-administration of a medication pursuant to this section or the failure of the pupil to self-administer such a medication; and

(b) Any other person as a result of exposure to or injury caused by needles, medical devices or other medical waste from



the self-administration of medication by a pupil pursuant to this section.

6. Upon receipt of a request that complies with subsection 3, the principal or, if applicable, the school nurse of the private school in which the pupil is enrolled shall provide written authorization for the pupil to carry and self-administer medication to treat his or her asthma, anaphylaxis or diabetes while the pupil is on the grounds of the private school, participating in an activity sponsored by the private school or on a school bus. The written authorization must be filed with the principal or, if applicable, the school nurse of the private school in which the pupil is enrolled and must include:

(a) The name and purpose of the medication which the pupil is authorized to self-administer;

(b) The prescribed dosage and the duration of the prescription;

(c) The times or circumstances, or both, during which the medication is required or recommended for self-administration;

(d) The side effects that may occur from an administration of the medication;

(e) The name and telephone number of the pupil's physician and the name and telephone number of the person to contact in the case of a medical emergency concerning the pupil; and

(f) The procedures for the handling and disposal of needles, medical devices and other medical waste.

7. The written authorization provided pursuant to subsection 6 is valid for 1 school year. If a parent or legal guardian submits a written request that complies with subsection 3, the principal or, if applicable, the school nurse of the private school in which the pupil is enrolled shall renew and, if necessary, revise the written authorization.

8. If a parent or legal guardian of a pupil who is authorized pursuant to this section to carry medication on his or her person provides to the principal or, if applicable, the school nurse of the private school in which the pupil is enrolled doses of the medication in addition to the dosage that the pupil carries on his or her person, the principal or, if applicable, the school nurse shall ensure that the additional medication is:

(a) Stored on the premises of the private school in a location that is secure; and

(b) Readily available if the pupil experiences an asthmatic attack, anaphylactic shock or diabetic episode during school hours.



9. An employee of a private school who willfully violates any provision of this section is guilty of a misdemeanor.

10. As used in this section:

(a) "Medication" has the meaning ascribed to it in NRS 392.425.

(b) "Physician" has the meaning ascribed to it in NRS 392.425.

(c) "Self-administer" has the meaning ascribed to it in NRS 392.425.

Sec. 9. NRS 600A.030 is hereby amended to read as follows:
600A.030 As used in this chapter, unless the context otherwise requires:

1. "Improper means" includes, without limitation:

(a) Theft;

(b) Bribery;

(c) Misrepresentation;

(d) Willful breach or willful inducement of a breach of a duty to maintain secrecy;

(e) Willful breach or willful inducement of a breach of a duty imposed by common law, statute, contract, license, protective order or other court or administrative order; and

(f) Espionage through electronic or other means.

2. "Misappropriation" means:

(a) Acquisition of the trade secret of another by a person by improper means;

(b) Acquisition of a trade secret of another by a person who knows or has reason to know that the trade secret was acquired by improper means; or

(c) Disclosure or use of a trade secret of another without express or implied consent by a person who:

(1) Used improper means to acquire knowledge of the trade secret;

(2) At the time of disclosure or use, knew or had reason to know that his or her knowledge of the trade secret was:

(I) Derived from or through a person who had used improper means to acquire it;

(II) Acquired under circumstances giving rise to a duty to maintain its secrecy or limit its use; or

(III) Derived from or through a person who owed a duty to the person seeking relief to maintain its secrecy or limit its use; or

(3) Before a material change of his or her position, knew or had reason to know that it was a trade secret and that knowledge of it had been acquired by accident or mistake.



3. "Owner" means the person who holds legal or equitable title to a trade secret.

4. "Person" means a natural person, corporation, business trust, estate, trust, partnership, association, joint venture, government, governmental subdivision or agency, or any other legal or commercial entity.

5. "Trade secret" ~~means~~ :

(a) *Means* information, including, without limitation, a formula, pattern, compilation, program, device, method, technique, product, system, process, design, prototype, procedure, computer programming instruction or code that:

~~(a)~~ (1) Derives independent economic value, actual or potential, from not being generally known to, and not being readily ascertainable by proper means by the public or any other persons who can obtain commercial or economic value from its disclosure or use; and

~~(b)~~ (2) Is the subject of efforts that are reasonable under the circumstances to maintain its secrecy.

(b) Does not include any information that a manufacturer is required to report pursuant to section 3.8 or 4 of this act, information that a pharmaceutical sales representative is required to report pursuant to section 4.6 of this act or information that a pharmacy benefit manager is required to report pursuant to section 4.2 of this act, to the extent that such information is required to be disclosed by those sections.

Sec. 10. Chapter 683A of NRS is hereby amended by adding thereto the provisions set forth as sections 11 to 21, inclusive, of this act.

Sec. 11. (Deleted by amendment.)

