

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)

November 2018

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TRANSPARENCY STRATEGIES FOR THE PHARMACEUTICAL SUPPLY CHAIN PURSUANT TO HOUSE BILL 4005 (2018)

Executive Summary

Background

In 2018, the Oregon Legislative Assembly enacted House Bill 4005 which included reporting provisions for pharmaceutical manufacturers and insurers and established the Task Force on the Fair Pricing of Prescription Drugs (Task Force). It directed the Task Force to develop a strategy to create transparency for drug prices in Oregon across the entire supply chain of pharmaceutical products. It also required the Task Force to include a cost-effective and enforceable solution to expose factors that impact pricing.¹ This summary describes the activities and recommendations of the Task Force.

Process and Activities

Over a six-month period, 18 members each contributed over 100 hours to develop a set of transparency recommendations for the Oregon Legislative Assembly. The Task Force met six times between May and October of 2018. The Task Force engaged in a series of iterative exercises to provide feedback on and revise a set of transparency proposals to create transparency across the entire supply chain of pharmaceutical products. Through this work, Task Force members engaged in seven separate exercises and surveys to provide feedback on over sixty transparency proposals for consideration as part of a transparency strategy for the pharmaceutical supply chain. The Task Force's recommendations, achieved through a consensus decision-making model, reflect its collective effort to achieve consensus in light of unique difficulties and complexities inherent in the pharmaceutical supply chain, including the roles of and interplay between federal and state regulatory schemes.

Recommendations

The Task Force recommends fifteen strategies, summarized below, intended to increase transparency across the entire pharmaceutical supply chain. Each recommendation addresses transparency for one or more of the key cost factors impacting the price of pharmaceuticals as identified by Task Force members. These cost factors are coupons, discounts, fees, incentive programs/kickbacks, insurance benefit design, list price, markups, pharmacist gag clause, and rebates. Further analyses on each transparency recommendation should be considered to fully understand the impact on the pharmaceutical supply chain.

Complete recommendations begin on page 24 of the Task Force's full report.

¹ Enrolled House Bill 4005 (2018) p. 14, Oregon Legislative Information System, website, <https://olis.leg.state.or.us/liz/2018R1/Downloads/MeasureDocument/HB4005>, accessed October 31, 2018.

JOINT INTERIM TASK FORCE ON THE FAIR PRICING OF PRESCRIPTION DRUGS
EXECUTIVE SUMMARY

Manufacturers - Disclosure of total and average spending on patient assistance programs from manufacturers; inclusion of the monthly wholesale acquisition cost of a drug in direct-to-consumer advertising within the state of Oregon; and reporting on new drugs with list price exceeding the list price of other drugs within the therapeutic class.

Pharmacy Benefit Managers - Evaluation of the utilization of rebate pass-through or fee-only pharmacy benefit manager (PBM) vendors for state-sponsored health plans.

Insurance Companies - Notice to insurance enrollees about a change in formulary, utilization management rules, or formulary tier placement with increased transparency on availability of brand and generic drugs, grievance and appeals processes, and disclosure of the lesser of the health plan's cost-share amount or the pharmacy usual and customary (cash) price to current or prospective enrollees.

Hospital and Medical Providers - Disclosure of hospital and medical provider markups on patient bills.

State Government Entities - Annual report from state agencies on the 10 highest drug expenditures, 10 highest increased cost paid by drug product, and 10 most prescribed drugs; identification of and manufacturer report on any prescription drug for which the cost of treatment is at least \$10,000 in the Medicaid program; and external audits for state government receipt and use of pharmaceutical rebates for state-sponsored health plans.

Coordinated Care Organization – Provision of information on accurate formulary, prior authorization, and use of point-of-prescribing electronic health records modules and information exchange.

Consumer - Disclosure of funding for nonprofit organizations advocating, outside of patient care, on issues regarding pharmaceutical treatment.

Several transparency strategies were consolidated into a singular recommendation when possible. The following recommendations involve transparency for multiple supply chain entities.

Multiple Supply Chain Entities

- Disclosure of total financial incentives that flow among manufacturers, PBMs, and commercial health insurers for entities that have a direct transactional relationship. Requires certification of commercial health insurance companies' percentage of rebates applied to consumer premiums or out-of-pocket costs.
- Require PBMs and insurers to report specified information on price, rebates, fees, reimbursements, or impact of rebates (when applicable).
- Promotion of PBMs and insurers to engage in practices that may increase the availability of lower-cost pharmaceuticals for consumers at pharmacies.

Next Steps

Additional topics related to pharmaceutical policy were identified by Task Force members and are summarized in its full report. The Task Force will continue to work on pharmaceutical policy through December 31, 2020, under the guidance of the Oregon Legislative Assembly.

TASK FORCE MEMBERS

Senator Dennis Linthicum
 Senator Elizabeth Steiner Hayward

Representative Teresa Alonso León
 Representative Ron Noble

Jon Bartholomew	AARP Oregon	Consumers
Ryan Dunlap	Molecular MD	Biopharmaceutical Industry
Dana Hargunani*	State Agency	Oregon Health Authority
Jack Holt	Hi-School Pharmacy	Independent Pharmacies
Robert Judge	Moda Health	Insurance Companies
Jason Kirby	Walgreens	Retail Pharmacies
Leah Lindahl	Healthcare Distribution Alliance	Wholesale Distributors
LuGina Mendez-Harper	Prime Therapeutics, LLC	Pharmacy Benefit Managers
Erin Moller	Yakima Valley Farm Workers Clinic	Medical Providers
Saumil Pandya	Pharmaceutical Research and Manufacturers of America	Pharmaceutical Manufacturers
John Santa		Oregon Health Policy Board
Joseph Schnabel	Salem Hospital	Hospitals
James Slater	CareOregon, Inc.	Coordinated Care Organization
Andrew Stolfi*	State Agency	Department of Consumer and Business Services

* indicates the individual served as co-chair of the Task Force

Former Task Force Members:

Jesse O'Brien	OSPIRG	Consumers
Abigail Stoddard	Prime Therapeutics, LLC	Pharmacy Benefit Managers

Invited Participant:

Brett Michelin	Association for Accessible Medicines	Generic Manufacturers
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ACKNOWLEDGMENTS

The Task Force engaged in a series of exercises and activities to develop its transparency recommendations. Each member contributed over 100 hours of work on exercises, surveys, and attending in-person meetings all designed to elicit members' feedback throughout the six-month process. Through this work, individuals not appointed to the Task Force also significantly contributed in the development of the exercises, fielding of multiple surveys, analyzing the survey results, as well as offered expertise to the Task Force. The following individuals are acknowledged for assisting the Task Force in its process and ensuring completion of its statutory obligations through a collaborative and engaging process.

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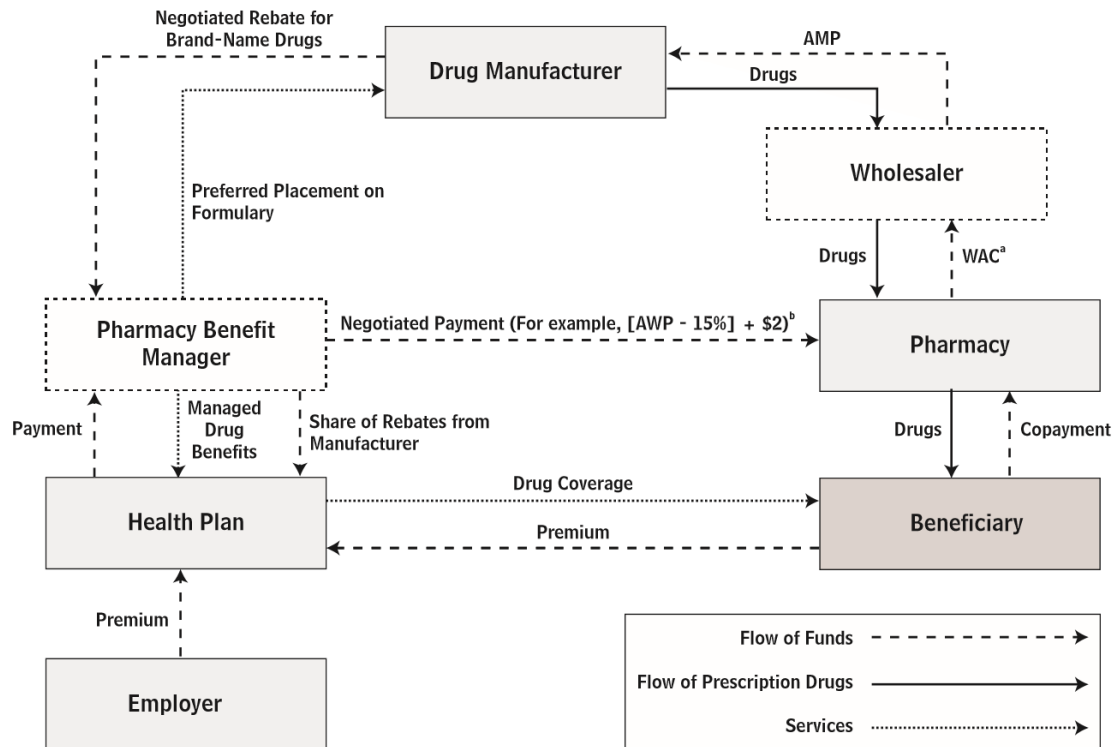
PHARMACEUTICAL MARKET ENTITIES

The pharmaceutical market involves distinct types of entities that serve specific purposes with a shared goal: provide quality drug products to consumers. Primary stakeholders within the pharmaceutical supply chain are:

- Manufacturers – Brand, Generic, Biopharmaceutical
- Wholesale Distributors
- Pharmacies – Retail, Independent, Mail-Order, Specialty
- Pharmacy Benefit Managers
- Insurance Companies
- Medical Providers

These entities interact with each other through a series of activities that involve the movement and pricing of pharmaceutical products, complex contractual arrangements and service arrangements, and operating under federal and state regulatory structures across the United States. Figure 1 provides a general overview of the supply chain and the flow of funds and services between pharmaceutical market entities.

Figure 1. Pharmaceutical Supply Chain for Brand-Name Drug at Retail Pharmacy with Employer Health Insurance Plan¹



Source: Congressional Budget Office

¹ Congressional Budget Office. *Prescription Drug Pricing in the Private Sector*, 2007. <<https://www.cbo.gov/sites/default/files/110th-congress-2007-2008/reports/01-03-prescriptiondrug.pdf>>, visited October 2018.

Market entities participating or referenced in Task Force deliberations are briefly described below to provide a general overview of their roles in the pharmaceutical market and how they interact with the flow and pricing of prescription drugs.²

Manufacturers

Pharmaceutical manufacturers research, develop, produce, market, and sell prescription drugs to treat medical conditions. The development of a new pharmaceutical product involves an investment of resources to create a product ready to be tested during clinical trials, where the safety and clinical efficacy of the drug are evaluated for a specific disease or condition. The U.S. Food and Drug Administration (FDA) reviews all applications for the sale of new drugs from manufacturers following clinical trials and decides whether the drug will be made available on the market to consumers.³ When a drug is approved, manufacturers then set the list price for medications and may change the list price over time. In Oregon, there are currently 1,019 manufacturers licensed with the Board of Pharmacy.⁴ The manufacturing industry can be separated into three distinct areas with unique characteristics to each – brand, generic, and biopharmaceutical manufacturers.

Brand Manufacturers

Manufacturers who produce brand-name drugs may conduct the initial research and development of a new pharmaceutical product. Brand-name drugs receive patents and exclusivities from the FDA.⁵ Manufacturers of these patent-protected brand-name products have market exclusivity to produce and sell their products during the life of the patent before therapeutically equivalent generic drugs can become available on the market.⁶

Generic Manufacturers

Once a brand-name drug is no longer patent-protected, generic manufacturers may begin producing therapeutically equivalent generic drug products. Similar to brand-name drugs, the FDA must also approve a generic drug application to ensure its equivalence to the branded drug before it can be produced.⁷ Generic drugs comprise the largest portion of

² Please see Appendix A for a glossary of pharmaceutical terms used throughout this report and other Task Force documents.

³ U.S. Food & Drug Administration. *The FDA's Drug Review Process: Ensuring Drugs are Safe and Effective*. <<https://www.fda.gov/Drugs/ResourcesForYou/Consumers/ucm143534.htm>>, visited October 2018.

⁴ Oregon Board of Pharmacy. *Active license statistics as of October 1, 2018*. <<https://www.oregon.gov/pharmacy/Pages/Licensing.aspx>>, visited October 2018.

⁵ U.S. Food & Drug Administration. *Frequently Asked Questions on Patents and Exclusivity*. <<https://www.fda.gov/Drugs/DevelopmentApprovalProcess/ucm079031.htm>>, visited October 2018.

⁶ According to the FDA, the term of a new patent is 20 years from the date on which the application for the patent was filed in the United States.

⁷ U.S. Food & Drug Administration. *Generic Drugs: Questions & Answers*. <<https://www.fda.gov/drugs/resourcesforyou/consumers/questionsanswers/ucm100100.htm>>, visited October 2018.

the pharmaceutical market, providing approximately 90 percent of all drugs dispensed to consumers.⁸

Biologic Manufacturers

Biologic manufacturers are distinct from traditional brand and generic manufacturers because they produce drug products made from living organisms, such as antitoxins or vaccines. Manufacturers of biologic drug products are similarly required to receive approval from the FDA to sell their products.⁹ A biosimilar drug product may be produced following the expiration of the biologic's patent and other data protections.

Comparable to the relationship between brands and generics, biosimilars are required to be extremely similar to approved biologics by having no clinically meaningful differences – i.e., the same strength, dosage form, and route administration (such as injection).¹⁰ Many biologics and biosimilars are categorized as specialty drugs due to their complex structures using living organisms, the storage requirements needed, and the cost and complexity of administering the product to a consumer. According to the FDA, biologic and biosimilar drug products are the fastest growing class of therapeutic products in the United States.¹¹

Wholesale Distributors

In a simplified distribution system, wholesaler distributors purchase prescription medicines and other medical products directly from manufacturers for storage in national and regional warehouses and distribution centers across the country. Pharmacies, hospitals, and health care facilities place orders with wholesalers for the medicine and products they need, and the wholesalers process and deliver these orders daily. There are currently 447 wholesalers who distribute prescription drugs in Oregon.¹²

Pharmacies

Pharmacy entities dispense pharmaceutical products directly to consumers. Pharmaceutical products are ordered by the pharmacy and delivered by a wholesale distributor or purchased directly from a manufacturer. Licensed pharmacists dispense

⁸ IQVIA Institute for Human Data Science. *Medicine Use and Spending in the U.S.*, April 2018 <<https://www.iqvia.com/-/media/iqvia/pdfs/institute-reports/medicine-use-and-spending-in-the-us-a-review-of-2017-and-outlook-to-2022.pdf>>, visited October 2018.

⁹ U.S. Food & Drug Administration. *Development & Approval Process (CBER)* <<https://www.fda.gov/BiologicsBloodVaccines/DevelopmentApprovalProcess/default.htm>>, visited October 2018.

¹⁰ U.S. Food & Drug Administration. *Biosimilars: More Treatment Choices and Innovation* <<https://www.fda.gov/ForConsumers/ConsumerUpdates/ucm436399.htm>>, visited October 2018.

¹¹ U.S. Food & Drug Administration. *Biosimilar Product – Regulatory Review and Approval*. <<https://www.fda.gov/downloads/Drugs/DevelopmentApprovalProcess/HowDrugsareDevelopedandApproved/ApprovalApplications/TherapeuticBiologicApplications/Biosimilars/UCM581309.pdf>>, visited October 2018.

¹² Oregon Board of Pharmacy. *Active license statistics as of October 1, 2018*. <<https://www.oregon.gov/pharmacy/Pages/Licensing.aspx>>, visited October 2018.

products to consumers according to prescriptions received by written note or electronic transmission. Pharmacies can be generally separated into three pharmacy types:

- Retail – local entities that are open to the public. These can be national corporate chain pharmacies, independently owned individual stores, or regional chains. Currently there are 1,377 retail pharmacies are licensed in Oregon.¹³
- Specialty – organizations that are not open to the general public but contract with payers or manufacturers for the delivery of specialty drugs which can require special storage and handling. These entities can be owned by a pharmacy benefit manager (PBM), retail pharmacy, or independently owned. Specialty pharmacies may deliver medications directly to a retail pharmacy location for patients to access.
- Mail-order – organizations that deliver pharmaceutical products through the mail. These pharmacies can be owned by a wholesale distributor, chain drug store, PBM, insurance company, or independently owned.