Sec. 12. *As used in sections 12 to 21, inclusive, of this act, unless the context otherwise requires, the words and terms defined in sections 13 to 16, inclusive, of this act have the meanings ascribed to them in those sections.*

Sec. 13. *"Covered person" means a person who is covered by a pharmacy benefits plan.*

Sec. 14. *"Pharmacy" has the meaning ascribed to it in NRS 639.012.*

Sec. 14.5. *"Pharmacy benefit manager" means an entity that contracts with or is employed by a third party and manages the pharmacy benefits plan provided by the third party.*

Sec. 15. *"Pharmacy benefits plan" means coverage of prescription drugs provided by a third party.*

Sec. 16. *"Third party" means:*



1. *An insurer, as that term is defined in NRS 679B.540;*
2. *A health benefit plan, as that term is defined in NRS 689A.540, for employees which provides a pharmacy benefits plan;*
3. *A participating public agency, as that term is defined in NRS 287.04052, and any other local governmental agency of the State of Nevada which provides a system of health insurance for the benefit of its officers and employees, and the dependents of officers and employees, pursuant to chapter 287 of NRS; or*
4. *Any other insurer or organization that provides health coverage or benefits or coverage of prescription drugs as part of workers' compensation insurance in accordance with state or federal law.*

↳ *The term does not include an insurer that provides coverage under a policy of casualty or property insurance.*

Sec. 17. 1. *Except as otherwise provided in subsection 2, the requirements of sections 12 to 21, inclusive, of this act and any regulations adopted by the Commissioner pursuant thereto do not apply to the coverage of prescription drugs under a plan that is subject to the Employee Retirement Income Security Act of 1974 or any information relating to such coverage.*

2. *A plan described in subsection 1 may, by contract, require a pharmacy benefit manager that manages the coverage of prescription drugs under the plan to comply with the requirements of sections 12 to 21, inclusive, of this act and any regulations adopted by the Commissioner pursuant thereto.*

Sec. 18. (Deleted by amendment.)

Sec. 19. *A pharmacy benefit manager has a fiduciary duty to a third party with which the pharmacy benefit manager has entered into a contract to manage the pharmacy benefits plan of the third party and shall notify the third party in writing of any activity, policy or practice of the pharmacy benefit manager that presents a conflict of interest that interferes with the ability of the pharmacy benefit manager to discharge that fiduciary duty.*

Sec. 20. 1. *A pharmacy benefit manager shall not:*

(a) *Prohibit a pharmacist or pharmacy from providing information to a covered person concerning the amount of any copayment or coinsurance for a prescription drug or informing a covered person concerning the clinical efficacy of a less expensive alternative drug;*

(b) *Penalize a pharmacist or pharmacy for providing the information described in paragraph (a) or selling a less expensive alternative drug to a covered person;*



(c) Prohibit a pharmacy from offering or providing delivery services directly to a covered person as an ancillary service of the pharmacy; or

(d) If the pharmacy benefit manager manages a pharmacy benefits plan that provides coverage through a network plan, charge a copayment or coinsurance for a prescription drug in an amount that is greater than the total amount paid to a pharmacy that is in the network of providers under contract with the third party.

2. As used in this section, "network plan" means a health benefit plan offered by a health carrier under which the financing and delivery of medical care is provided, in whole or in part, through a defined set of providers under contract with the carrier. The term does not include an arrangement for the financing of premiums.

Secs. 21-26. (Deleted by amendment.)

Sec. 26.3. NRS 689A.405 is hereby amended to read as follows:

689A.405 1. An insurer that offers or issues a policy of health insurance which provides coverage for prescription drugs shall include with any summary, certificate or evidence of that coverage provided to an insured, notice of whether a formulary is used and, if so, of the opportunity to secure information regarding the formulary from the insurer pursuant to subsection 2. The notice required by this subsection must:

(a) Be in a language that is easily understood and in a format that is easy to understand;

(b) Include an explanation of what a formulary is; and

(c) If a formulary is used, include:

(1) An explanation of:

(I) How often the contents of the formulary are reviewed;

and

(II) The procedure and criteria for determining which prescription drugs are included in and excluded from the formulary; and

(2) The telephone number of the insurer for making a request for information regarding the formulary pursuant to subsection 2.

2. If an insurer offers or issues a policy of health insurance which provides coverage for prescription drugs and a formulary is used, the insurer shall:

(a) Provide to any insured or participating provider of health care, upon request:



(1) Information regarding whether a specific drug is included in the formulary.

(2) Access to the most current list of prescription drugs in the formulary, organized by major therapeutic category, with an indication of whether any listed drugs are preferred over other listed drugs. If more than one formulary is maintained, the insurer shall notify the requester that a choice of formulary lists is available.

(b) Notify each person who requests information regarding the formulary, that the inclusion of a drug in the formulary does not guarantee that a provider of health care will prescribe that drug for a particular medical condition.

(c) During each period for open enrollment, publish on an Internet website that is operated by the insurer and accessible to the public or include in any enrollment materials distributed by the insurer a notice of all prescription drugs that:

(1) Are included on the most recent list of drugs that are essential for treating diabetes in this State compiled by the Department of Health and Human Services pursuant to subsection 1 of section 3.6 of this act; and

(2) Have been removed or will be removed from the formulary during the current plan year or the next plan year.

(d) Update the notice required by paragraph (c) throughout the period for open enrollment.

Sec. 26.6. The provisions of subsection 1 of NRS 218D.380 do not apply to any provision of this act which adds or revises a requirement to submit a report to the Legislature.

Sec. 26.9. 1. Notwithstanding any other provision of this act to the contrary:

(a) On or before November 1, 2017, the Department of Health and Human Services shall place on the Internet website maintained by the Department the information prescribed by section 3.6 of this act.

(b) On or before July 1, 2018:

(1) The manufacturer of a drug included on the list:

(I) Described in subsection 1 of section 3.6 of this act shall submit to the Department a report which includes the information prescribed by section 3.8 of this act.

(II) Described in subsection 2 of section 3.6 of this act shall submit to the Department a report which includes the information prescribed by section 4 of this act.

(2) A pharmacy benefit manager shall submit to the Department a report which includes the information prescribed by section 4.2 of this act.



(c) On or before September 1, 2018, the Department shall analyze the reports submitted pursuant to paragraph (b) and compile and post on the Internet website maintained by the Department the initial report required by section 4.3 of this act.

2. As used in this section:

(a) "Manufacturer" has the meaning ascribed to it in section 2 of this act.

(b) "Pharmacy benefit manager" has the meaning ascribed to it in section 14.5 of this act.

Sec. 27. 1. The provisions of sections 19 and 20 of this act do not apply to any contract existing on January 1, 2018, for the pharmacy benefit manager to manage a pharmacy benefits plan for a third party until the contract is renewed.

2. As used in this section:

(a) "Pharmacy benefit manager" has the meaning ascribed to it in section 14.5 of this act.

(b) "Pharmacy benefits plan" has the meaning ascribed to it in section 15 of this act.

(c) "Third party" has the meaning ascribed to it in section 16 of this act.

Sec. 28. 1. This section and section 26.9 of this act become effective upon passage and approval.

2. Section 8.6 of this act becomes effective on July 1, 2017.

3. Sections 1 to 6.5, inclusive, 7.5, 8, 9 and 26.6 of this act become effective upon passage and approval for the purpose of adopting regulations and performing any other administrative tasks that are necessary to carry out the provisions of this act and on October 1, 2017, for all other purposes.

4. Sections 10 to 26.3, inclusive, and 27 of this act become effective upon passage and approval for the purpose of adopting regulations and performing any other administrative tasks that are necessary to carry out the provisions of this act and on January 1, 2018, for all other purposes.

5. Section 7 of this act becomes effective upon passage and approval for the purpose of adopting regulations and performing any other administrative tasks that are necessary to carry out the provisions of this act and on May 1, 2018, for all other purposes.



Appendix H: National Academy for State Health Policy Drug Price Transparency Model Legislation





DRAFT DRUG TRANSPARENCY MODEL LEGISLATION

AN ACT TO PROMOTE PRESCRIPTION DRUG PRICE TRANSPARENCY AND COST CONTROL

WHEREAS the cost of prescription drugs is rising rapidly, year over year;¹ and

WHEREAS, the cost of prescription drugs represents a significant challenge to the State budget for Medicaid and CHIP expenditures, state employee and retiree health insurance, corrections' health care, and the cost of coverage for the employees of public schools and institutions of public higher education for which the State shares the cost; and

WHEREAS the cost of prescription drugs represents 21 percent of spending for employer sponsored insurance, creating a significant challenge to employers that struggle to provide health insurance to employees and their dependents while maintaining a competitive and viable business concern in the State; and

WHEREAS the cost of prescription drugs represents a significant and daily challenge to thousands of the State's residents, who experience difficulty accessing affordable medications; and

WHEREAS the unpredictability of new, high cost drugs and significant price increases for older drugs can strain the ability of State agencies, private payers, and consumers to manage their budgets and access treatments;

WHEREAS the lack of transparency in health insurance issuer costs, and wholesaler and pharmacy benefits manager discounts and margins, prevents policymakers and the public from gaining a true understanding of the cost of the prescription drugs purchased;

WHEREAS providing pricing information across the prescription drug supply chain will help achieve pricing transparency;

WHEREAS a minimum data set in common with other States will minimize burden on entities that are required to report;

WHEREAS a minimum data set in common with other States will enable analyses and comparisons across states; and

WHEREAS the Legislature finds that greater transparency in the current opaque pricing and payment environment for prescription drugs will be a critical tool in developing strategies to address rising drug prices and managing State budgets in a responsible manner; now, therefore

Be it enacted by the People of the State of _____ as follows:

SECTION 1. DEFINITIONS

“Acquisition date” is the month and year that the manufacturer registered with the FDA as the labeler for the drug.