Pharmacy Benefit Managers

Pharmacy benefit managers (PBMs) are intermediaries between health insurers, pharmacies, wholesalers, and manufacturers. Most health insurers contract with PBMs to provide third-party administrative services for insurer’s pharmacy benefit, with the goal of cost containment. PBM services can include claims processing, formulary and benefit design (tiers, utilization management, cost-sharing), pharmacy network contracting, and rebate negotiation with manufacturers.¹⁴ Additional services PBMs provide include administration of mail-order or specialty pharmacy services. Insurers can choose if and what services they contract with PBMs to perform on their behalf. In Oregon, 55 PBMs are currently registered with the Department of Consumer and Business Services.¹⁵

Insurance Companies

Health insurance companies provide medical and pharmacy benefits among other benefits. Insurers offer health plans that specify which pharmaceutical drugs are covered by the plan, called a formulary. Insurers also utilize management tools in the pharmacy benefit such as prior authorization, step therapy, or quantity limits. The benefit design for drugs specifies consumer cost-sharing arrangements such as deductibles, out-of-pocket maximums, copayments or coinsurance amounts for the different drugs. Formularies often utilize tiers to sort prescription drugs primarily based on utilization and cost-sharing for consumers. Higher formulary tiers have higher consumer cost-sharing than lower formulary tiers. Typically, manufacturers negotiate with insurers (or their PBM) for a drug’s formulary tier placement.

¹³ Oregon Board of Pharmacy. *Active license statistics as of October 1, 2018*.

<<https://www.oregon.gov/pharmacy/Pages/Licensing.aspx>>, visited October 2018

¹⁴ Kaiser Family Foundation. *Follow the Pill: Understanding the U.S. Commercial Pharmaceutical Supply Chain*. March 2005.

<<https://olis.leg.state.or.us/liz/201711/Downloads/CommitteeMeetingDocument/148677>>.

¹⁵ Department of Consumer and Business Services. “Re: Number of PBMs Registered.” Email message to Cassie Soucy, October 10, 2018.

Health Care Providers

Health care providers prescribe, dispense, or administer drugs to patients in hospitals or in community settings through written, oral, or electronic communications to a pharmacy. Prescribing health care providers assess and diagnose patients to provide treatment options including prescription medications.

Consumers

Consumers receive prescriptions for pharmaceutical drugs from prescribing health care professionals. If a consumer has health insurance coverage, privately or publicly financed (e.g. employer-sponsored, Medicare, or Medicaid), the costs of a prescription may be fully covered or require cost-sharing (i.e. out-of-pocket costs to a consumer). Cost-sharing may include deductibles, out-of-pocket maximums, copayments, or coinsurance. An uninsured consumer is often responsible for the total cost of the drug. Consumers are dependent on a prescribing health professional, pharmacist, insurer, and the negotiated agreements between pharmaceutical market entities to establish the price and cost of prescribed drugs at the point of dispensing (e.g., a pharmacy).

Related Entities

The pharmaceutical market has several other entities that interact with or influence the delivery and pricing of pharmaceuticals including:

- Hospitals – purchase drugs for inpatient and outpatient use. Many hospitals operate their own pharmacies to dispense pharmaceutical products to patients, employees, or the general public after it has been prescribed by a qualified health provider.
- Coordinated Care Organizations (CCOs) – function similarly to managed care organizations and are regulated under federal and state Medicaid laws. The majority of Oregon’s Medicaid participants are enrolled in CCOs with the remainder in fee-for-service.
- Governmental Entities – Several government entities administer programs dedicated to purchasing pharmaceutical products, regulating pharmaceutical products, or providing oversight to entities within the pharmaceutical supply chain.
 - U.S. Food and Drug Administration (FDA) – provides oversight and regulation regarding approval of pharmaceutical drugs.
 - Centers for Medicare and Medicaid Services (CMS) – provides oversight and regulation regarding Medicare and Medicaid programs which purchase pharmaceutical drugs.
 - Oregon Health Authority (OHA) – implements and regulates Oregon’s Medicaid program, contracts and administers benefits for eligible employees through the Public Employees’ Benefit Board (PEBB) and the Oregon Educators Benefit Board (OEBB), and oversees Oregon’s

Prescription Drug Program, a state prescription discount card and group purchasing program.

- Department of Consumer and Business Services (DCBS) – provides oversight and regulation of commercial health insurers and PBMs, reviews and approves health insurance rates and forms, and oversees the Prescription Drug Transparency Program.
- Group Purchasing Organization (GPO) – represents a group of drug purchasers, such as hospitals and health systems that negotiate with manufacturers to enable members of the buying group to purchase pharmaceutical products. A GPO negotiates with manufacturers on behalf of its clients for either price discounts or rebates. GPOs may provide additional client administrative services as well.
- Pharmacy Services Administration Organization (PSAO) - an entity that represents a group of independent retail pharmacies. PSAOs collectively negotiate prices and contracts with PBMs and wholesalers. They also offer a variety of administrative services to pharmacies. PSAOs are often owned by entities within the pharmaceutical supply chain.

PRICING OF PHARMACEUTICAL PRODUCTS

Prescription drug pricing and costs are determined by industry practices, consumer demand, and financial negotiations between pharmaceutical market entities. Common pricing terms include the wholesale acquisition cost, the average wholesale price, average manufacturer price, and maximum allowable cost. For a full glossary of pharmaceutical terms utilized by the Task Force, please see Appendix A.

- Wholesale acquisition cost (WAC) - frequently referred to as the list price for a pharmaceutical drug, which is set by manufacturers. This is the price the wholesalers or other direct purchasers pay the manufacturer, without factoring in any rebates, discounts, or other price reductions.
- Average wholesale price (AWP) - price for a prescription medicine that is created and published in commercial pricing publications (i.e., MediSpan, Redbook). For brand medicines, this price is almost always higher than the list (WAC) price and represents the starting point for contract negotiations for drug prices between payers and pharmacies/providers.
- Average Manufacturer Price (AMP) – average price paid to a manufacturer by wholesalers for drugs distributed to retail pharmacies.

The list price of a prescription drug is set and changed by the manufacturer, but the price and/or cost may change due to discounts and other price negotiations as the product goes through the supply chain. The discounts, rebates, and fees that accrue throughout the pharmaceutical supply chain can impact the costs to consumers for prescription drugs they purchase or the monthly health care premium they pay. On a system level, prescription drug spending can be affected by the price of new drugs, price increases for existing drugs, and changes in the volume of drugs used by consumers.¹⁶ The next section briefly describes the financial flows among market entities.

Financial Negotiations by Pharmaceutical Market Entities

Manufacturers determine the initial price of brand-name pharmaceutical products based on revenue needs, patent protections, and market conditions such as competition, length of remaining patent, and expected sales, among other factors.¹⁷ This results in the established list price (WAC) for a pharmaceutical product. The generic list price can be significantly different relative to the brand list price because there is more competition among manufacturers of certain generic drugs.¹⁸ Manufacturers provide rebates and

¹⁶ Congressional Research Service. *Frequently Asked Questions About Prescription Drug Pricing and Policy*. April 2018.

<<https://olis.leg.state.or.us/liz/201711/Downloads/CommitteeMeetingDocument/149350>>, visited October 2018.

¹⁷ Kaiser Family Foundation. *Follow the Pill: Understanding the U.S. Commercial Pharmaceutical Supply Chain*, March 2005.

<<https://olis.leg.state.or.us/liz/201711/Downloads/CommitteeMeetingDocument/148677>>, visited October 2018.

¹⁸ Ibid.

discounts to purchasers of their products. These are confidential and are typically based on the volume of dispensed drugs as well as other factors and paid by a manufacturer after a drug has been dispensed or administered.

Wholesalers purchase drugs from manufacturers at a discounted price based on the list price. Wholesalers keep track of sales to different purchasers (pharmacies, hospitals) under prices negotiated between the manufacturer and the purchaser.

Pharmacies purchase pharmaceutical drug products from wholesalers or directly from manufacturers or other supply chain entities. Pharmacies interact with other pharmaceutical market entities, specifically PBMs to negotiate for inclusion in an insurers' pharmacy network. Pharmacy networks include contracted agreements on reimbursement guarantees from the PBM and health insurers for dispensed pharmaceuticals.¹⁹ Pharmacies also charge a dispensing fee for the professional services delivered to the insurer's member.

PBMs interact with manufacturers, pharmacies, and health insurers. PBMs are contracted by health insurance companies to manage the insurer's pharmacy benefits through contractual administrative services which may include processing claims, maintaining pharmacy network adequacy, utilization management, and formulary management. PBMs typically negotiate rebates from manufacturers on behalf of their clients (i.e., commercial insurers or self-insured health plans) and can determine a manufacturer's inclusion or placement on the drug formulary. These rebates can be retroactively distributed back to the health insurer from the PBM.

Health insurance companies determine the cost-sharing for enrolled consumers. Cost-sharing for prescription drug benefits can include pre-established copayment prices, specific percentages of coinsurance, or payment of a deductible amount before receiving coverage for services. In addition to cost-sharing, insurers manage any mid-year formulary changes, prior authorization, and step therapy protocols which affect a consumer's pharmacy benefit.

¹⁹ Kaiser Family Foundation. *Follow the Pill: Understanding the U.S. Commercial Pharmaceutical Supply Chain*, March 2005.
<<https://olis.leg.state.or.us/liz/201711/Downloads/CommitteeMeetingDocument/148677>>, visited October 2018.

PHARMACEUTICAL TRANSPARENCY IN OREGON

Pharmaceutical policies have been an interest in many states over the past couple of years, particularly on the topic of transparency, due to rising pharmaceutical costs. The National Conference of State Legislatures (NCSL) reports that since 2015, states have introduced over 3,500 pieces of legislation relating to pharmaceutical policy throughout the United States.²⁰ In Oregon, pharmaceutical legislation has addressed several topics, including transparency within the pharmaceutical supply chain. For the purposes of this report, five pieces of recent legislation are highlighted as they specifically sought to address pharmaceutical transparency in Oregon.

House Bill 3486 (2015)

Oregon examined pharmaceutical price transparency in 2015 with House Bill 3486.²¹ This bill would have required manufacturers of prescription drugs with a WAC of \$10,000 or more per course of treatment to file an annual report with OHA on the costs associated with the prescription drug for the previous calendar year. House Bill 3486 had two public hearings and was not moved out of committee upon adjournment of the legislative session.

Senate Bills 792 and 793 (2017)

A pair of bills were introduced during the 2017 legislative session addressing pharmaceutical price transparency involving pharmaceutical manufacturers. Senate Bill 792 would have required pharmaceutical manufacturers to disclose the wholesale price of a drug on any advertisement within the state.²² The second bill, Senate Bill 793, would have required pharmaceutical manufacturers to report to the DCBS annually on the prices of prescription drugs sold in Oregon and price increases for prescription drugs.²³ Both bills received public hearings and were not moved out of committee upon adjournment of the legislative session.

House Bill 2387 (2017)

Another bill introduced during the 2017 legislative session was House Bill 2387.²⁴ This bill would have established the Oregon Premium Protection Program in DCBS and provided several requirements regarding pharmaceutical transparency such as:

- 60-day notice of an increased prescription drug cost over 3.4 percent over a 12-month period.
- reporting of prescription drug costs and patient assistance programs.
- specified health plans to make available online information about prescription drug coverage and costs.

²⁰ National Conference of State Legislatures. *Statewide Prescription Drug Database | 2015 – Present*. <<http://www.ncsl.org/research/health/prescription-drug-statenet-database.aspx>>, visited October 2018.

²¹ House Bill 3486 (2015)

²² Senate Bill 792 (2017)

²³ Senate Bill 793 (2017)

²⁴ House Bill 2387 (2017)

House Bill 2387 passed out of the House Committee on Health Care and was referred to the Joint Ways and Means Committee, where it did not move out of committee upon adjournment.

House Bill 4005 (2018)

During the 2018 legislative session, House Bill 4005 was enacted into law as the *Prescription Drug Price Transparency Act*.²⁵ House Bill 4005 has several provisions requiring pharmaceutical manufacturers and insurance companies to report specific information to DCBS.

Manufacturers are required to report the price of a one-month prescription drug supply or a course of treatment costing \$100 or more if the net price increases 10 percent or more over the previous calendar year. Any manufacturer required to report on a prescription drug, as outlined above, must also provide information on any patient assistance programs for that specific drug.

Additionally, manufacturers are required to provide notification and specified information for any new prescription drug for sale with a price that exceeds the CMS threshold for specialty drugs in Medicare Part D.

Insurance companies have different reporting requirements as specified in House Bill 4005, and must report on the following:

- twenty-five most frequently prescribed drugs;
- twenty-five most costly drugs as a portion of total annual spending;
- twenty-five drugs that have caused the greatest increase in total plan spending from one year to the next; and
- the impact of prescription drug costs on premium rates.

House Bill 4005 also established the Task Force on the Fair Pricing of Prescription Drugs to examine and develop a transparency strategy for prescription drug prices across the pharmaceutical supply chain.

²⁵ House Bill 4005 (2018)

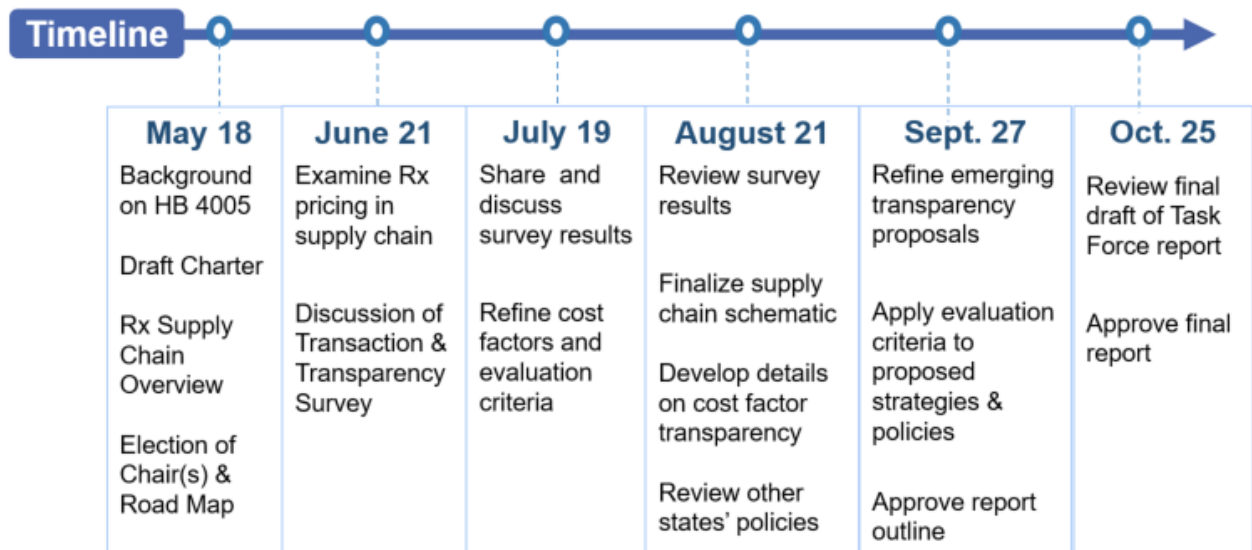
TASK FORCE OVERVIEW AND PROCESS

The Joint Interim Task Force on the Fair Pricing of Prescription Drugs was directed to develop the following:

1. Strategy to create transparency for drug prices across the entire supply chain of pharmaceutical products, and
2. Cost-effective and enforceable solution that exposes the cost factors that negatively impact prices paid by Oregonians for pharmaceutical products.²⁶

The Task Force began meeting in May 2018 and completed work on its first report in November 2018. The Task Force will continue to work to address other pharmaceutical topics through December 31, 2020 at the guidance of the Legislative Assembly.

Figure 2: Timeline of Task Force Meetings (May 2018 - November 1, 2018)



Source: Legislative Policy and Research Office

Members of the Task Force represent different stakeholders of the pharmaceutical supply chain from manufacturer, PBMs, state agencies to consumer representation.²⁷ A representative of generic pharmaceutical manufacturers (Association for Accessible Medicines) participated in many Task Force activities as a non-voting, invited participant following the first meeting.

To develop a strategy for transparency in the pharmaceutical supply chain, the co-chairs and staff intentionally involved all members of the supply chain that were appointed to the Task Force by Governor Kate Brown.

²⁶ HB 4005 (2018)

²⁷ Joint Interim Task Force on the Fair Pricing of Prescription Drugs. *Updated Roster*. September 2018. <<https://olis.leg.state.or.us/liz/201711/Downloads/CommitteeMeetingDocument/150804>>, visited October 2018.

Due to the complexities of the pharmaceutical market and the aggressive timeline to provide transparency strategy recommendations, a professional facilitator was brought in to help provide a process in which all stakeholders were encouraged to constructively collaborate and arrive at consensus regarding transparency for drug prices. The Institute for Conflict Management, Inc. (ICMresolutions) was selected from the list of public policy facilitators to work with the Task Force.²⁸

An official charter was adopted outlining responsibilities and expectations of Task Force members that include:²⁹

- review of background materials and analysis to understand the issues to be addressed in the review process;
- attendance at Task Force meetings;
- consideration and integration of public input into Task Force findings as appropriate; and
- work collaboratively with one another to explore issues and develop recommendations.

House Bill 4005 directed the Task Force to elect a chairperson(s) to provide leadership to the Task Force and serve as the liaison to the Legislative Assembly. The Task Force unanimously elected Dana Hargunani, Chief Medical Officer, OHA, and Andrew Stolfi, Administrator and Insurance Commissioner, DCBS, due to their neutral roles within the pharmaceutical supply chain as representatives of state agencies.

The charter also outlined the consensus voting process during Task Force decision points. If a consensus on a recommendation was not obtained, the votes of those present at the meeting were taken and recorded as a majority - minority vote. Majority is defined as at least 51 percent, or eight of the fourteen voting members.

A public comment period was held at each meeting. This provided the public the opportunity to share information or feedback directly with the Task Force on topics related to its work. Submitted public comment and summarized meeting materials can be found on the Task Force webpage.³⁰

Before the first meeting, Governor Brown submitted a letter to the Task Force describing the importance of transparency to consumers.³¹

²⁸ ICMresolutions. *Mediation* <<https://www.mediate.com/icm/>>, visited October 2018.

²⁹ Joint Interim Task Force on the Fair Pricing of Prescription Drugs. *Charter and Operating Procedures*, 06/21/2018 <<https://olis.leg.state.or.us/liz/201711/Downloads/CommitteeMeetingDocument/149545>>, visited October 2018.

³⁰ Joint Interim Task Force on the Fair Pricing of Prescription Drugs. *Committee Overview* <<https://olis.leg.state.or.us/liz/201711/Committees/JFPRX/Overview>>, visited October 2018.

³¹ Governor Kate Brown, *To: Members of the Task Force on the Fair Pricing of Prescription Drugs*, 04/16/2018 <<https://olis.leg.state.or.us/liz/201711/Downloads/CommitteeMeetingDocument/148672>>, visited October 2018.

Governor Brown offered two considerations for members to keep in mind while developing transparency proposals:

- focus on consumer interests by developing solutions that educate and help Oregonians manage their prescription drug costs, and
- examine the role of each pharmaceutical market participant and the various components when creating strategies for drug price transparency.

Overview of Task Force Activities

Members participated in seven exercises over the course of six months to develop a transparency strategy for drug prices in the supply chain. This involved dedication and hard work from all members to provide information, feedback, and decisions to the co-chairs, the facilitator, and staff to guide the process to develop recommendations. Table 1 describes the series of steps the Task Force engaged in throughout the six months dedicated to developing transparency recommendations.

Table 1: Timeline of Task Force Activities

Timeline	Activities
May	Member perspectives on the pharmaceutical supply chain
June	Development of the Transaction and Transparency Survey
July	Overview of Survey Results
	Refinement of Cost Factors and Evaluation Criteria
August	National Research and Strategies on Pharmaceutical Transparency
	Updated Supply Chain and Cost Factors
September	Evaluation of Proposed Transparency Strategies
	Refinement of Proposed Transparency Strategies
October	Preliminary Vote on Refined Transparency Strategies
	Adopt and Recommend Transparency Strategies for the Pharmaceutical Supply Chain

Task Force Perspectives on the Pharmaceutical Supply Chain

Beginning in May, the Task Force collected information to provide foundational knowledge of the pharmaceutical supply chain but also to begin identifying what cost factors or areas within the pharmaceutical supply chain needed more transparency. Task Force members were asked specifically:

- How does your industry/stakeholder group interact with the development or movement of pharmaceutical products in Oregon?
- How does your industry/stakeholder group interact with the pricing of pharmaceutical products in Oregon? What pricing mechanisms are utilized?
- What successes, difficulties, or obstacles involving pricing transparency within the pharmaceutical supply chain impact your industry/stakeholder group?

Each member provided information on their industry and role within the pharmaceutical supply chain.³² The perspectives from members gave an overview of how the pharmaceutical supply chain functions regarding the delivery of pharmaceutical products and how pharmaceuticals are priced. Highlighted in the discussion of the pharmaceutical supply chain were the complex interactions and negotiations that occur within the system. Transparency was also discussed by members with differing viewpoints about the types of transparency that may benefit consumers and the limitations of transparency throughout the supply chain.

Supply Chain Transaction and Transparency Survey

In June, the Task Force completed the Transaction and Transparency Survey to understand the prescription drug distribution system and types of transactions between entities in Oregon. The specific goals of the survey were to identify:

1. Types of transactions among and between individual stakeholders in the supply chain;
2. Cost factors involved in each transaction;
3. Perspectives on each cost factor's influence on types of drugs and contractual elements;
4. Relative need for transparency among identified cost factors; and
5. Evaluation criteria for proposed cost factor transparency recommendations.

Task Force members reviewed a draft of the survey and provided feedback at the June meeting. Staff from the Legislative Policy and Research Office (LPRO), with technical assistance from OHA, edited the survey based on member feedback and designed the survey utilizing Qualtrics. The survey was finalized and sent to the stakeholders on June 30th.³³ All voting members completed the survey prior to the July 19th meeting.

³² Joint Interim Task Force on the Fair Pricing of Prescription Drugs. *Task Force Member Responses to Questions, Combined*, May 2018.

<<https://olis.leg.state.or.us/liz/201711/Downloads/CommitteeMeetingDocument/148992>>, visited October 2018.

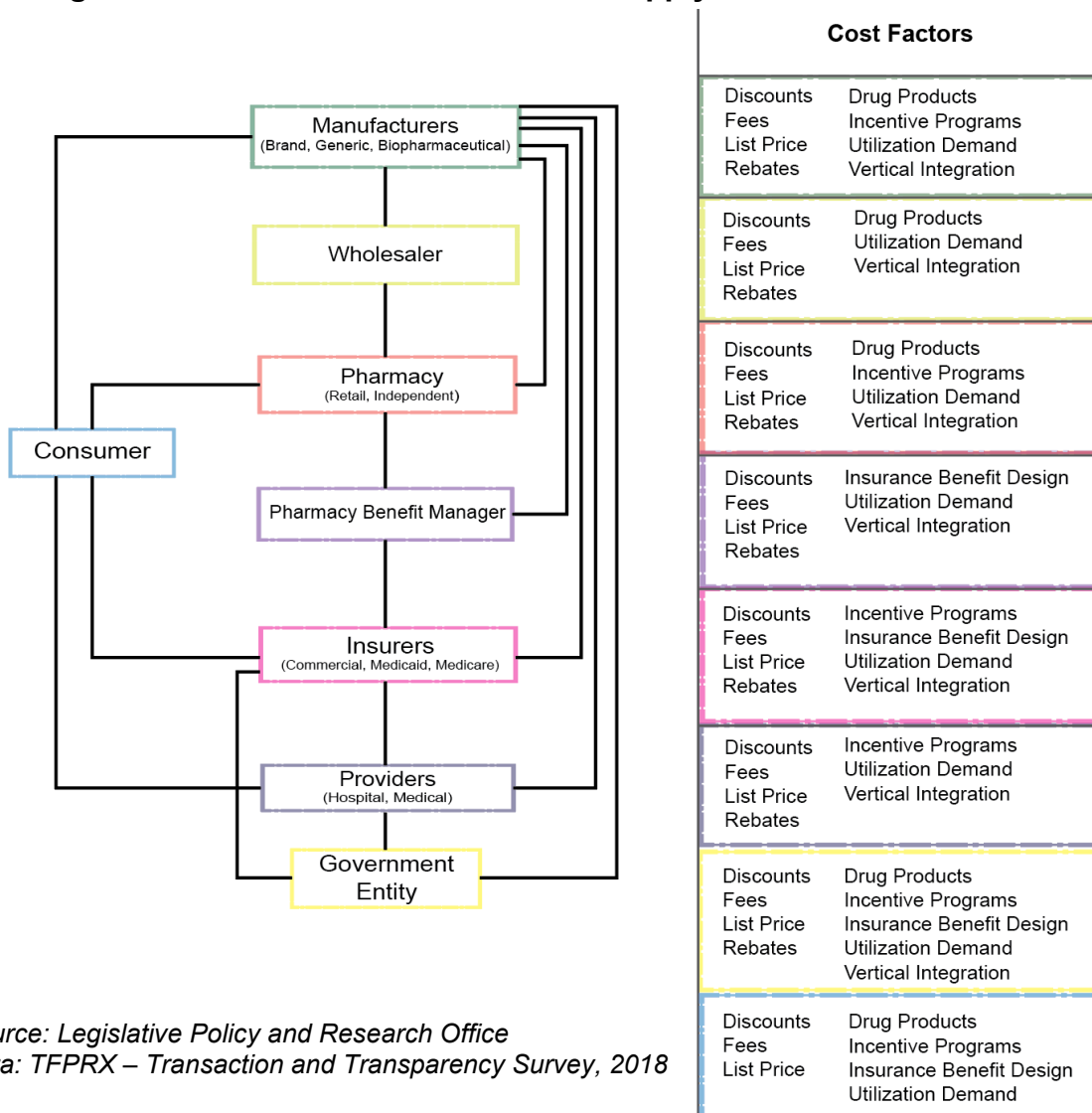
³³ Joint Interim Task Force on the Fair Pricing of Prescription Drugs. *Transaction and Transparency Survey*. 7/19/2018.

<<https://olis.leg.state.or.us/liz/201711/Downloads/CommitteeMeetingDocument/149715>>, visited October 2018.

Survey Results

Task Force members were asked to identify all stakeholders with whom they had direct transactional relationships.³⁴ Once members had selected stakeholders with whom they had relationships, they were asked to identify from a provided list the cost factors for each transaction that may impact the prices Oregonians pay for pharmaceutical products. Results were simplified by combining similar entities and displaying only bi-directional relationships (in which both entities acknowledged transmittal of goods, services, or compensation).³⁵ The Task Force pharmaceutical supply chain with associated cost factors is depicted below (Figure 3).

Figure 3: Task Force Pharmaceutical Supply Chain and Cost Factors



Source: Legislative Policy and Research Office
 Data: TFPRX – Transaction and Transparency Survey, 2018

³⁴ Transactional relationship was defined as an exchange of pharmaceutical products, services, or money, whether pursuant to an explicit written contract (e.g. manufacturer to wholesaler) or not (e.g. pharmacy to consumer).

³⁵ Please see Appendix B for the pharmaceutical supply chain outlining all transactional relationships identified by members.

Members were asked to give their perspectives on the relative influence each cost factor has on increasing and decreasing prices of prescription drugs. Cost factors identified by members that influence the prices of pharmaceutical drugs paid by Oregonians within each of the supply chain relationships across all supply chain entities were, in alphabetical order:³⁶

- Discounts
- Drug Products
- Fees
- Incentive programs (kickbacks)
- Insurance benefit design
- List price
- Rebates
- Utilization demand
- Vertical integration

Members then ranked cost factors according to their ability to influence price. In addition to ranking the cost factors that have the biggest influence on price and cost, members provided their perspectives on which factors should or should not have greater transparency, with the opportunity to suggest other cost factors for transparency.³⁷ Certain cost factors were selected for both the ability to increase or decrease price as well as whether there should be more or less transparency. Finally, members were asked to provide input on the evaluation criteria to assist the Task Force in developing an evaluation framework for use in selecting cost factor transparency recommendations.³⁸

The results of the survey provided unique data specific to Oregon for development of transparency strategies, particularly the cost factors and evaluation criteria identified. Cost factors and evaluation criteria were further refined using a dot exercise during the July meeting to finalize the top cost factors and evaluation criteria. Information provided in the survey served as the foundation for the Task Force to begin developing and refining transparency proposals for consideration.

Finalization of Cost Factors and Evaluation Criteria

In July, members discussed the proposed cost factors and suggested including markups and pharmacist gag clauses for consideration. Each cost factor was defined in the glossary to establish a common understanding of these terms.³⁹ Task Force members accepted the following cost factors and their definitions for consideration in transparency proposals:

- Coupons
- Discounts
- Fees
- Incentive Programs (Kickbacks)
- Insurance Benefit Design
- List Price
- Markups
- Pharmacist Gag Clause
- Rebates

³⁶ Please see the Transaction and Transparency Summary of Survey Results for further information.

³⁷ Ibid.

³⁸ Ibid.

³⁹ Please see Appendix A for the Glossary of Pharmaceutical Terms.

LPRO and facilitation staff evaluated the frequency of evaluation criteria proposed by members throughout the survey to develop a list of criteria for Task Force consideration. Additional evaluation criteria were included based on the statutory charge for “cost effective and enforceable solutions.”⁴⁰ Similar to the cost factors, each evaluation criterion was defined in the glossary to establish a common understanding amongst members.⁴¹

Members discussed and accepted the following evaluation criteria and their definitions for assessing transparency proposals:

- Ability to Monitor
- Better Decision-making
- Cost Effective
- Cost Reduction
- Enforceability

The finalized cost factors formed the framework the Task Force used to evaluate the proposed transparency strategies developed from academic pharmaceutical research and legislative concepts from other states.

Pharmaceutical Policy and Research

The Task Force was presented with information on the flow of money through the pharmaceutical supply chain and what other states have done regarding pharmaceutical policy during the August meeting. This information supplemented the results from the Transaction and Transparency survey, which provided individual perspectives on transparency in the pharmaceutical supply chain.

Flow of Money in the Pharmaceutical Supply Chain

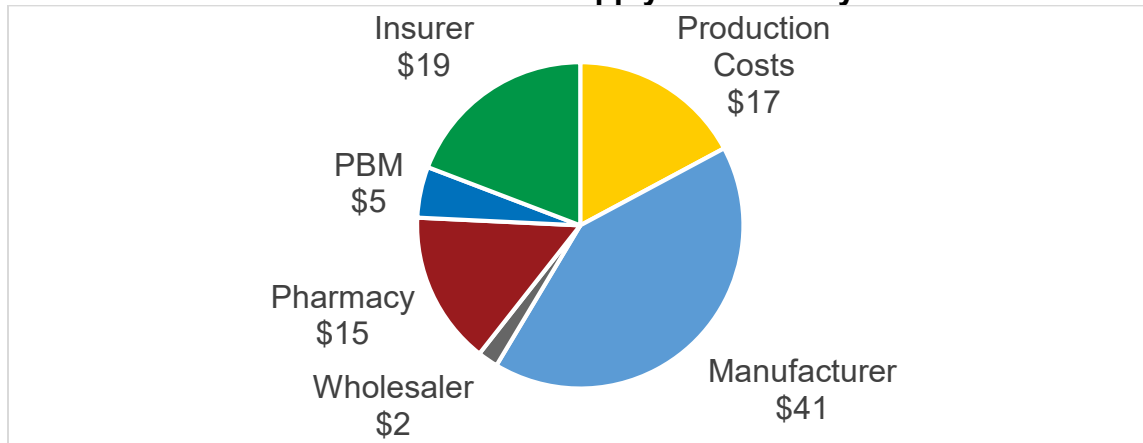
Dr. Neeraj Sood of the University of Southern California was invited to present on his research about the flow of money in the pharmaceutical supply chain.⁴² Dr. Sood explained how drugs reach consumers, how much money pharmaceutical supply chain entities retain, and suggested policies to improve drug price transparency in Oregon. Dr. Sood’s research mapped the flow of a \$100 prescription drug expenditure through the U.S. pharmaceutical supply chain. The flow of money was determined by identifying the top companies for each market segment in the pharmaceutical supply chain and using the Securities and Exchange Commission (SEC) filings to estimate the gross and net profits and illustrate the flow of money for a drug purchased. The result of these estimates found entities in the supply chain retain the following from a \$100 prescription drug expenditure (Figure 4).

⁴⁰ HB 4005

⁴¹ Please see Appendix A for the evaluation criteria definitions.

⁴² Sood, N. et. al. *The Flow of Money Through the Pharmaceutical Distribution System*, June 2017 <<https://olis.leg.state.or.us/liz/201711/Downloads/CommitteeMeetingDocument/149980>>, visited October 2018.

Figure 4. Estimated Amount of \$100 Prescription Drug Expenditure Retained by Pharmaceutical Supply Chain Entity



Source: Sood, N. June 2017

Dr. Sood noted the results are estimates and have many limitations due to the lack of transparency within the pharmaceutical supply chain.⁴³ Additionally, Dr. Sood provided his perspective and recommendations on how Oregon can improve drug price transparency throughout the supply chain. He proposed designing a case study of specific types of drugs to examine the cost factors potentially influencing price. This included parallel disclosures from different supply chain entities on factors such as list price, discounts, rebates, fees, and copay assistance programs. Finally, Dr. Sood provided recommendations not related to transparency including transitioning the rebate system to a discount model and mandating the pass-through of discounts to consumers.

Information from Dr. Sood's research was combined with research performed by the Pharmaceutical Researchers and Manufacturers of America⁴⁴ and the Association for Accessible Medicines⁴⁵ to illustrate the different perspectives on how money flows through the pharmaceutical supply chain of brand and generic drugs (Figure 5). Task Force members utilized this document to explore the cost factors identified in the Transaction and Transparency Survey and their potential influence on the flow of money.⁴⁶

⁴³ Sood, N. et. al. *Technical Appendix for the Flow of Money Through the Pharmaceutical Distribution System*. June 2017.

<https://olis.leg.state.or.us/liz/201711/Downloads/CommitteeMeetingDocument/149981>.

⁴⁴ Pharmaceutical Researchers and Manufacturers of America. *Follow the Dollar: Understanding how the Pharmaceutical Distribution and Payment System Shapes the Prices of Brand Medicines*, November 2017. <https://olis.leg.state.or.us/liz/201711/Downloads/CommitteeMeetingDocument/150035>, visited October 2018.

⁴⁵ Association for Accessible Medicines. *Introduction to the Generic Drug Supply Chain and Key Considerations for Policymakers*. October 2017.