“Brand-name drug” is a prescription drug approved under 21 USC § 355(b) or 42 USC § 262.

“Current calendar year projections” are the amounts the manufacturer anticipates will occur in the current calendar year; or if so allowed by [the State Agency], has occurred in the current calendar year to date.

“Drug group” is as defined by [the State Agency] for the purpose of facilitating revenue and cost reporting by manufacturers.

“Drug grouper” is the name of the standard system the manufacturer is using to group drugs for the purpose of reporting, or a system designated by [the State Agency].

“Generic drug” is a prescription drug approved under 21 USC § 355(j).

“Ingredient cost” is the total amount that third parties pay to pharmacies or pharmacy networks for a drug or drug group.

“Insurance issuer” is a company or organization that is licensed by the Department of Insurance or equivalent agency or agencies in the State to issue coverage entitling a beneficiary to receive a defined set of health care benefits in exchange for a defined consideration such as a premium.

“Justification for current-year price increase” is the reason or reasons that the manufacturer increased the WAC of the drug or drug group compared with last year.

“Manufacturer” is any entity that holds the NDC for a prescription drug and is either engaged in the production, preparation, propagation, compounding, conversion, or processing of drug products; or is engaged in the packaging, repackaging, labeling, relabeling, or distribution of drug products and is not a wholesale distributor of drugs or a retail pharmacy licensed under State law.

“Manufacturer cost” is total costs directly related or allocated to the reported drug specifically for sales in the United States or the State as indicated. Such costs include the cost of goods sold and allocated operating expenses, consistent with Generally Accepted Accounting Principles (GAAP).

“Manufacturer sales volume” is the number of WAC units of the drug or drug group that the manufacturer has sold or expects to sell in the reference year, to any wholesaler or other direct purchaser in the United States or the State, as indicated.

“Market introduction” is the month and year in which the manufacturer acquired or first marketed the drug for sale in the United States.

“National drug code (NDC)” is the numerical code maintained by the FDA that includes the labeler code, product code, and package code.

“Nonproprietary name” is the generic name assigned by the United States Adopted Names (USAN) Council.

“Patient volume” is the number of patients expected to be prescribed the drug in the indicated year.

“Pharmacy benefits manager” is any entity that administers the prescription drug, prescription device, and pharmacist services portion of a health care plan on behalf of an issuer. This definition includes issuers that do not use a separate pharmacy benefits manager to administer their prescription drug programs.

“Pharmacy benefits manager net income” is revenue received from insurance issuers for the drug or drug group, after subtracting (i) the ingredient cost for the drug or drug group paid to pharmacies, pharmacy networks, or pharmacy services administrative organizations for the drug or drug group; and (ii) the pharmacy benefits manager’s operating expenses allocated specifically to the drug or drug group. Net revenue includes revenue from margin pricing, if used by the pharmacy benefits manager, plus any other revenue associated with or allocated to the drug or drug group. Net income is defined consistent with GAAP.

“Pharmacy dispensing fee” is the amount paid to a pharmacy or pharmacy network to cover charges for professional services and overhead costs.

“Pharmacy services administrative organization” is an entity that provides contracting and other administrative services to pharmacies to assist them in their interaction with third-party payers, pharmacy benefit managers, wholesale drug distributors, or other entities.

“Product cost” is the cost of material, direct labor, and overhead. Product cost is defined consistent with GAAP.

“Proprietary name” is the brand or trademark name of the drug reported to the FDA.

“Rebate” is a discount or concession that affects the price of a prescription drug manufactured by the pharmaceutical manufacturer, and that the pharmaceutical manufacturer directly provides to a (i)

health insurance issuer, (ii) pharmacy benefits manager after the manager processes a claim from a pharmacy or a pharmacist, or (iii) a wholesale drug distributor. "Rebate" does not mean a bona fide service fee, as such term is defined in Section 447.502 of Title 42 of the Code of Federal Regulations, as amended from time to time.

"Reporting entity" is any manufacturer, insurance issuer, pharmacy benefits manager, wholesale drug distributor, or any other entity required to report to [the State Agency] under this Act.

"Revenue" is the total gross revenue associated with the drug or drug group in the United States or the State, as indicated. Revenue is defined consistent with GAAP.

"Tax identification number" is the 9-digit tax Taxpayer Identification Number (TIN) used by the Internal Revenue Service (IRS).

"Total spending" is the total of allowed amounts associated with payment for a specified drug or drug group, for all covered lives.

"Volume" is the total number of WAC units of each drug or summed across all drugs in a drug group.

"Wholesale acquisition cost (WAC)" is the manufacturer's list price to wholesalers or direct purchasers in the United States on December 31 of the reference year, as reported in wholesale price guides or other publications of drug or biological pricing data; it does not include prompt pay or other discounts, rebates or reductions in price. The current or proposed WAC is the amount that prompts reporting under this Act. If reported by drug group, it is the average WAC weighted by the relevant number of WAC units.

"Wholesale acquisition cost (WAC) Unit" is the lowest identifiable quantity of the drug or biological that is dispensed, exclusive of any diluent without reference to volume measures pertaining to liquids. If reporting by drug group as indicated by [the State Agency], it is the total number of WAC units in the drug group.

“Wholesale drug distributor” is an entity engaged in the sale of prescription drugs to persons other than a consumer or patient, and licensed by the State Board of Pharmacy or equivalent agency or agencies, as the State requires.

“Wholesale drug distributor net income” is the amount received from all purchasers for the drug or drug group after subtracting the wholesale drug distributor’s cost of goods sold and operating expenses allocated specifically to the drug or drug group. Net income includes revenue from margin pricing, if used by the wholesale drug distributor, plus any other revenue associated with or allocated to the drug or drug group. Net income is defined consistent with GAAP.

SECTION 2. PRICE INCREASE AND NEW DRUG PRICE JUSTIFICATION

- (1) A manufacturer shall notify [the State Agency] if it is increasing the WAC of a brand-name drug by more than 20 percent per WAC unit during any 12-month period, or if it is increasing the WAC of a generic drug priced at \$100 or more per WAC unit by 200 percent or more during the immediately preceding 12-month period. The notice shall be provided in writing at least 60 days prior to the planned effective date of the increase.
- (2) A manufacturer shall notify [the State Agency] if it intends to introduce a new drug in the United States that has a WAC of \$670 per WAC unit or more. The notice shall be provided in writing at least 60 days prior to market introduction.
- (3) A manufacturer that must notify [the State Agency] under Paragraph 1 of this Section shall report to [the State Agency] the following minimum data, and other data that may be specified by [the State Agency], at least 30 days before the price increase:
 - (a) Drug identification
 - (i) National drug code
 - (ii) Proprietary drug name
 - (iii) Non-proprietary drug name
 - (iv) WAC unit
 - (v) Drug group code or name
 - (vi) Drug grouper

- (vii) Manufacturer tax identification number
- (viii) Manufacturer name
- (b) U.S. Sales volume by drug and drug group as specified by [the State Agency], in WAC units
 - (i) Projected current-year sales volume
 - (ii) Sales volume in the current year minus 1
 - (iii) Sales volume in the current year minus 2
 - (iv) Sales volume in the current year minus 3
 - (v) Sales volume in the current year minus 4
- (c) Sales volume in this State for the drug and drug group as specified by [the State Agency], in WAC units:
 - (i) Projected current-year sales volume
 - (ii) Sales volume in the current year minus 1
 - (iii) Sales volume in the current year minus 2
 - (iv) Sales volume in the current year minus 3
 - (v) Sales volume in the current year minus 4
- (d) Wholesale price and related information for the drug:
 - (i) Year of market introduction;
 - (ii) WAC at market introduction;
 - (iii) Current WAC;
 - (iv) WAC in the current year minus 1, year end
 - (v) WAC in the current year minus 2, year end
 - (vi) WAC in the current year minus 3, year end
 - (vii) WAC in the current year minus 4, year end
 - (viii) Justification for proposed current-year WAC increase
- (e) Drug acquisition (if applicable):
 - (i) Acquisition date (MMYYYY)
 - (ii) Company from which acquired
 - (iii) WAC at acquisition, in U.S. dollars
- (f) Revenue from the sale of the drug and (or) drug group in the United States by drug and drug group as specified by [the State Agency], in U.S. dollars per unit:
 - (i) Projected revenue in the current year
 - (ii) Revenue in the current year minus 1

- (iii) Revenue in the current year minus 2;
 - (iv) Revenue in the current year minus 3;
 - (v) Revenue in the current year minus 4.
- (g) Revenue from the sale of the drug and (or) drug group in the State by drug or drug group as specified by [the State Agency], in U.S. dollars per WAC unit:
 - (i) Projected revenue in the current year
 - (ii) Revenue in the current year minus 1
 - (iii) Revenue in the current year minus 2
 - (iv) Revenue in the current year minus 3
 - (v) Revenue in the current year minus 4
- (h) Manufacturer cost associated with sales in the United States by drug or drug group as specified by [the State Agency]:
 - (i) Projected cost in the current year
 - (ii) Cost in the current year minus 1
 - (iii) Cost in the current year minus 2
 - (iv) Cost in the current year minus 3
 - (v) Cost in the current year minus 4
- (i) Current calendar-year projections or incurred cost year to date, as [the State Agency] may indicate, related directly or allocated specifically to sales of this drug and drug group in the United States:
 - (i) Number of WAC units produced
 - (ii) Product cost;
 - (iii) Research and development costs
 - (iv) A description of research and development costs
 - (v) Other company-level capital expenditures allocated to the drug and drug group
 - (vi) A description of other capital expenditures and, if allocated, the rationale for allocation
 - (vii) Financial assistance provided in the United States through patient prescription assistance programs or coupons provided to consumers
 - (viii) Rebates to pharmacy benefits managers
 - (ix) Other rebates, discounts, and price concessions
 - (x) Marketing and advertising expense