<https://www.accessiblemeds.org/sites/default/files/2017-10/AAM-Generic-Brand-Drug-Supply-Chain-Brief.pdf>, visited October 2018.

⁴⁶ Joint Interim Task Force on the Fair Pricing of Prescription Drugs. *Flow of Money Through the Pharmaceutical Supply Chain – Discussion Draft*. August 2018.

<https://olis.leg.state.or.us/liz/201711/Downloads/CommitteeMeetingDocument/150028>.

Figure 5. Flow of Money through the Pharmaceutical Supply Chain

	Flow of Money USC ¹		Follow the Dollar PhRMA ²			Generic Supply Chain AAM ³		Task Force Cost Factors	USC Report Cost Factors	PhRMA Cost Elements	AAM Cost Elements			
	Brand	Generic	Brand Ex. 1	Brand Ex. 2	Brand Ex. 3	Brand	Generic							
Starting Amount	\$100	\$100	\$100 (WAC) \$120 (AWP)	\$400 (WAC) \$480 (AWP)	\$3000 (WAC) \$3600 (AWP)	\$100	\$100	Market concentration Coinsurance Copayment Premiums Copay assistance Drug development Market exclusivity Patents Discounts Fees Incentive Program/Kickbacks Insurance Benefit Design List Price Rebates Higher cost-sharing tiers	Market concentration					
Actual Total	\$83	\$84	\$116	\$408	\$4272.5	\$101	\$100							
Consumers			\$40 Co-payment	\$408 Deductible	\$612 Coinsurance							Copayment Deductible Premium		
Manufacturers	69.9% (\$58)	21.4% (\$18)	51.7% (\$62)	21.6% (\$88)	44.6% (\$1,905)	75.2% (\$76)	36% (\$36)					AWP WAC	AMP Legal fees Market competition Marketing products Patents Regulatory approval Volatile pricing	
Wholesalers	1.20% (\$1)	9.52% (\$8)	0.43% (\$0.50)	0.49% (\$2)	0.35% (\$15)	0.99% (\$1)	8% (\$8)					Drug product Negotiated purchasing rate	Distribution fee Drug product Pharmacy ingredient acquisition cost WAC discount	Discounts Drug product sales Pricing Stocking fees
Pharmacies	3.61% (\$3)	38.1% (\$32)	4.18% (\$4.85)	6.19% (\$25.25)	5.01% (\$214.25)	2.97% (\$3)	32% (\$32)					Drug product Negotiated wholesale rate Negotiated reimbursement	Administrative and data fees Consumer cost-sharing Dispensing fee Ingredient cost reimbursement	Blended cost reimbursements Dispensing fee National Average Drug Acquisition Cost (NADAC)
PBMs	2.41% (\$2)	8.33% (\$7)	9.18% (\$10.65)	13.2% (\$53.75)	7.21% (\$308)	1.98% (\$2)	7% (\$7)					Fees Discounts for list price Incentive payments Negotiated reimbursement Payments Rebates	Administrative fee Administrative service fee Base rebate Ingredient cost reimbursement Price protection rebate Transaction & E-prescribing fees	Maximum Allowable Cost (MAC) Rebates Utilization management (prior authorization, step therapy)
Insurers	22.9% (\$19)	20.2% (\$17)	32.8% (\$38)	58.9% (\$239)	42.8% (\$1,830.25)	18.8% (\$19)	17% (\$7)							Rebates Service contract Utilization management
Providers														
Government Entities														

¹ Sood, N. et. al. *The Flow of Money through the Pharmaceutical Distribution System*. July 2017. <https://healthpolicy.usc.edu/wp-content/uploads/2017/06/USC_Flow-of-MoneyWhitePaper_Final_Spreads.pdf>.

Data displays gross profit margins as fraction of net revenue from 2015 SEC filings (forms 10K and 20F); CMS data; and other publicly available sources

² **Pharmaceutical Research and Manufacturers of America**. *Follow the Dollar: Understanding How the Pharmaceutical Distribution and Payment System Shapes the Prices of Brand Medicines*. November 2017. <<http://phrma-docs.phrma.org/files/dmfile/Follow-the-Dollar-Report.pdf>>.

Data displays money retained by the specified entity. Source for data is published materials and industry experts.]

³ **Association for Accessible Medicines**. *Introduction to the Generic Drug Supply Chain and Key Considerations for Policymakers*. October 2017. <<https://www.accessiblemeds.org/sites/default/files/2017-10/AAM-Generic-Brand-Drug-Supply-Chain-Brief.pdf>>.

Data displays gross profit margins and money retained for specified entities. Source for data is N. Sood, et. al. *Flow of Money through the Pharmaceutical Distribution System*.

Other States' Pharmaceutical Policies

The Task Force was also presented information on pharmaceutical policies other states have proposed or enacted. NCSL reports states have introduced over 3,500 pieces of legislation relating to pharmaceutical policy in the United States since 2015.⁴⁷ Legislation has spanned a range of policy topics related to prescription drugs that includes but is not limited to:

- Access to prescription drugs
- Biologics and biosimilars
- Clinical trials and right to try
- Compounding pharmacy regulation
- Cost-sharing and deductibles for consumers
- Coverage of prescription drugs by insurers
- Drug importation from Canada
- Utilization and costs of prescription drugs in state Medicaid programs
- Price increases and rate-setting
- Pricing and payment in the drug supply chain
- Regulation of PBMs
- Prescription drug safety and errors
- Specialty pharmaceuticals
- Transparency
- Utilization management

LPRO staff collected this information based on a high-level sampling of the hundreds of pharmaceutical drug-related bills introduced throughout the country.⁴⁸ In August, members engaged in discussion around pharmaceutical policies presented, and commented that many policy proposals are not unique to a single state and have been reworded and considered in other states. Concepts discussed included price gouging, clawbacks, pharmacist gag orders, drug importation, formularies, and increased transparency for specific supply chain entities. Following this discussion, the Task Force requested LPRO to develop straw transparency proposals utilizing the information collected from the Transaction and Transparency Survey, original ideas offered by members, and transparency proposals from other states.

Transparency Proposal Development

The Task Force engaged in a series of iterative exercises to provide feedback on and revise a set of transparency proposals to create transparency across the entire supply chain of pharmaceutical products. Through this work, members engaged in seven separate exercises and surveys to provide feedback on over sixty transparency proposals for consideration as part of a transparency strategy for the pharmaceutical supply chain.

⁴⁷ National Conference of State Legislatures. *Statewide Prescription Drug Database | 2015 – Present*. <<http://www.ncsl.org/research/health/prescription-drug-statenet-database.aspx>>, visited October 2018.

⁴⁸ Joint Interim Task Force on the Fair Pricing of Prescription Drugs. *Other States' Prescription Drug Legislative Proposals (2015-2018) – Discussion Document*. <<https://olis.leg.state.or.us/liz/201711/Downloads/CommitteeMeetingDocument/150038>>, visited October 2018.

Members were asked to provide feedback on thirty-two cost factor transparency straw proposals from other states, proposals generated from the June Task Force Transparency Survey results, and original ideas offered by members. LPRO staff collected and reviewed the feedback provided by Task Force members to edit and refine the initial preliminary set of cost factor transparency proposals.⁴⁹ Members provided LPRO staff with:

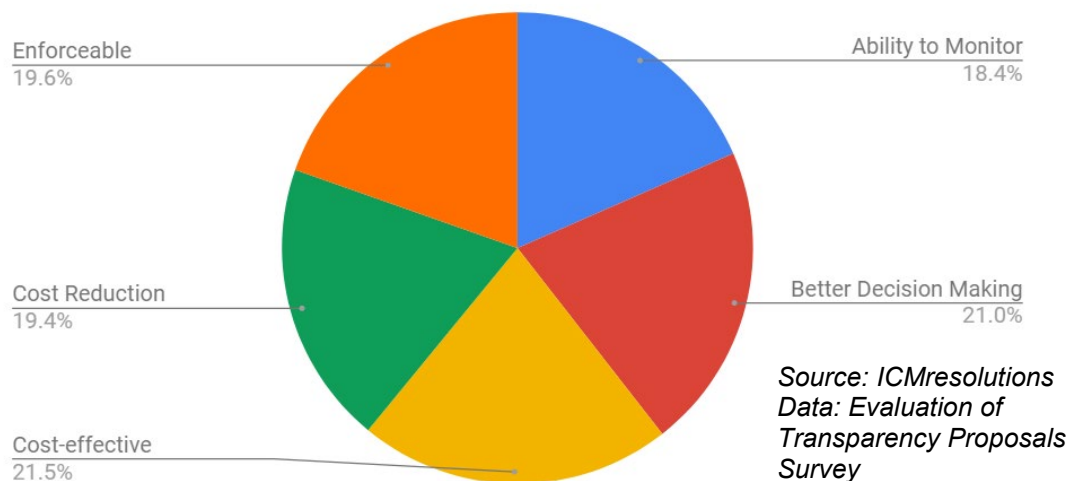
- Written revisions to thirty of the thirty-two individual proposals, and
- Thirty-three “new” proposals, several of which were similar or nearly identical to each other.

Several proposals addressed the same topic and were combined by staff. Other proposals were identified as needing further clarification and discussion prior to evaluation. Staff compiled all the responses into a single document, reviewed members’ suggested revisions for each proposal, and developed consolidated proposals.⁵⁰ These refined transparency proposals were then evaluated by members using the adopted evaluation criteria (previously described on pg. 17).

Evaluation of Transparency Proposals Survey

Using the finalized evaluation criteria, members were surveyed and asked to weigh each evaluation criteria based on how important they thought it was in assessing the transparency proposals.⁵¹ The aggregate results of weighing the five evaluation criteria are displayed in Figure 6.

Figure 6. Results of Collective Task Force Weight of Evaluation Criteria



⁴⁹ Joint Interim Task Force on the Fair Pricing of Prescription Drugs. *Transparency Proposal Exercise*. September 2018. <https://olis.leg.state.or.us/liz/201711/Downloads/CommitteeMeetingDocument/150473>, visited October 2018.

⁵⁰ Joint Interim Task Force on the Fair Pricing of Prescription Drugs. *Proposal Exercise Responses Comparison Table*. September 2018. <https://olis.leg.state.or.us/liz/201711/Downloads/CommitteeMeetingDocument/150403>.

⁵¹ Joint Interim Task Force on the Fair Pricing of Prescription Drugs. *Evaluation Factors Survey*. <https://olis.leg.state.or.us/liz/201711/Downloads/CommitteeMeetingDocument/150931>.

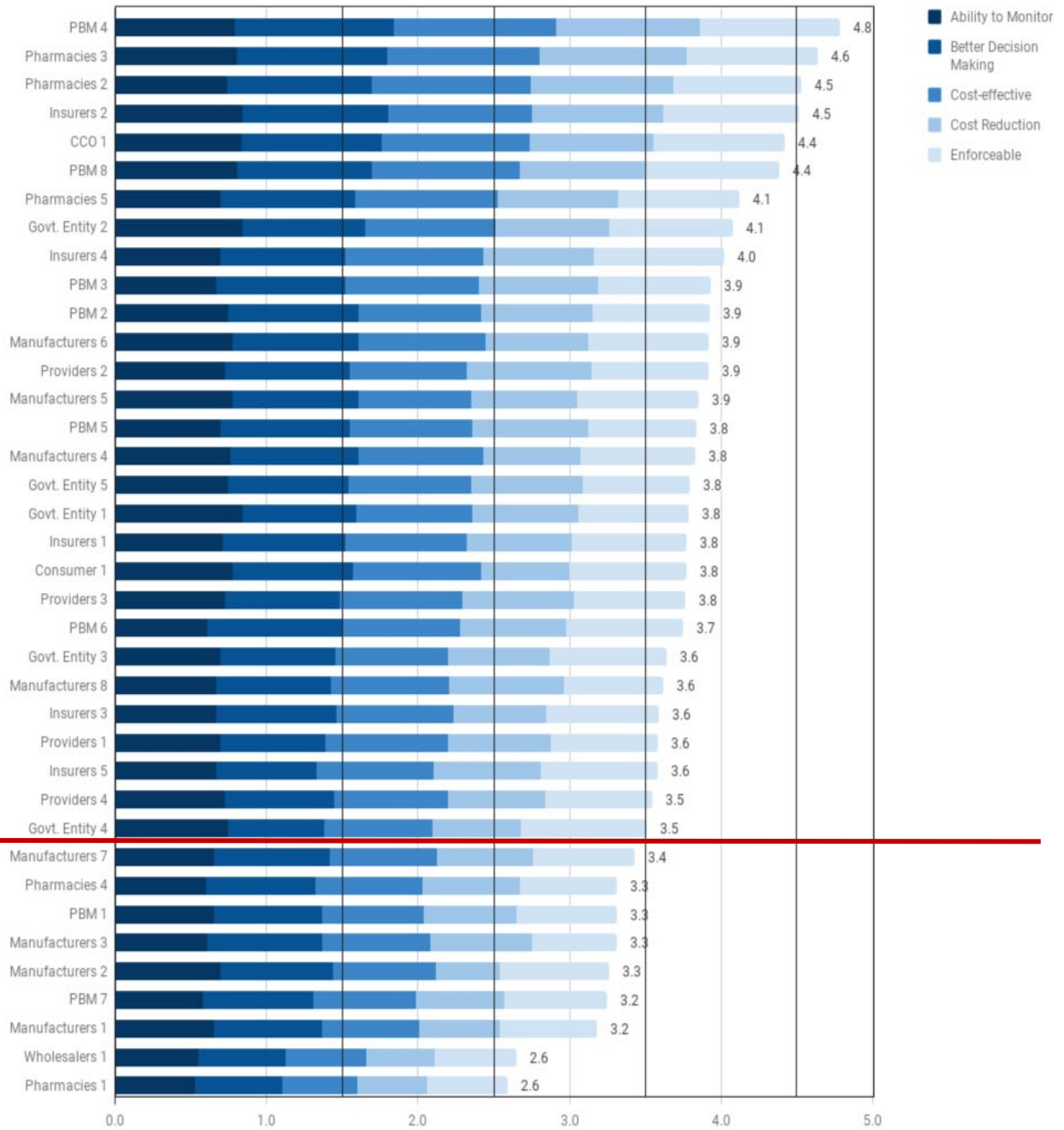
The highest weighted evaluation criteria for assessing transparency proposals was cost-effective followed by better decision-making, enforceable, cost reduction, and ability to monitor. These results demonstrate that Task Force members weighed the evaluation criteria relatively equal to one another with only slight differences between them.

The Task Force was asked to apply the evaluation criteria to assess thirty-eight transparency proposals by choosing one of the following statements – well-aligned, neutral, or poorly aligned with the evaluation criteria. Twenty-nine transparency proposals scored above 3.5 out of 5 of the thirty-eight transparency proposals evaluated.⁵² Figure 7 below displays all the transparency proposals evaluated by total score with the red line indicating the 3.5 score cutoff.⁵³

⁵² Joint Interim Task Force on the Fair Pricing of Prescription Drugs, *TFPRX – September Survey Results*, <<https://olis.leg.state.or.us/liz/201711/Downloads/CommitteeMeetingDocument/150807>>, visited October 2018.

⁵³ Please see Appendix C for a summary of transparency proposals scoring less than 3.5.

**Figure 7. All Task Force Transparency Proposals by Total Score
(Evaluation Factor Weight x Average Member Score)**



Source: ICMresolutions
Data: Evaluation of Transparency Proposals Survey

Transparency Proposal Refinement

Using the results of the Evaluation of Transparency Proposals Survey, the Task Force engaged in discussion on further refinement of transparency proposals scoring 3.5 or higher. All members provided feedback on the proposals primarily focused on their industry's perspective. This was done informally through discussion and formally through written feedback for improving the transparency proposals and offering rationale about the proposed changes. Feedback and rationale were integrated into a revised set of transparency proposals.⁵⁴

Following the in-person discussion of each transparency proposal, members were asked whether the revisions to the transparency proposal would increase, decrease, or maintain their initial scoring of each proposal. Task Force member feedback was integrated following the September meeting by LPRO staff to produce preliminary final transparency proposals.

Preliminary Vote Exercise

Transparency proposals scoring 3.5 or higher were refined or combined with similar proposals by LPRO staff based on member feedback from the September meeting. Using these proposals, members were asked to provide their preliminary votes on twenty transparency proposals by indicating the following:

- “One” indicated a member’s full support for the proposal.
- “Two” indicated the member agreed with the proposal as stated but prefer it modified in some manner to give the proposal full support.
- “Three” indicated a member’s refusal to support the proposal as stated, but suggested revisions would move their support from a 3 to either a 2 or 1.

All transparency proposals except one received a vote of support from the majority of voting members (eight or more members) (votes of 1 or 2). Several proposals received at least one preliminary vote of disagreement (vote of 3). Only one proposal received a majority preliminary vote of refusal. The results from the preliminary vote exercise were used to inform the final considerations of the transparency proposals.

⁵⁴ Joint Interim Task Force on the Fair Pricing of Prescription Drugs. *Transparency Recommendations - REVISED*. <<https://olis.leg.state.or.us/liz/201711/Downloads/CommitteeMeetingDocument/151100>>.