- (xi) Other administrative expense allocated to the drug or drug group
- (xii) A description of other administrative expenditures and rationale for allocation

(4) A manufacturer that must notify [the State Agency] under Paragraph 2 of this Section shall report to the State the following minimum data and other data that may be specified by [the State Agency], at least 60 days before the date of market introduction:

(a) Drug identification

- (i) National drug code
- (ii) Proprietary drug name
- (iii) Non-proprietary drug name
- (iv) Manufacturer tax identification number
- (v) Manufacturer name
- (vi) Drug grouper
- (vii) Drug group code or name
- (viii) Date of market introduction
- (IX) WAC unit
- (X) Brand or generic

(b) Patient volume, revenue and price

- (i) Projected patient volume in the current year for the drug and drug group in the United States
- (ii) Projected patient volume in the current year for the drug and drug group in the State
- (iii) Projected revenue for the drug and drug group in the current year in the United States
- (iv) WAC at market introduction

(5) Disclosure of all information reported under this Section is subject to protections defined in Section 9.

SECTION 3. PHARMACY BENEFITS MANAGER DISCOUNTS AND NET INCOME

- (1) Each pharmacy benefit manager shall, to the extent allowed by law, report annually to [the State Agency] the following minimum data, and other data that may be specified by [the State Agency], within 60 days after receiving notification by [the State Agency] indicating the specific drugs or drug groups for which reporting is required:
 - (a) Wholesale acquisition cost
 - (i) Minimum and maximum WAC for each indicated drug and drug group for which the pharmacy benefit manager has negotiated directly with the manufacturer in the last calendar year, related to prescriptions under an insurance policy issued in the State.
 - (ii) Minimum and maximum WAC for each indicated drug and drug group for which the pharmacy benefits manager has negotiated directly with the manufacturer in the current calendar year, related to prescriptions under an insurance policy issued in the State.
 - (b) Volume in WAC units of each indicated drug and drug group that the pharmacy benefit manager negotiated directly with the manufacturer in the last calendar year, for business in the State, in total and for each payer type as relevant.
 - (i) Total
 - (ii) Commercial insurance payers
 - (iii) Medicaid
 - (iv) Medicare
 - (v) Other payers
 - (c) Projected volume in WAC units of each indicated drug and drug group that the pharmacy benefit manager expects to negotiate directly with the manufacturer in the current calendar year, for business in the State, in total and for each payer type as relevant.
 - (i) Total
 - (ii) Commercial insurance payers
 - (iii) Medicaid
 - (iv) Medicare
 - (v) Other payers

- (d) Total rebates, discounts, and price concessions received or negotiated directly with the manufacturer for each drug and drug group as indicated by [the State Agency] in the last calendar year, for business in the State, in total and for each payer type as relevant.
 - (i) Total
 - (ii) Commercial insurance payers
 - (iii) Medicaid, before Federal and state rebates
 - (iv) Medicaid Federal and state rebates
 - (v) Medicare
 - (vi) Other payers
- (e) Projected total rebates, discounts, or price concessions that the pharmacy benefit manager expects to receive or to negotiate directly with the manufacturer for each drug and drug group as indicated by [the State Agency] in the current calendar year, for business in the State, in total and for each payer type as relevant.
 - (i) Total
 - (ii) Commercial insurance payers
 - (iii) Medicaid, before Federal and state rebates
 - (iv) Medicaid Federal and state rebates
 - (v) Medicare
 - (vi) Other payers
- (f) Total discounts, dispensing fees, and other fees negotiated last year with pharmacies, prescription drug networks, or pharmacy services administrative organizations for each drug and drug group as indicated by [the State Agency] in the last calendar year, for business in the State, in total and for each payer type as relevant.
 - (i) Total
 - (ii) Commercial insurance payers
 - (iii) Medicaid
 - (iv) Medicare
 - (v) Other payers
- (g) Projected total discounts, dispensing fees, or other fees that the pharmacy benefits manager expects to negotiate in the current calendar year with pharmacies, prescription drug networks, or pharmacy services administrative organizations for each drug and drug

group as indicated by [the State Agency] in the current calendar year, for business in the State, in total and for each payer type as relevant

- (i) Total
- (ii) Commercial insurance payers
- (iii) Medicaid

- (iv) Medicare
- (v) Other payers

(h) Total net income received in the last calendar year for each drug and drug group as indicated by [the State Agency], for business in the State, in total and for each payer type as relevant.