TASK FORCE RECOMMENDATIONS

The Task Force presents the following transparency strategies to the Oregon Legislative Assembly for consideration. The result of this work is a set of recommendations that span across the pharmaceutical supply chain with the intent to improve transparency of cost factors affecting pharmaceutical prices in Oregon. Fifteen of the eighteen transparency proposals voted on are recommended by the Task Force.⁵⁵ Three proposals received tie votes and therefore are not recommended by the Task Force.⁵⁶ During the process, members were provided the opportunity to submit additional comments, feedback or offer alternative suggestions for any of the transparency recommendations. This information is summarized for each transparency strategy recommendation.⁵⁷

It is important to recognize the complexity of the pharmaceutical supply chain and the pricing of pharmaceuticals. While members were given several opportunities to provide feedback to refine the transparency proposals, the complexity of the supply chain and the aggressive Task Force timeline presented limitations to engagement in a comprehensive analysis of the recommendations. Due to these reasons, the recommendations outlined below will benefit from further analysis to assess their impact on the pharmaceutical supply chain, including the individual market participants impacted by each transparency strategy.

Table 2 below displays the cost factors identified by Task Force members and corresponding transparency recommendations that address each cost factor.

⁵⁵ Joint Interim Task Force on the Fair Pricing of Prescription Drugs. *Final Vote – Individual Tallies*. <<https://olis.leg.state.or.us/liz/201711/Downloads/CommitteeMeetingDocument/151099>>, visited October 2018.

⁵⁶ Please see Appendix C for transparency proposals not recommended by the Task Force.

⁵⁷ Please see Appendix D for the full feedback submitted by Task Force members.

Table 2. Cost Factors Addressed in Transparency Recommendations

Market Participant	Cost Factors								
	Coupons	Discounts	Fees	Incentive Programs Kickbacks	Insurance Benefit Design	List Price	Markups	Pharmacist Gag Clause	Rebates
Manufacturers	●	●		●		●			●
Pharmacies		●					●	●	
PBMs		●	●					●	●
Insurers					●				●
Providers							●		
Government Entities						●			●
CCOs					●				
Consumers				●					
Multiple Entities		●			●	●			●

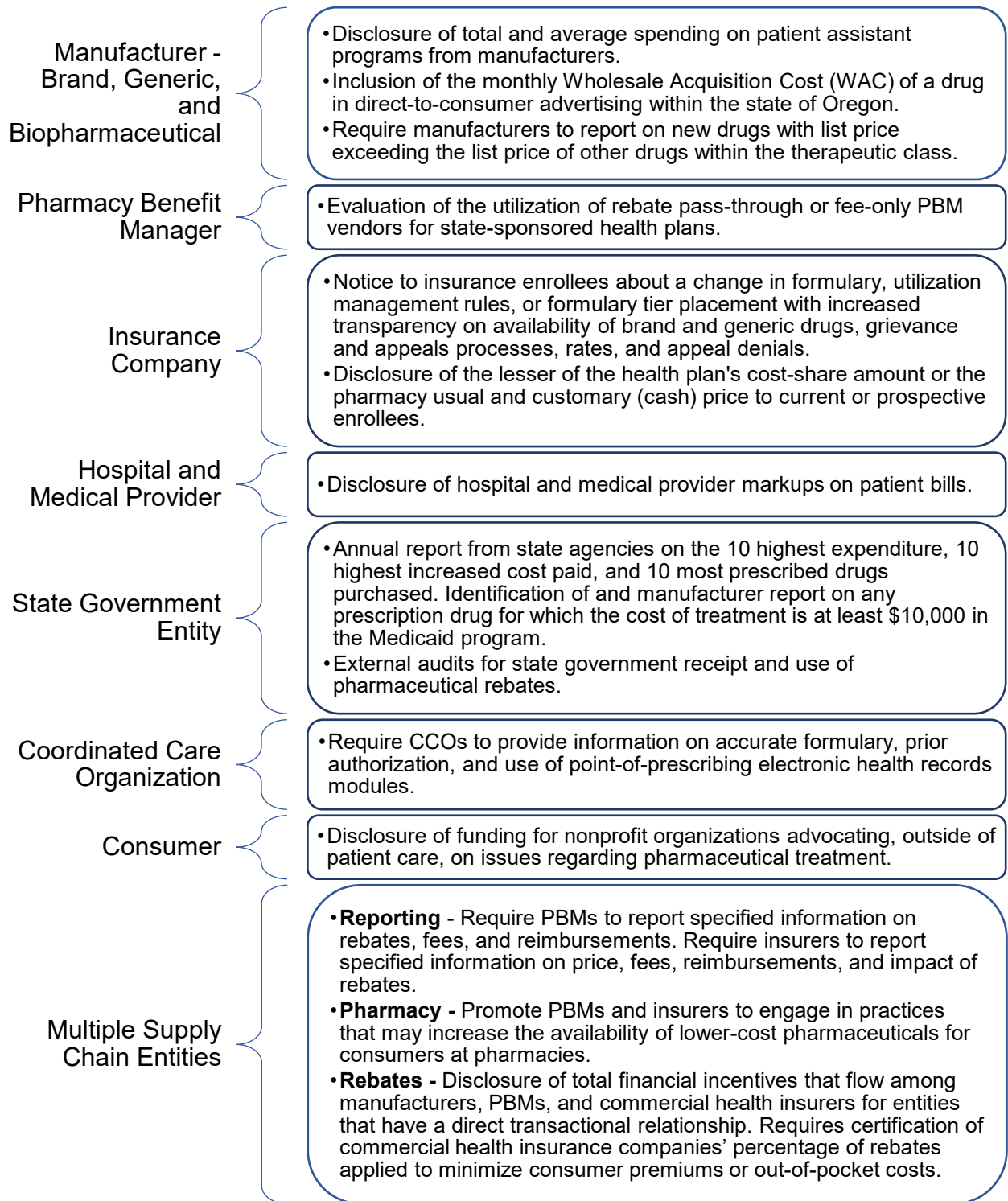
Source: Legislative Policy and Research Office

Recommendations in this report are sorted by the pharmaceutical supply chain entity primarily affected by the described transparency recommendation. Following each recommendation is a table that describes the final votes cast by members.⁵⁸

The first two numbers, colored green, describe those who voted either a 1 or 2 to support the proposal for recommendation to the legislature. The third number, colored red, describes the member(s) who voted a 3 to not recommend the proposal. The final number, colored black, represents the member(s) who abstained from voting for the proposal. An overview of the recommendations is displayed in Figure 8.

⁵⁸ For individual vote results please see Joint Interim Task Force on the Fair Pricing of Prescription Drugs. *Final Vote – Individual Tallies*. <<https://olis.leg.state.or.us/liz/201711/Downloads/CommitteeMeetingDocument/151099>>, visited October 2018.

Figure 8. Overview of Task Force Transparency Recommendations



Source: Legislative Policy and Research Office

MANUFACTURER RECOMMENDATIONS

Three proposals are recommended to the Legislative Assembly to improve transparency of pharmaceutical drugs regarding manufacturers. These recommendations address cost factor transparency for list price, discounts, fees, and rebates.

Manufacturer Recommendation #1

Disclosure of total and average spending on patient assistant programs from manufacturers.

The Task Force recommends requiring manufacturers to report on spending in Oregon for the prior calendar year:

- Total dollar amount spent on patient assistance programs,
- Aggregate dollar amount spent on patient assistance programs (or drug base name using Medispan GPI or by 9-digit national drug code (NDC)); and,
- Any financial assistance provided to pharmacies, government agencies, and patient groups (other than rebates or discounts) for the purchase of pharmaceuticals reported separately.

Recommend		Do Not Recommend	Abstain
9	3	1	1

Feedback for Manufacturer Recommendation #1

Members provided the following feedback on this recommendation:

- This is proprietary information and should not be disclosed.

Manufacturer Recommendation #2

Inclusion of the monthly WAC cost of a drug in direct-to-consumer advertising within the state of Oregon.⁵⁹

The Task Force recommends requiring pharmaceutical manufacturer direct-to-consumer advertising in media markets primarily reaching Oregonians (to be determined by rulemaking), to include the WAC cost of the drug for a month, or if less, for a single course of treatment. The direct-to-consumer advertising can also state that any one consumer may pay less than this amount. Potential for civil penalties for violations.

Recommend		Do Not Recommend	Abstain
10	1	2	1

⁵⁹ The Centers for Medicare and Medicaid Services announced on October 18, 2018 the proposed regulation to require television direct-to-consumer drug advertising include the WAC under certain conditions.

Feedback for Manufacturer Recommendation #2

Members provided the following feedback on this recommendation:

- Including list prices in these advertisements is not sufficient and could discourage patients from seeking needed medical care. Additionally, this policy is being proposed at the federal level.

Manufacturer Recommendation #3

Require manufacturers to report on new drugs with price exceeding the price of other drugs within the therapeutic class.

The Task Force recommends requiring manufacturers to provide to DCBS justification for a list price that exceeds the list price of other drugs in the class for new drugs and biologics licensed under a new drug application (NDA) or biologic license application (BLA), that are not first-in-class or a biosimilar.

For each report, a manufacturer is required to report the rationale for the list price, including the specific considerations that explain 95 percent of the list price and the contribution of each of those components (i.e., research, production, marketing, administration). A report will be considered incomplete and out of compliance if it does not clearly distinguish and identify separately research, marketing, and administrative costs. Any manufacturers that fail to report will incur civil penalties similar to those established in House Bill 4005 (2018).

Recommend		Do Not Recommend	Abstain
10	1	2	1

Feedback for Manufacturer Recommendation #3

Members provided the following feedback on this recommendation:

- This is trade secret information and should not be disclosed.

PHARMACY BENEFIT MANAGER RECOMMENDATION

The Task Force has one recommendation involving PBMs. Additionally, all of the multiple supply chain entity recommendations (see page 38) include PBMs for improving transparency through disclosure of specific information from the PBM to DCBS and allowing pharmacists to provide information on lower-priced therapeutically equivalent drugs. The PBM recommendations collectively address the cost factors of discounts, rebates, fees, insurance benefit design, and pharmacist gag clause.

Pharmacy Benefit Manager Recommendation

Evaluation of the utilization of rebate pass-through or fee-only PBM vendors for state-sponsored health plans.

The Task Force recommends requiring state-sponsored health plans (e.g., Public Employees' Benefit Board/Oregon Educators Benefit Board, CCOs) to evaluate rebate pass-through or fee-only contracts with PBM vendors. If a state-sponsored health plan can demonstrate it can obtain greater savings with the shared rebate contract model, state-sponsored health plans have the option to utilize either PBM model. State-sponsored health plans' contracts with PBMs are to be transparent with respect to whether they are a rebate pass-through contract or a fee-only contract and the amount of rebates and/or fees and/or any other markups being charged.

Recommend		Do Not Recommend	Abstain
5	8	0	1

Feedback for PBM Recommendation

Members provided the following feedback on this recommendation:

- Payers already have the ability to contemplate the use of rebate pass-through/fee-only PBM contracts as well as rebate sharing PBM contracts.
- State purchasers should select benefit arrangements that result in the lowest net cost to taxpayers.

INSURER RECOMMENDATIONS

Task Force members recommend two strategies to improve transparency for insurance companies regarding insurance benefit design and rebates.

Insurer Recommendation #1

Notice to insurance enrollees about a change in formulary, utilization management rules, or formulary tier placement. This requires an insurer’s website on pharmacy benefit be made available to the general public with information on brand and generic drugs, grievance and appeals processes, rates of pharmaceutical grievances, and rates of appeal denials.

To improve transparency regarding pharmacy benefits within a health plan, the Task Force recommends that insurers be required to have easily accessible website information on pharmacy benefits – available to the general public in a standardized format that is easily accessible and regularly updated. Information is to include the following:

Alphabetical list of drugs by brand name and generics should include:

- whether a generic alternative is available, whether step therapy or prior authorization requires generic substitution for the product;
- if there are quantity limits, prior authorization, or step therapy required for the drug;
- index of formulary tier levels, definitions, and associated fee structure for each level of a formulary tier; and
- member’s cost share amounts pursuant to their health plan benefits that include information on when enrollees will be charged the lesser of pharmacy usual and customary price (cash price) pursuant to their health plan.

Additional required information insurers are to provide enrollees:

- 60-day notice to each enrollee who will be affected by a negative change in the formulary – new utilization management rules, new or modified tier placement, or coverage only of a forthcoming generic.
- grievance and appeals requirements and processes.

Recommend		Do Not Recommend	Abstain
11	0	2	1

Feedback for Insurer Recommendation #1

Members provided the following feedback on this recommendation:

- There is a real need for patients to have information about out-of-pocket costs and clinical tools being used when it comes to their coverage, and how they can express grievances and appeal negative coverage decisions.
- This type of information is important for patients, enabling them to find the best health care plan to meet their needs.

- Utilization of FDA-rated generics is permissible pursuant to Oregon Pharmacy Practice statutes and regulations unless prescriber or patient indicates “dispense as written”.
- There is no way to determine what specific data should be provided to the general public nor what value the information would be to the consumer.
- Requiring plan-specific pharmacy benefit information be made generally available, disclosing rates of grievances and rates of appeal denials, and providing an index of formulary tier levels - presents a burden on insurers due to the amount of information to be reported with little to no consumer benefit.
- Language that requires insurers to explicitly state whether a generic alternative is available is already included in step therapy or prior authorization criteria which is required to be made public.

Insurer Recommendation #2

Disclosure of the lesser of the health plan’s cost-share amount or the pharmacy usual and customary (cash) price to current or prospective enrollees.

The Task Force recommends requiring health insurers to disclose to current and prospective enrollees and plan sponsors, who are under a co-insurance benefit, that they will be charged the lesser of the member’s cost-share amount pursuant to their health plan benefits or the pharmacy usual and customary (cash) price.

Recommend		Do Not Recommend	Abstain
12	1	0	1

Feedback for Insurer Recommendation #2

Members provided the following feedback on this recommendation:

- Insurers cannot be required to share specific costs, specifically the cash price at the pharmacy, as this amount is known only to the pharmacy and only at the point of sale.
 - An earlier version of this proposal required health insurers to disclose to current and prospective enrollees and plan sponsors that they may be charged "excess cost-sharing," defined as an amount greater than, or based on a price greater than what the plan pays (net of rebates accrued directly or indirectly to the plan). This would inform patients who are paying cost sharing that is based on list price as opposed to net price (reflecting rebates).
-

HOSPITAL AND MEDICAL PROVIDER RECOMMENDATION

One transparency strategy for hospital and medical providers is recommended focused on markups. These are an increase in the amount paid by purchasers of pharmaceutical products as determined by the entity selling the pharmaceutical product.

Provider Recommendation

Disclosure of hospital and medical provider markups on patient bills.

The Task Force recommends requiring hospitals and medical providers to disclose markups on an itemized bill to patients that may include the drug acquisition cost and the fees for medication preparation, dispensing, and administration.

Recommend		Do Not Recommend	Abstain
7	4	1	2

Feedback for Provider Recommendation

Members provided the following feedback on this recommendation:

- Imposing this requirement may conflict with private party negotiations and their contract requirements

STATE GOVERNMENT ENTITY RECOMMENDATIONS

State government entities such as the OHA or DCBS interact with many entities throughout the pharmaceutical supply chain. These interactions are varied and include the delivery of health care benefits to Oregonians, rate review for insurance companies, provider and supplier licensing, and regulation of certain aspects of the pharmaceutical industry.

Government Entity Recommendation #1

Annual report from state agencies on the 10 highest drug expenditure, 10 highest increased cost, and 10 most prescribed drugs purchased. Identification of and manufacturer report on any prescription drug for which the cost of treatment is at least \$10,000 in the Medicaid program.

The Task Force recommends requiring the following:

- State agencies purchasing pharmaceutical drugs to report annually on the top ten most prescribed, top ten highest cost paid, and top ten highest increased cost over the prior year of state-purchased prescription drugs.
- identify any prescription drug under the Medicaid program for which the annual wholesale cost or the per-course cost of treatment of the drug is at least \$10,000 and direct the OHA to notify the manufacturer that the manufacturer is required to prepare a report on the drug to Oregon’s drug utilization review board.

Recommend		Do Not Recommend	Abstain
9	5	0	0

Feedback for Government Entity Recommendation #1

Members provided the following feedback on this recommendation:

- These lists should be established using the net of applicable rebates but must not disclose net costs.
- The proposal should be modified to clarify that the costs indicated in the proposal are “net” costs. Manufacturers pay hundreds of millions of dollars in rebates to the state of Oregon and any reporting should factor in these significant rebates.

Government Entity Recommendation #2

External audits for state government receipt of and use of pharmaceutical rebates.

The Task Force recommends requiring the state to hire an external independent auditor no less than every five years to review the state’s receipt and use of pharmaceutical rebates and associated decisions and evaluate their positive or negative effects on total cost of care, evidence-based care, and their financial effects on those to whom the state

has delegated financial risk. The analysis will need to evaluate how federal law interacts with pharmaceutical rebates and Medicaid-related expenditures.

Recommend		Do Not Recommend	Abstain
10	1	2	1

Feedback for Government Entity Recommendation #2

Members provided the following feedback on this recommendation:

- This proposal could help expose and improve how state and federal Medicaid dollars are spent.
 - External audits are a typical contract provision and limiting audits to one cost driver may lead to inaccurate conclusions.
 - It is unclear how this proposal will impact the positive or negative effects of rebates on the total cost of care, evidence-based care, or the financial effects on those to whom the state has delegated financial risk.
 - By limiting the audit to the state's use of pharmaceutical rebates the recommendation doesn't include all elements that are necessary to evaluate impact to total cost of care.
-

COORDINATED CARE ORGANIZATION RECOMMENDATION

The recommendation outlined below requires CCOs to improve transparency for insurance benefit design.

CCO Recommendation #1

Require CCOs to provide information on accurate formulary, prior authorization, and use of point-of-prescribing electronic medical records modules.

The Task Force recommends requiring CCOs to declare on an annual basis their progress on providing accurate formulary, prior authorization, and relevant cost information to a web-based, on-demand health information exchange (HIE) for point-of-prescribing electronic medical records modules to use by date determined by the legislature in consultation with appropriate health IT/HIE policy boards.

Recommend		Do Not Recommend	Abstain
13	1	0	0

Feedback for CCO Recommendation

No member feedback was submitted regarding this recommendation.

CONSUMER RECOMMENDATION

Groups that advocate for support of specific diseases and patients with those diseases may be supported by the pharmaceutical industry or other supply chain entities, and that support can be substantial. The Task Force recommends transparency for consumers advocacy groups addressing incentives received by other pharmaceutical supply chain entities.

Consumer Recommendation

Disclosure of funding for nonprofit organizations advocating, outside of patient care, on issues regarding pharmaceutical treatment.

The Task Force recommends requiring nonprofit organizations, with an annual budget of more than \$50,000 and that advocate on issues regarding pharmaceutical treatment, to annually report the funding that comes from any entity or individual in any part of the pharmaceutical supply chain. Reporting requirements are:

- Information is to be reported to the Oregon Government Ethics Commission.
- Information is to be reported as a total dollar amount of funding, if total dollar amount exceeds 10 percent of annual budget, their trade associations, or other entities known to be similarly funded, for pharmaceutical supply chain entities or individuals.
- Total dollar amount is also to be reported as a percentage of total annual organization funding.
- Disclosure of such funding should be made on the organization's web page.

Recommend		Do Not Recommend	Abstain
10	0	3	1

Feedback for Consumer Recommendation

Members provided the following feedback on the consumer recommendation:

- States should not create perceived obstacles that prevent nonprofit organizations from receiving funds for their activities that advocate for patients or fund medical research.

MULTIPLE SUPPLY CHAIN ENTITIES RECOMMENDATIONS

Several of the transparency proposals were consolidated into a singular proposal when possible to eliminate duplication of transparency strategy recommendations. For example, one recommendation involves requiring PBMs and commercial health insurers to report specific pharmaceutical information. Another combined recommendations aimed at promoting engagement in practices that may increase the availability of lower-cost pharmaceuticals for consumers involving pharmacies, PBMs, and health insurance companies. The third proposal combined strategies primarily focused on rebate transparency for manufacturers, PBMs, and health insurers. Collectively these proposals aim to increase the transparency across the supply chain on the following cost factors: list price, discounts, fees, rebates, insurance benefit design, and pharmacist gag clause.

The Task Force initially proposed an overall supply chain recommendation to improve transparency of specific pricing information on the prioritized set of cost factors across multiple entities. However, Task Force members ended up voting on each separate proposal rather than the combined proposal. This was because the preliminary vote on the combined proposals received a tie vote. When voted on separately, the Task Force voted to recommend two of five proposals, involving PBMs and commercial insurers.⁶⁰

Reporting Recommendations

Require PBMs and commercial insurers to report on specific pricing information to the state.

The reporting recommendation requires these two entities to submit any reports and information listed below to DCBS annually with conditional exemptions from public disclosure under ORS 192.345 as a trade secret. Any reporting is to be limited to prescription drugs that are \$100 or more for a one-month supply or for a course of treatment lasting less than one month. DCBS will release a report summarizing aggregate information provided by reporting entities; reports will not disclose any proprietary information or trade secrets.

PBM Reporting Recommendation

Require PBMs to report the following information by nine-digit NDC:

- Average manufacturer rebate received
- Average manufacturer fee received
- Average product reimbursement made to pharmacies
- Product reimbursement received from insurers/clients

Recommend		Do Not Recommend	Abstain
7	1	6	0

⁶⁰ Please see Appendix C for the reporting transparency proposals that were not recommended.

Commercial Insurer Reporting Recommendation

Require commercial insurers to report the following information:

- Average price paid per prescription minus prescription dispensing fee
- Average product reimbursement
- Impact of rebates on premium expressed as a percentage

Recommend		Do Not Recommend	Abstain
7	1	6	0

Feedback for Reporting Recommendations

Members provided the following feedback on this recommendation:

- Reporting should be at the aggregate level and not at the product (NDC-9) level to not violate confidential contractual agreements.
- Transparency of manufacturer rebates would result in pressure to reduce rebates, which could increase costs for payers and consumers.
- Disclosure of proprietary and/or competitive information could potentially negatively impact PBMs ability to negotiate with manufacturers and pharmacies.

Pharmacy Transparency Recommendation

Promote supply chain entities to engage in practices that may increase the availability of lower-cost pharmaceuticals for consumers at pharmacies.

The Task Force recommends that health insurance carriers and PBMs, registered in Oregon by DCBS, are required to allow the following:

- A pharmacy or pharmacist to have the right to provide an insured consumer information regarding the amount of the insured's cost share for a prescription drug. Neither a pharmacy nor a pharmacist shall be proscribed by a PBM from discussing any such information or for selling a more affordable alternative to the insured if one is available.
- Pharmacists to inform customers of the availability of any therapeutically equivalent alternative medications that are less expensive than the cost of the original prescription medication and dispense:
 - (a) FDA A/B rated generic for a brand-name drug, unless "dispense as written" is on the prescription or
 - (b) Lower-cost, FDA-approved interchangeable biosimilar rather than a biologic – unless "dispense as written" is on the prescription.

Pharmacist must notify the prescriber of the substitution in accordance with ORS 689.522.

- A pharmacy or pharmacist to conduct cost queries on behalf of a consumer without any transaction fees, including capturing the pharmacy's usual and customary

(cash) price and report to a pharmacy, and thus the consumer, the lower of that price or the contracted cost-share amount; whichever is less.

- An enrollee to make a payment for a covered prescription drug at the point of sale in an amount that does not exceed the lesser of:
 - (1) the contracted cost-sharing amount; or
 - (2) the pharmacy’s retail usual and customary (cash) price for the prescription drug, whichever is less.

Carriers and PBMs registered in Oregon by DCBS are required to have:

- Pharmacy network requirements that allow pharmacies to seek the lowest cost option for the customer, including usual and customary (cash), and utilize a pharmacy benefit design that prohibits customer cost-sharing that exceeds the amount the pharmacist will be reimbursed.

Recommend		Do Not Recommend	Abstain
8	5	1	0

Feedback for Pharmacy Transparency Recommendation

Members provided the following feedback on this recommendation:

- Pharmacist reimbursement is pursuant to contracting terms and not a cost factor that affects consumers.
- The requirement regarding cost inquiries and transaction fees is not needed.
- Recommendation may be superseded by recent federal gag clause language that has been signed into law for both commercial⁶¹ and Medicare plans.⁶²

Rebate Transparency Recommendation

Disclosure of total financial incentives that flow among manufacturers, PBMs, and commercial health insurers for entities that have a direct transactional relationship. Requires certification of commercial health insurance companies’ percentage of rebates applied to minimize consumer premiums or out-of-pocket costs.

The Task Force recommends the following for manufacturers, pharmacy benefit managers, and insurance companies regarding rebates:

Manufacturers are required to disclose the total aggregate amount of financial incentives paid to each PBM serving the covered lives of health plans offered by carriers in Oregon. Disclosure should include financial incentives paid to PBMs

⁶¹ Patient Right to Know Drug Prices Act, S. 2554, 115th Congress. PL 115-263 (2018).

⁶² Know the Lowest Price Act of 2018, S. 2553, 115th Congress. PL 115-262 (2018).

related to market share including any remuneration for preferred or exclusive status on formularies.

Pharmacy benefit managers are required to disclose to their health plan sponsors the aggregate amount of manufacturer rebates; fees including any differences in what is paid to pharmacies and what is reported to health plans; and other payments, gifts, or incentives received on behalf of the plan’s enrollees, and the percentage of those funds retained by the PBM.

Commercial health insurers are required to certify through their annual filing documents the percentage of rebates that were applied to directly offset consumers’ premiums, out-of-pocket costs, and/or directly benefit the consumer. Commercial health insurers are required to report where any percentage of rebates, not applied to minimize consumers’ premiums, were spent.

Any information disclosed to DCBS would be with conditional exemptions from public disclosure under ORS 192.345 as a trade secret.

Recommend		Do Not Recommend	Abstain
8	2	3	1

Feedback for Rebate Transparency Recommendation

Members provided the following feedback on the third supply chain recommendation:

- Clarification needed regarding reporting of “other payments, gifts, or incentives”.
- Transparency of manufacturer rebates may result in pressure to reduce rebates, which could increase costs for payers and consumers.
- Disclosure of proprietary and/or competitive information could potentially negatively impact PBMs ability to negotiate with manufacturers and pharmacies.
- Conflicts with opinions released by the Federal Trade Commission on this topic which concluded reporting of rebates would lead to a less competitive market.
- From a carrier perspective, mandatory rebate disclosure could limit the ability to negotiate as one element of a negotiating strategy when developing pricing strategies, thus limiting market competitiveness.
- The recommendation has several beneficial policy options but suffers from the way in which disparate proposals were combined, from a lack of clarity, and from insufficient protections related to the conditional exemption from public disclosure of confidential trade secret information.

ADDITIONAL CONSIDERATIONS AND NEXT STEPS

Through the course of Task Force deliberations on transparency, many other topics related to pharmaceutical policy were discussed. NCSL organized recently enacted pharmaceutical policies from 2015-2017 in 45 states covering topics such as: access, cost-sharing, and deductibles, coverage in insurance, Medicaid pharmaceutical use and cost, pricing and payment, pharmaceutical utilization and management, pharmacy benefit managers, and transparency.⁶³ Task Force members acknowledged that some of these topics were not directly related to the charge of the Task Force to develop transparency strategies, but were generally related to its work as a whole. Members were given the opportunity to submit other policy considerations for the Task Force. Topics submitted by Task Force members included the following:

- specified list of biological products for substitution
- expansion of pharmacy networks
- reconciliation of payment and reimbursement differences
- examining changes to mail-order pharmacy
- payment of billed manufacturer rebates within 30 days
- identification of consumer support organizations for pharmaceuticals
- pass on all discounts, rebates, incentives, gifts, and other financial negotiations to the consumer
- transparency of patient copay assistance including coupons and copay accumulator programs
- pooled purchasing of pharmaceuticals by the State
- diversity and equity focus when enacting and implementing pharmaceutical policy
- patient education on pharmaceuticals and insurance benefits
- fee-for-service model for rebates
- consumer advisory group for pharmaceuticals

Next Steps

The recommendations in this report represent the Task Force's work to address transparency throughout the pharmaceutical supply chain to expose the cost factors affecting the prices paid by Oregonians. The Task Force will continue to work to address other pharmaceutical topics until December 31, 2020 at the guidance of the Oregon State Legislative Assembly.

⁶³ National Conference of State Legislatures. *Statewide Prescription Drug Database | 2015 – Present*. <<http://www.ncsl.org/research/health/prescription-drug-statenet-database.aspx>>, visited October 2018.

APPENDIX

- I. [Appendix A](#) – Glossary of Pharmaceutical Terms
- II. [Appendix B](#) – Pharmaceutical Supply Chain with All Transactional Relationships
- III. [Appendix C](#) – Transparency Proposals Not Recommended
- IV. [Appendix D](#) – Viewpoints from Task Force Members on Transparency Recommendations

Appendix A – Glossary of Pharmaceutical Terms

The glossary is to inform the exercises and advance the work of the Task Force. Definitions reflect information provided by members in advance of administering the June survey, as well as key discussions shared at the July meeting. Sources used for definitions include information provided by Task Force members and government resources such as the Office of the Inspector General, Department of Justice, Food and Drug Administration, and the Department of Health and Human Services.

Drug Product Terminology:

<i>Biologic</i>	A therapeutic drug or a vaccine, virus, serum, toxin, antitoxin, blood product, allergenic product, protein, or analogous product made from living cells and applicable to the treatment, prevention, or cure of a disease. Licensed under a Biologic License Application by the FDA. Biologics are also referred to as “large molecule drugs.” They are infused or injected and are not typically self-administered.
<i>Biosimilar</i>	Biologics that are “highly similar” to a previously approved biologic (whose patent or exclusivity period has expired) and which have “no clinically meaningful” differences with the previously approved biologic. Unlike generic drugs, biosimilars are not considered to be the “same” as previously approved biologics.
<i>Brand Product</i>	Branded products are not generics. A brand can be first-in-class or not. It is protected by a patent or statutory exclusivity, or has an expired patent or exclusivity. Licensed under a New Drug Application by the FDA, brand products are also generally referred to as “innovator drugs.”
<i>Drug Product</i>	A prescription drug product requires a licensed health professional’s authorization to purchase and is usually a finished dosage form that contains a drug substance, generally, but not necessarily in association with other active or inactive ingredients.

Generic Drug	Products considered the “same as” a branded product, (i.e., same active ingredient, route of administration) and that compete with branded products after patent or exclusivity expires. Licensed under an Abbreviated New Drug Application by the FDA, generic drugs are generally considered to be “therapeutically equivalent” to brand products.
In-Line or Post-Market Drugs	Products that are licensed and in the market.
Large Molecule Products	See “biologic”.
Limited Distribution Drug	Limited distribution drugs (LDD) are medications that have been restricted by the manufacturer to select pharmacies and wholesalers. Typically, these drugs are used to treat rare conditions affecting small patient populations and have complex dosing requirements, severe side effects, and require close monitoring. Through limited distribution, drug manufacturers can confirm those who provide the medication maintain training on appropriate distribution, dispensing, and monitoring which will reduce risk to patients, and fulfill inventory tracking requirements.
Multisource Drugs	Drugs where both an innovator and one or more generics is available.
Orphan Drug	A drug or biologic for the treatment of diseases and disorders that affect fewer than 200,000 people in the United States or that affect more than 200,000 people but where manufacturers are not expected to recover the costs of developing and marketing a treatment drug.
Physician Administered Drugs	Any kind of drug that cannot typically be self-administered. Usually billed on an office visit claim.
Pipeline Drugs	Drugs (small or large molecule) under development by a manufacturer.
Retail Drugs	Any kind of drug typically available at a pharmacy counter. Usually billed on a pharmacy claim.

<i>Small Molecule Products</i>	Non-large molecule drugs, such as chemically synthesized compounds (e.g., capsules, tablets, powders, ointments, sprays).
<i>Specialty Drug</i>	A drug that is costly, requires special supply chain features (such as freezing or cold storage), typically indicated for a small group of patients, and where the patients may need special case management services. This is the broadest definition. There is no single agreed upon definition, so sometimes “specialty drug” will only mean high cost. For instance, specialty drugs in the Medicare Part D program are only defined by cost – currently \$670/month (2018) and indexed annually.

Distribution System

<i>Specialty Pharmacy</i>	These organizations may or may not take ownership of the drug product. Their clients are drug manufacturers that need limited distribution of specialty drugs. Specialty drugs are typically (but not always) high cost, require special shipping and storage (freezing or cold storage), or are indicated for relatively small patient populations treated by physician specialists. Specialty pharmacy can deliver “just in time” products by working with treating providers to supply the appropriate drug in time for a patient visit at the location where the drug will be used. There is a lack of consistency as to how a drug is determined to be a specialty drug and who makes such a determination.
<i>Wholesaler</i>	In a simple distribution system, the wholesaler is the first purchaser of a drug product – direct from the manufacturer. Primary distributors (wholesalers) purchase prescription medicines and other medical products directly from manufacturers for storage in national and regional warehouses and distribution centers across the country. Health care providers place orders with distributors for the medicine and

	products they need, and the distributors process and deliver the orders daily.
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Administrative Organizations in the Supply Chain & Administrative Services

<i>Data-sharing Agreements</i>	The contractual agreement between two entities to share information collected on specified topics or groups of people with each other.
<i>Group Purchasing Organization (GPO)</i>	These entities represent groups of drug purchasers, such as hospitals and health systems. A GPO negotiates with manufacturers on behalf of its clients for either up-front, on-invoice discounts or back-end rebates. Importantly, GPOs do not take ownership of a drug; they are not part of the supply chain. GPOs essentially negotiate a purchase-order from which members of the buying group can purchase in whatever quantities needed. Wholesalers supplying to GPO members typically provide the drug at the discounted price on the invoice and then receive a rebate from the manufacturer of the drug after the fact. GPOs may provide additional client administrative services as well.
<i>Pharmacy Benefit Manager (PBM)</i>	PBMs handle some or all the pharmacy benefit for health plans (e.g., formulary design, cost sharing and tiers, pharmacist networks and contracts, price concession negotiation with manufacturers). PBMs may own mail order pharmacies and/or specialty pharmacies.
<i>Pharmacy Services Administration Organization (PSAO)</i>	Similar to a GPO, but serve independent pharmacies. In addition to price negotiation with PBMs, PSAOs offer a variety of administrative services to pharmacies. PSAOs are often owned by wholesalers or PBMs.