- (i) Total
- (ii) Commercial insurance payers
- (iii) Medicaid
- (iv) Medicare
- (v) Other payers

(i) Projected net income that the pharmacy benefits manager expects to receive in the current calendar year for each drug and drug group as indicated by [the State Agency], for business in the State, in total and for each payer type as relevant.

- (i) Total
- (ii) Commercial insurance payers
- (iii) Medicaid
- (iv) Medicare
- (v) Other payers

(2) Disclosure of all information reported under this Section is subject to protections defined in Section 9.

SECTION 4. WHOLESALE DRUG DISTRIBUTOR DISCOUNTS AND NET INCOME

(1) Each wholesale drug distributor shall report annually to [the State Agency] the following minimum data, and other data that may be specified by [the State Agency], within 60 days after receiving

notification by [the State Agency] indicating the specific drugs or drug groups for which reporting is required:

- (a) Wholesale acquisition cost
 - (i) Minimum and maximum WAC for each indicated drug and drug group for which the wholesale drug distributor has negotiated directly with the manufacturer in the last calendar year, related to prescriptions under an insurance policy issued in the State.
 - (ii) Minimum and maximum WAC for each indicated drug and drug group for which the wholesale drug distributor has negotiated directly with the manufacturer in the current calendar year, related to prescriptions under an insurance policy issued in the State.
- (b) Volume in WAC units of each indicated drug and drug group that the wholesale drug distributor negotiated directly with the manufacturer in the last calendar year, for business in the State, in total and for each payer type as relevant.
 - (i) Total
 - (ii) Commercial insurance payers
 - (iii) Medicaid
 - (iv) Medicare
 - (v) Other payers
- (c) Projected volume (in WAC units) of each indicated drug and drug group that the wholesale drug distributor expects to negotiated directly with the manufacturer in the last calendar year, for business in the State, in total and for each payer type as relevant.
 - (i) Total
 - (ii) Commercial insurance payers
 - (iii) Medicaid
 - (iv) Medicare
 - (v) Other payers
- (d) Total rebates, discounts, and price concessions negotiated directly with the manufacturer for each drug and drug group as indicated by [the State Agency] in the last calendar year, for business in the State, in total and for each payer type as relevant
 - (i) Total
 - (ii) Commercial insurance payers
 - (iii) Medicaid

- (iv) Medicare
 - (v) Other payers
- (e) Projected total rebates, discounts, or price concessions that the wholesale drug distributor expects to negotiate directly with the manufacturer for each drug and drug group as indicated by [the State Agency] in the current calendar year, for business in the State, in total and for each payer type as relevant.
 - (i) Total
 - (ii) Commercial insurance payers
 - (iii) Medicaid, before Federal and state rebates
 - (iv) Medicaid Federal and state rebates
 - (v) Medicare
 - (vi) Other payers
- (f) Total discounts, dispensing fees, and other fees negotiated last year with pharmacies, prescription drug networks, or pharmacy services administrative organizations for each drug and drug group as indicated by [the State Agency] in the last calendar year, for business in the State, in total and for each payer type as relevant.
 - (i) Total
 - (ii) Commercial insurance payers
 - (iii) Medicaid
 - (iv) Medicare
 - (v) Other payers
- (g) Projected total discounts, dispensing fees, or other fees that the wholesale drug distributor expects to negotiate in the current calendar year with pharmacies, prescription drug networks, or pharmacy services administrative organizations for each drug and drug group as indicated by [the State Agency] in the current calendar year, for business in the State, in total and for each payer type as relevant.
 - (i) Total
 - (ii) Commercial insurance payers
 - (iii) Medicaid
 - (iv) Medicare
 - (v) Other payers

(h) Total net income received in the last calendar year for each drug and drug group as indicated by [the State Agency], for business in the State, in total and for each payer type as relevant.

- (i) Total
- (ii) Commercial insurance payers
- (iii) Medicaid
- (iv) Medicare
- (v) Other payers

(i) Projected total margin that the wholesale drug distributor expects to receive in the current calendar year for each drug and drug group as indicated by [the State Agency], for business in the State, in total and for each payer type as relevant.

- (i) Total
- (ii) Commercial insurance payers
- (iii) Medicaid
- (iv) Medicare
- (v) Other payers

(2) Disclosure of all information reported under this section is subject to protections defined in Section 9.

SECTION 5. INSURANCE ISSUER COSTS

(1) Each insurance issuer designated by [the State Agency] as a reporting entity shall report annually to [the State Agency], to the extent allowed by law, spending on prescription drugs before enrollee cost sharing, in total and per prescription drug user, in total and for each of the top 25 prescription drugs and drug groups as defined by [the State Agency] in four categories, defined as: (i) the greatest total spending before enrollee cost sharing in the last calendar year; (ii) the greatest total spending per user of any drug in the drug group before enrollee cost sharing in the last calendar year; and (iii) highest year-over-year increase in total spending before enrollee cost sharing; and (iv) the highest year-over-year increase in total spending per user of any drug in the drug group before enrollee cost sharing.