Pricing Terminology

<i>Actual Acquisition Cost (AAC)</i>	The net cost of a drug paid by a pharmacy. It varies with the size of container purchased (e.g., ten bottles of 100 tablets typically costs more than one bottle of 1,000 tablets) and the source of purchase (manufacturer or wholesaler). A drug's AAC includes discounts, rebates, chargebacks, and other adjustments to the price of the drug, but excludes dispensing fees.
<i>Average Wholesale Price (AWP)</i>	The price for prescription medicines that is created and published in commercial pricing publications. For brand medicines, this price is almost always higher than the list (WAC) price and represents the starting point for contract negotiations for medicines between payers and pharmacies/providers. AWP serves as an important pricing benchmark for payers because underlying data is continuously current and publicly available, and represents the average cost for a drug purchased at wholesale and published for public knowledge. AWP is a benchmark used for pricing and reimbursement of prescription drugs for both government and private payers. AWP is not a true representation of actual market prices.
<i>List Price</i>	This is also known as the Wholesale Acquisition Cost (WAC). The Average Wholesale Price (AWP) may also be called the "list price" and is the price for prescription drugs created and published in commercial pricing publications. Refers to the price of drug products that direct purchasers pay the manufacturer, without factoring in any rebates, discounts, or other price reductions.
<i>National Average Drug Acquisition Cost (NADAC)</i>	Designed by Centers for Medicaid and Medicare to create a national benchmark that is reflective of the prices paid by retail community pharmacies to acquire prescription and over-the-counter covered outpatient drugs.
<i>National Drug Code (NDC)</i>	Drug products are identified and reported using a unique, three-segment number, called the National Drug Code (NDC), which serves as a

	universal product identifier for drugs. FDA publishes the listed NDC numbers and the information submitted as part of the listing information in the NDC Directory which is updated daily.
Wholesale Acquisition Cost (WAC)	The price the wholesaler or other direct purchasers pay the manufacturer, without factoring in any rebates, discounts, or other price reductions. Generally considered the “list” price, this price is set by a manufacturer and publicly reported.

Types of Price Concessions

Charge Back	The amount a distributor bills back to a manufacturer when a product is sold to a customer at a contract price that is less than the distributor's cost. This serves as a pricing mechanism used by wholesalers which allows them to carry products destined for customers paying very different prices to manufacturers. The wholesaler keeps track of sales to various customers under prices negotiated between the manufacturer and the customer. The wholesaler then “charges back” the manufacturer for any difference between the negotiated prices paid by the customer and the wholesaler’s cost of goods (WAC).
Copay Assistance Program	Pharmaceutical manufacturers may provide financial assistance or drug free product (through in-kind product donations) to specified individuals to augment any existing prescription drug coverage. These programs may be focused on specific populations (insurance specific, low-income) or specific medical conditions.
Cost Minus	Refers to when a wholesaler returns some of their revenue stream to larger customers in the form of a "cost minus" distribution fee, which results in the customer paying a lower price than the contract cost or WAC for a noncontracted item.

<p><i>Coupons</i></p>	<p>A voucher that is offered to cover all or part of a patient's copayment obligation, which the patient redeems at the point of service (the pharmacy counter). Pharmacies redeem the coupons with the manufacturer or its coupon administration vendor. Coupons are not permitted in federal health care programs such as Medicare and Medicaid.</p>
<p><i>Discounts</i></p>	<p>These are discounts, charge backs or any other type of consideration provided by supply chain entities to a pharmacy that is not included on the invoice and may impact the price paid for a drug. These discounts are provided periodically to the pharmacy based on the fulfillment of contractual terms such as prompt payment or volume purchased.</p>
<p><i>Incentive Programs/Kickbacks</i></p>	<p>The payment of remuneration to induce or reward patient referrals or the generation of business regarding pharmaceutical products. Remuneration includes anything of value and can take many forms besides cash, such as free rent, expensive hotel stays and meals, and excessive compensation for medical directorships or consultancies.</p>
<p><i>Markups</i></p>	<p>An increase in the amount paid by purchasers of pharmaceutical products as determined by the entity selling the pharmaceutical product.</p>
<p><i>Rebates</i></p>	<p>Provided by supply chain entities to other supply chain entities and are typically based on the ability of a purchaser to move market share for the manufacturer's product. Rebates are confidential and are typically based on the volume of dispensed drug as well as other factors and paid by a manufacturer after a drug has been dispensed or administered. Rebates are billed periodically by the purchaser based on the contractual terms (e.g., drug utilization subject to the rebate).</p>
<p><i>Shadow Pricing</i></p>	<p>Pricing that is determined by certain assumptions that are not easily quantifiable.</p>

Medicaid Rebate Terminology

<i>Average Manufacturer Price (AMP)</i>	Used in Medicaid, AMP is calculated by the manufacturer and provided to the Centers for Medicare and Medicaid Services, which uses it to let state Medicaid programs calculate the unit rebate amount that they receive from manufacturers. It is the average of manufacturer prices to the wholesale and retail class of trade (does not include sales from wholesalers to retailers but only the prices in any direct agreement between manufacturer and a retail seller). AMP is confidential and not publicly available.
<i>Best Price (BP)</i>	Best price is the lowest price the manufacturer offers to any purchaser in the commercial market in the U.S.; this could be a clinic, a hospital, a health plan, a PBM, and so on. Generally speaking, if the BP is greater than 23.1 percent off of the AMP for brand medicines or 13.1 percent off of AMP for generic medicines, all state Medicaid programs will get the BP rebate. BP is confidential and not publicly available.
<i>CPI Penalty</i>	An additional rebate that holds the state Medicaid program harmless for any price increases taken by the manufacturer that exceed inflation based on the Consumer Price Index for all Urban Consumers (CPI-U). Any price increase in excess of CPI-U has to be rebated back to the Medicaid program by the manufacturer.

Provider Drug Reimbursement Payment Terms

<i>340B Program</i>	A federal program that requires manufacturers to provide outpatient drugs to covered entities, including qualifying hospitals, at significantly reduced prices. The 340B Program enables covered entities to stretch scarce Federal resources as far as possible, reaching more eligible patients and providing more comprehensive services.
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<p><i>Administrative Fee</i></p>	<p>Administrative and service fees charged by PBMs to manufacturers and to plan sponsors. These fees are typically a percentage of the list (WAC) price of a medicine. PBMs offer a range of administrative (e.g., enrollment, marketing), clinical (e.g., pharmacy and therapeutics committee, appeals support), and other business services to their customers.</p>
<p><i>Average Sales Price (ASP)</i></p>	<p>This is a Medicare Part B reimbursement term used to pay for Medicare Part B drugs (which are typically physician-administered drugs). This is the weighted average manufacturer net price for a product in the market. This applies to multi source drugs and patented products. Medicare reimburses physicians ASP+6% for Part B drugs.</p>
<p><i>Clawback</i></p>	<p>Practice of charging copayments to consumers for certain prescription drugs that exceed the cost of medicines, with the difference required to be returned to the PBM by the pharmacy.</p>
<p><i>Dispensing Fee/Professional Fee</i></p>	<p>There are two parts to pharmacy payment: ingredient cost and dispensing fee. The ingredient cost reflects the applicable MAC, AWP, AAC etc. The dispensing fee pays for the professional services of the pharmacist.</p>
<p><i>Fees (general)</i></p>	<p>Including but not limited to dispensing, administrative, or service fees charged by supply chain entities to other supply chain entities. Fees are usually based on a range of administrative (e.g., enrollment, marketing), clinical (e.g., pharmacy and therapeutics committee, appeals support), and other business services provided to their customers.</p>

<p><i>Insurance Benefit Design</i></p>	<p>Coverage design for health care services in a health insurance plan including prescription drugs covered by the plan, often referred to as formularies, and cost-sharing mechanisms such as copays, deductibles, premiums and coinsurance. Formularies often utilize tiers to sort prescription drugs based on type of drug (brand or generic), utilization, and cost-sharing with consumers. Typically, manufacturers and pharmacy benefit managers work to negotiate price and placement on insurance formularies (i.e., formulary placement).</p>
<p><i>Maximum Allowable Cost (MAC) and Federal Upper Limits (FUL)</i></p>	<p>Briefly, these payment limit methods apply only to multisource drugs (including off-patent brand drugs). MAC/FUL is the average price of all the multisource drugs in a group. The frequency the MAC/FUL is recalculated is at the discretion of the payer. The multisource drugs to which a MAC is applied are also at the discretion of the payer.</p>
<p><i>Pass-through Pricing Model</i></p>	<p>This alternative contracting approach requires that the PBM pass through the price they pay for medications and earn a negotiated administrative fee.</p>
<p><i>Pharmacist Gag Clause</i></p>	<p>Clauses in PBM contracts with pharmacies that prohibit pharmacists from telling customers that they could save money by paying cash for prescription drugs rather than using their health insurance.</p>
<p><i>Price Protection</i></p>	<p>PBMs negotiate price protection provisions with manufacturers as a standard feature of contracts. Under these arrangements, manufacturer price increases in excess of predetermined thresholds result in increased rebates to the PBM. These rebates are separate from standard formulary access rebates. Price protection rebates are calculated as a percentage of the list (WAC) price of a medicine.</p>

<p>Reference Price</p>	<p>This is not used in the US for drugs. A reference price limits the amount the insurer will pay for one product to the price of a similar product in the market. There are a number of ways to structure reference pricing, an example would be to tie the amount an insurer will reimburse to the lowest price of any drug in the same therapeutic class, or limit the insurer payment to the average price of drugs in the same class. If the consumer chooses a product that exceeds the reference price, the consumer will be responsible for paying the difference between the reference price and the pharmacy's costs/charge for the more expensive drug.</p>
<p>Some percentage of Average Wholesale Price (AWP)</p>	<p>Payers assume that a published AWP is higher than what a pharmacy or provider actually pays for a drug, so payers reimburse pharmacies and other providers some percentage less than AWP, for instance AWP – 17%.</p>
<p>Spread Pricing Model</p>	<p>Under this payment model, plan sponsors (health plan or employer) compensate the PBM by permitting the PBM to retain differences, or spreads, between the amount that a PBM charges to a plan sponsor and the amount that the PBM pays to the pharmacy that dispenses the drug to a consumer. So, the amount paid by the plan sponsor to the PBM for a prescription can be greater than the amount paid by the PBM to the pharmacy, with the difference retained as revenue by the PBM.</p>

Task Force Evaluation Criteria

<p>Ability to Monitor</p>	<p>Enables a regulatory body the oversight of specified entities or cost factors within the pharmaceutical supply chain.</p>
<p>Better Decision Making</p>	<p>Improves the ability for purchasers or regulators of pharmaceutical products to make informed decisions based on accurate information</p>

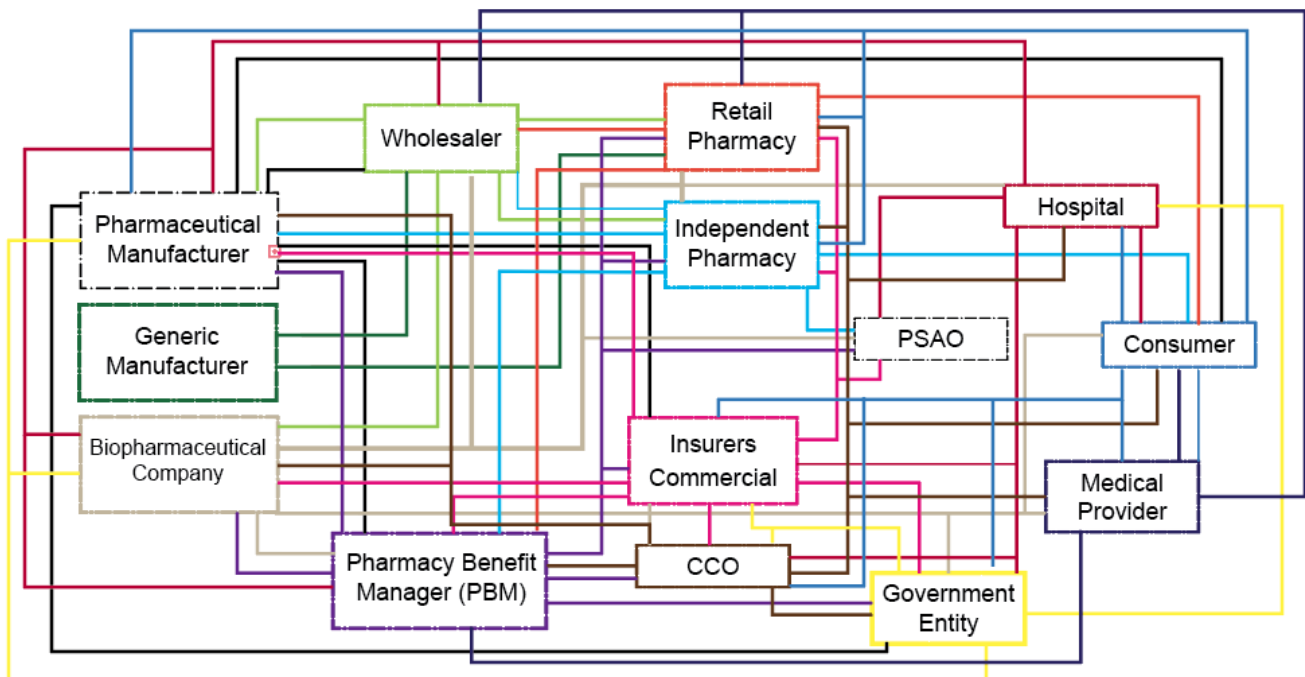
	regarding selection and payment for pharmaceutical products.
<i>Cost-effective</i>	A strategy or policy with a positive impact relative to the needed expenditure.
<i>Cost Reduction</i>	Exposes factors that may inform strategies to reduce cost to purchasers of pharmaceutical products.
<i>Enforceable</i>	The ability for a regulatory body or an entity in the pharmaceutical supply chain to enforce a strategy or policy.

Appendix B – Pharmaceutical Supply Chain with All Transactional Relationships

Members identified all stakeholders with whom they had a direct transactional relationship in their responses to the June Transaction and Transparency Survey.⁶⁴ Once members had selected stakeholders with whom they had relationships, they were asked to identify the cost factors that might impact the prices Oregonians pay for pharmaceutical products from a list of cost factors. Members were also provided an opportunity to identify cost factors in addition to the list of fifteen provided in the survey.

Staff created a pharmaceutical supply chain schematic using the information provided by members in Question 3 of the survey. The result of this is a complex supply chain in Figure 9.⁶⁵

Figure 9: Pharmaceutical Supply Chain - All Direct Transactional Relationships



⁶⁴ Transactional relationship was defined as an exchange of pharmaceutical products, services, or money, whether pursuant to an explicit written contract (e.g. manufacturer to wholesaler) or not (e.g., pharmacy to consumer).

⁶⁵ Please see the Transaction and Transparency Summary of Survey Results for further information.

Appendix C – Transparency Proposals Not Recommended

The following tables outline the proposals that were not recommended in the final vote or scored less than 3.5 in the evaluation survey.

Transparency Proposals Not Recommended in Final Vote

Proposal	Language	Final Vote			
		Recommend		Do Not Recommend	Abstain
Supply Chain 1 - Manufacturers 1	Require manufacturers to disclose and report by 9-digit NDC: <ul style="list-style-type: none"> • Average fee paid to wholesalers • Average chargeback paid to wholesalers • Aggregate rebate paid to PBMs • Average administrative fee paid to PBMs 	6	1	7	0
Supply Chain 1 – Wholesalers 1	Require the top three largest wholesalers to disclose and report by 9-digit NDC: <ul style="list-style-type: none"> • Average price paid to manufacturer • Average chargeback received from manufacturer • Average fees paid by manufacturer • Average pharmacy payment • Average administrative or other fees paid by the wholesaler's largest 3 chain pharmacy customers by sales 	6	1	7	0
Supply Chain 1 – Pharmacies 1	Require pharmacies to report by 9-digit NDC: <ul style="list-style-type: none"> • Average price paid to wholesalers • Average fee paid to wholesalers • Average rebate from manufacturers (if the manufacturer price concession was not reflected in payment to wholesaler) • Average product reimbursement from PBM/insurer 	5	2	7	0

Transparency Proposals Scoring Less than 3.5 on Evaluation Survey

Proposal Code	Language	Evaluation Score
Manufacturers 7	Require manufacturers to update their pricing (WAC, AWP) for all products, whether discontinued or active, on a frequent basis (at least monthly if not more frequently).	3.4
Pharmacies 4	Require disclosure of pharmacy's WAC price for their medication at the pharmacy counter by printing both their WAC price and the member's cost share on the prescription receipt or label.	3.3
Manufacturers 3	Clearly define and differentiate costs of "research" and "marketing" by manufacturers as marketing activities may be categorized incorrectly as research.	3.3
Manufacturers 2	Require each drug manufacturer or pharmaceutical marketer, who engages in any form of prescription drug marketing to a provider, prescriber, their designee, or any member of his or her staff to report to the Oregon Board of Pharmacy the current WAC information by NDC unit for each of the FDA-approved drugs marketed in the state by that manufacturer.	3.3
PBM 7	Require PBMs to disclose information related to patients enrolled in discount programs administered by the PBM obtained through data sharing agreements with pharmacies or intermediaries.	3.2

Appendix D – Feedback from Task Force Members on Transparency Recommendations

Task Force members provided their final vote on the transparency recommendations during the October meeting. Members were invited to submit an optional position statement explaining their support of one or more proposals, express concerns on specific proposals, or suggest additional revisions and clarifications in writing.