- (2) For each drug and drug group as indicated by [the State Agency], the insurance issuer shall report the following minimum data and other data that may be specified by [the State Agency] within 60 days of the close of each calendar year:
- (a) Total spending
 - (i) Total issuer spending before enrollee cost sharing in the last calendar year.
 - (ii) Projected total issuer spending for each drug (as listed in Section 1) before enrollee cost sharing, in the current calendar year.
 - (b) Price concessions and fees paid to pharmacy benefits managers
 - (i) Margins and fees (for each drug listed in Section 1) paid directly to pharmacy benefits managers or pharmacy services administrative organizations in the last calendar year
 - (c) Other retail price concessions and fees
 - (i) Other retail discounts, price concessions, and fees (for each drug listed in Section 1) paid in the last calendar year

SECTION 6. REGISTRATION REQUIREMENTS

Each reporting entity shall register with [the State Agency] in a form and manner specified by [the State Agency] no later than January 31 of each calendar year.

SECTION 7: ASSESSMENTS

- (1) Each reporting entity shall pay an annual assessment to support the operational costs of [the State Agency's] activities as required by this Act. Such costs will include staff salaries, administrative expenses, data system expenses, and consulting fees of [the State Agency] to effect this Act. Total annual assessments shall be based on the total annual allocation authorized by the [State] State Legislature for the operational costs of [the State Agency's] activities under this Act, as indicated in [the State Agency's] fiscal year budget. The amount to be assessed shall be reduced by the difference between the total annual authorized allocation for the next fiscal year and the beginning fund balance in [the State Agency's] account for the prior fiscal year. Any assessment reduction shall be applied proportionately to the categorical groups assessed. Annual assessments shall be at least \$100 for each individual entity required to pay an assessment under this Act.

- (2) Requests for payment of the final assessments shall be sent by [the State Agency] to all reporting entities under this Act. All assessments shall be due to [the State Agency] within 30 days of receipt of the request for payment.

SECTION 8. OVERSIGHT, CERTIFICATION, AND PENALTIES FOR NON-COMPLIANCE

- (1) The reporting entity shall certify required reporting under this Act as accurate under the penalty of perjury.
- (2) Failure of a reporting entity to comply with any Section of this Act may result in a civil penalty as determined by the Director of [the State Agency]. Civil penalties under this Act may not exceed \$30,000 each day that the reporting entity is found to have not complied with any Section of this Act.
- (3) [The State Agency] may audit the data submitted to [the State Agency] by a reporting entity pursuant to Section 2, Section 3, Section 4, and Section 5 of this Act, in a form and manner specified by [the State Agency]. The reporting entity shall pay all costs associated with the audit.
- (4) [The State Agency] may require a reporting entity to submit a corrective action plan, in a form and manner specified by [the State Agency], to correct deficiencies in reporting pursuant to Section 2, Section 3, Section 4, and Section 5 of this Act.
- (5) [The State Agency] may call one or more public hearings and may subpoena any reporting entity to explain its reporting pursuant to Section 2, Section 3, Section 4, and Section 5 of this Act.

SECTION 9. HEARING AND PUBLIC REPORTING

- (1) [The State Agency] shall annually prepare and make available on its website a report on emerging trends in prescription drug prices, and conduct an annual public hearing based on the report findings. The report shall include, but may not be limited to, analysis of manufacturer prices and price increases as reported under this Act, and analysis of information as reported by issuers, pharmacy benefit managers, and wholesale drug distributors under this Act, so as to make clear the major components of prescription drug pricing along the supply chain, and the impacts on insurance

premiums and consumer cost sharing. The data in the report may not reveal information specific to any individual reporting entity.

- (2) Except as provided in this Section, [the State Agency] shall keep confidential all information submitted by an individual reporting entity, and protect it from public disclosure. [The State Agency] may share such information with Department of Insurance or equivalent agency or agencies; such agency or agencies shall keep confidential any information shared by [the State Agency] under this Act and protect it from public disclosure.

SECTION 10. SEVERABILITY

- (1) The provisions of this act are severable. If any part of this Act is declared invalid or unconstitutional, that declaration shall not affect the part which remains.

**Updated May 23, 2019*

¹ Total spending for prescription drugs increased at an average annual rate of 5.2 percent between 2012 and 2017, compared with an average increase of 4.5 percent for all other health care services, equipment, and supplies. Centers for Medicare & Medicaid Services. Table 2 - National Health Expenditures; Aggregate, Annual Percent Change, Percent Distribution and Per Capita Amounts, by Type of Expenditure: Selected Calendar Years 1960-2017 [<https://www.cms.gov/Research-Statistics-Data-and-Systems/Statistics-Trends-and-Reports/NationalHealthExpendData/NationalHealthAccountsHistorical.html>].