This appendix includes the full feedback submitted by three members on the transparency recommendations.

- I. LuGina Mendez-Harper, PBM representative
- II. Robert Judge, Insurance Company representative
- III. Saumil Pandya, Pharmaceutical Manufacturer representative

Joint Interim Task Force on Fair Pricing of Prescription Drugs

Member Position Statement – Optional

LuGina Mendez-Harper – Prime Therapeutics

Pharmacy Benefit Manager Representative

Position Explanation

Proposal Code: Pharmacy Benefit Manager 1 Evaluation of the utilization of rebate pass-through/fee-only PBM vendors for state-sponsored health plans.

- Payers already have the ability to contemplate use of rebate pass-through/fee only Pharmacy Benefit Manager (PBM) contracts as well as rebate sharing PBM contracts through the Request for Proposal process. Therefore, legislation is not needed.
- The term “State-sponsored health plans” lacks definition. Questions remain regarding applicability to self-funded and/or fully funded state-sponsored health plans.

Proposal Code: Pharmacy Combined: Promote supply chain entities to engage in practices that increase the availability of lower-cost pharmaceuticals for consumers at point of sale.

- The PBM industry supports pharmacists’ ability to discuss clinical drug information with their patients as well as their ability to discuss the availability of lower-cost pharmaceuticals at the point of sale. The PBM industry supports claim submission to ensure member’s out of pocket costs are applied to deductibles or out of pocket maximums. The PBM industry also supports claim submission to ensure drug utilization review occurs.
- Pharmacist reimbursement is pursuant to contracting terms. Pharmacist reimbursement is separate from and not a cost factor for consumers. The only two price points for consumers is the cost share using their benefits or the cash price (aka Pharmacy Usual and Customary [U&C]). The PBM industry does not support pharmacist reimbursement being a factor in this consumer-facing recommendation. The inclusion of the last paragraph and final bullet in the proposal go beyond consumer protection and instead addresses pharmacy reimbursement.
- The requirement regarding cost inquiries and transaction fees associated with these inquiries is not needed as the proposal already requires PBMs to ensure consumers will be charged the lesser of their cost share (e.g., copay) or the cost of the medication without insurance. There is no need for cost inquiries due to “lesser of” logic being required.
- The language PBMs continue to support is:
 - Prohibit PBM practice that prevents or penalizes a pharmacist or pharmacy from the following:
 - A pharmacy or pharmacist shall have the right to provide an insured information regarding the amount of the insured's cost share for a prescription drug as well as other more affordable purchasing options such as a generic alternative or paying cash for the prescription. Neither a pharmacy nor a pharmacist shall be prohibited by a pharmacy benefits manager from discussing any such information or for selling a more affordable alternative to the insured if one is available.
 - A health plan that covers prescription drugs may not include a provision that requires an enrollee to make a payment for a covered prescription drug at the point of sale in an amount that exceeds the lesser of:
 - (1) the contracted cost share amount; or
 - (2) the pharmacy’s retail usual and customary price (cash price) for the prescription drug.

Proposal Code: Rebate 1: Disclosure of total financial incentives that flow among manufacturers, PBMs, and commercial health plan insurers for entities that have a direct transactional relationship. Requires certification of health insurance companies' percentage of rebates applied to minimize consumer premiums or out-of-pocket costs.

- Payers contract with PBMs to administer benefits consistent with contract terms which include payment mechanisms using manufacturer rebates and/or administrative fees. Client contracts with PBMs include auditing the terms and performance of the contracted services.
- Clarification is needed regarding reporting of "other payments, gifts, or incentives" as these are not terms used in the PBM industry. This language was proposed by a supply chain representative unfamiliar with PBM contract terms and constructs.
- PBMs contract independently with pharmacies and payers.
- The PBM industry has provided the Task Force with several Federal Trade Commission (FTC) opinions, as well as both Congressional Budget Office (CBO) and Office of the Inspector General (OIG) analysis which concluded the transparency of manufacturer rebates would result in a pressure to reduce rebates which, in turn, could increase costs for payers and consumers.
- Given the specificity of data required from all supply chain entities, the potential to disclose proprietary and/or competitive information, and the unintended consequences of disclosure potentially resulting in higher drug costs for payers and patients, accompanied with negatively impacting PBMs ability to negotiate with manufacturers and pharmacies, we cannot support this proposal.

Proposal Code: Supply Chain 1 – PBMs 1 and Insurers 1

- The Task Force supply chain 1 proposal contemplated transparency across the entire supply chain. Initial voting from Task Force members resulted in 7 pro and 7 con votes. According to Task Force voting rules, any proposal not obtaining majority votes for approval (which included a tie if less than the majority) would not be further contemplated. This proposal did not obtain majority votes when presented for the entire supply chain. Under the Task Force rules, it should have received no further consideration.
- During the October meeting, Task Force members were asked to contemplate and vote on the transparency proposal for each supply chain segment rather than as collectively contemplated (in which a majority was not reached). This approach is counter to transparency throughout the supply chain recommended to the Task Force.
- After discussion on transparency proposals segmented by each supply chain participant, the Task Force reached majority support for only PBM and Insurer transparency.
- The PBM industry has provided the Task Force with several FTC opinions, as well as both CBO and OIG analysis which concluded the transparency of manufacturer rebates would result in a pressure to reduce rebates which, in turn, could increase costs for payers and consumers.
- Given the specificity of data required from all supply chain entities, the potential to disclose proprietary and/or competitive information, and the unintended consequences of disclosure potentially resulting in higher drug costs for payers and patients, accompanied with negatively impacting PBMs ability to negotiate with manufacturers and pharmacies, we cannot support this proposal.

Proposal Code: Combined Insurance 2 and 3: Notice to insurance enrollees about a change in formulary, utilization management rules, or formulary tier placement. This requires an insurer's website on pharmacy benefit be made available to the general public with information on brand and generic drugs, grievance and appeals processes, rates of pharmaceutical grievances, and rates of appeal denials.

- 60-day notice to enrollees should be limited to negative formulary changes only to help avoid confusing beneficiaries.

LuGina Mendez-Harper – Prime Therapeutics
Pharmacy Benefit Manager Representative

- Utilization of FDA-rated generics is permissible pursuant to Oregon Pharmacy Practice statutes and regulations unless prescriber or patient indicates “dispense as written.” This requirement will delay generic utilization, driving up costs for both payers and consumers.
- Disclosure of information to enrollees is already available. However, the requirement to provide a variety of information to the general public is not supported as most of this information is plan-specific pharmacy benefit information. There is no way to determine what specific data should be provided to the general public nor what value the information would be to the consumer in evaluating coverage given most of this information is specific to plan design.
- Disclosure to plan beneficiaries that they will be charged the lesser of the pharmacy Usual and Customary price (aka “cash” price) OR their cost share (e.g., copay) should be a general statement provided by insurers. Requiring insurers to provide specific values of these two prices is specific to each plan design and would generate a great deal of paperwork with little to no consumer benefit.
- The requirement to disclose grievances and rates of appeal denials is also plan-specific. This requirement does not provide the general public with useful information to evaluate health insurance benefits.
- For these reasons, we cannot support this proposal.

Proposal Code: Government Entity 4: External audits for state government receipt of and use of pharmaceutical rebates.

- External audits are a typical contract provision and do not require legislation.
- Rebates are just one drug price cost driver. This proposal does not include consideration of other cost drivers.
- Limiting auditing to one cost driver may lead to inaccurate conclusions.
- It is unclear how this proposal will impact the positive or negative effects of rebates on the total cost of care, evidence-based care, or the financial effects on those to whom the state has delegated financial risk.

Proposal Code: Insurer 4: Disclosure of the lesser of the member’s cost share amount or the pharmacy usual and customary price (cash price) to current or prospective enrollees.

- Insurer Evidence of Coverage shall inform current or prospective members that their prescription drug cost will be the lesser of their cost share or the pharmacy’s usual and customary i.e., cash price. Insurers cannot be required to share specific costs as the cash price at the pharmacy is known only to the pharmacy and only at the point of sale.

Joint Interim Task Force on Fair Pricing of Prescription Drugs
 Member Position Statement – Optional

Robert Judge – Moda Health
 Insurance Company Representative

Position Explanation
<p>Proposal Code: <u>Supply Chain Recommendation #2 (Pharmacist Gag Clause)</u> - Promote supply chain entities to engage in practices that may increase the availability of lower-cost pharmaceuticals for consumers.</p> <ul style="list-style-type: none"> • Recommendation is superseded by recent federal gag clause language that has been signed into law for both commercial and Medicare plans. • Moda would support gag clause language that states the following: <ul style="list-style-type: none"> – A pharmacy or pharmacist shall have the right to provide an insured information regarding the amount of the insured’s cost share for a prescription drug. Neither a pharmacy nor a pharmacist shall be proscribed by a pharmacy benefits manager from discussing any such information or for selling a more affordable alternative to the insured if one is available. – A health plan that covers prescription drugs may not include a provision that requires an enrollee to make a payment for a prescription drug at the point of sale in an amount that exceeds the lesser of: <ul style="list-style-type: none"> ○ The contracted copayment amount; or ○ The amount an individual would pay for a prescription if that individual were paying cash.
<p>Proposal Code: <u>3. Supply Chain Recommendation #3 (Rebates)</u> - Disclosure of total financial incentives that flow among manufacturers, PBMs, and insurers for entities that have a direct transactional relationship. Requires certification of health insurance companies’ percentage of rebates applied to minimize consumer premiums or out-of-pocket costs.</p> <ul style="list-style-type: none"> • Recommendation conflicts with numerous FTC opinions on this topic. FTC has analyzed state legislation that would regulate PBMs, or mandate uniform disclosure of PBM rebates and determined that if rebates were required to be reported by PBMs, it would lead to a less competitive market than what we have today. • From a carrier perspective, mandatory rebate disclosure could limit the ability to negotiate as one element of a negotiating strategy when developing pricing strategies, thus limit market competitiveness.
<p>Proposal Code: <u>Pharmacy Benefit Manager Recommendation #1</u> - Utilization of rebate pass-through/fee- only PBM vendors for state-sponsored health plans.</p> <ul style="list-style-type: none"> • While supportive of initiatives to increase transparency in general, we are opposed to mandating rebate pass-through requirements on state purchasers of pharmacy benefits, especially those that are fully insured. • State purchasers should select benefit arrangements that result in the lowest net cost to taxpayers.
<p>Proposal Code: <u>Insurer Recommendation #1</u> - Notice to insurance enrollees about a change in formulary, utilization management rules, or formulary tier placement. This requires an insurer’s website on pharmacy benefit be made available to the general public with information on brand and generic drugs, grievance and appeals processes, rates of pharmaceutical grievances, and rates of appeal denials.</p> <ul style="list-style-type: none"> • Moda does not support the adopted language of this recommendation for the following

reasons:

- Requiring plan-specific pharmacy benefit information be made available generally places an unworkable burden on insurers as there are thousands of benefits designs created to support individual group benefit requirements.
- Requiring that insurers list rates of pharmaceutical grievances and rates of appeal denials does not assist consumers with improving their ability to evaluate an insurance benefit; appeals are specific to clinical criteria and the individual's circumstances as they relate to those criteria.
- Requiring insurers to provide an index of formulary tier levels is unworkable as plan designs are unique to each payer. There are literally thousands of fee structures that would need to be reported to support this requirement.
- Language that requires insurers to explicitly state whether a generic alternative is available is already included in Step therapy or Prior Authorization criteria which is required to be made public.

Proposal Code: Provider Recommendation #1 - Disclosure of hospital and medical provider markups on patient bills.

- Imposing this requirement may conflict with private party negotiations and their contract requirements.

Proposal Code: Government Entity Recommendation #2 - External audits for state government receipt of and use of pharmaceutical rebates.

- By limiting the audit to the state's use of pharmaceutical rebates the recommendation doesn't include all elements that are necessary to evaluate impact to total cost of care.

Proposal Code: Supply Chain 1 – Insurers 1 and PBMs 1

- The Task Force was charged with developing a strategy to create transparency for drug prices across the entire supply chain of pharmaceutical products. When concepts were being created it was agreed that among the list of recommendations that would be contemplated would be a supply chain transparency recommendation that would apply across the entire supply chain. However, when the vote was taken on this, it did not secure a majority vote and the Supply Chain recommendation should have been omitted from the final report.

However, during the October 25 meeting, task force members were asked to vote on a transparency proposal for each supply chain segment instead. This was counter to the intent of establishing greater transparency across the entire supply chain. As a consequence, instead of establishing greater transparency in its entirety, the resulting recommendation limits its focus to a subset of the supply chain by targeting only 2 participants for transparency reporting. This limitation will contribute very little to the Task Force objective of enhancing transparency around the factors that impact cost across the entire supply chain.

Joint Interim Task Force on Fair Pricing of Prescription Drugs

Member Position Statement – Optional

Saumil Pandya- PhRMA

Pharmaceutical Manufacturer Representative

Position Explanation
<p>Proposal Code: Combined Government Entity 2 and 5 Government Entity 2 requires state agency reporting on the top 10 prescribed, top 10 highest cost paid, and top 10 highest increased cost. These lists should be established net of applicable rebates but must not disclose net costs. Government Entity 5 requires the Oregon Health Authority to require reporting on certain prescriptions under the Medicaid program. The proposal should be modified to clarify that the costs indicated in the proposal are “net” costs. Manufacturers pay hundreds of millions of dollars in rebates to the state of Oregon and any reporting should factor in these significant rebates. For example, manufacturer Medicaid rebates totaled \$357 million in 2016. Rebate amounts for individual products are confidential and must not be disclosed.</p>
<p>Proposal Code: Combined Insurer 2 and 3 Combined Insurer 2 and 3 provide patients with basic pharmacy benefit information and notification. There is a real need for patients to have information about out-of-pocket costs and clinical tools being used when it comes to their coverage, and how they can express grievances and appeal negative coverage decisions. This type of information is important for patients, enabling them to find the best health care plan to meet their needs.</p>
<p>Proposal Code: Government Entity 4 This proposal requires the state to conduct external audits for state government receipt of and use of pharmaceutical rebates. This proposal could help expose and improve how state and federal Medicaid dollars are spent. In Ohio, Pharmacy Benefits Managers are under scrutiny for both their lack of transparency and for the findings of an audit report that showed that two PBMs were keeping 8.8 percent of the state’s Medicaid pharmacy budget.</p>
<p>Proposal Code: Insurer 4 The adopted version of Insurer 4 requires health insurers to disclose the lesser of the member’s cost share amount or the pharmacy usual and customary price (cash price) to current or prospective enrollees. While this is helpful, an earlier version of this proposal required health insurers to disclose to current and prospective enrollees and plan sponsors that they may be charged "excess cost-sharing," defined as an amount greater than, or based on a price greater than what the plan pays (net of rebates accrued directly or indirectly to the plan). This would inform patients who are paying cost sharing that is based on list price as opposed to net price (reflecting rebates).</p>
<p>Proposal Code: Manufacturer 6 This proposal requires manufacturers to disclose total and average spending on patient assistance programs in addition to the patient assistance program reporting required in HB 4005. This is proprietary information and should not be disclosed.</p>

Proposal Code: Manufacturer 8

This proposal requires manufacturers to report on new drugs with a price exceeding the price of other drugs within the therapeutic class. This is trade secret information and should not be disclosed.

Proposal Code: Manufacturer 4

PhRMA remains concerned that just including list prices in these advertisements is not sufficient and could discourage patients from seeking needed medical care. Additionally, this is already being proposed at the federal level. Patients want to know how much a medicine will actually cost them at the pharmacy counter and what help is available for affording their medicines. To help patients make more informed health care decisions, PhRMA member companies recently announced their voluntary commitment to providing more transparency about medicine costs. PhRMA member companies' direct-to-consumer (DTC) television advertisements will soon direct patients to information about medicine costs, including the list price and average, estimated, or typical patient out-of-pocket costs, or other context about the potential cost of the medicine.

Proposal Code: Combined Manufacturer 5, PBM 3, and Insurer 5

The Rebate Transparency Recommendation has a number of beneficial policy options, but suffers from the way in which disparate proposals were combined, from a lack of clarity, and from insufficient protections related to the conditional exemption from public disclosure of confidential trade secret information. Additionally, the requirements included in Insurer 5 don't go far enough. PhRMA put forward language at several occasions that would have required health insurers to certify through their annual filing documents that for the prior calendar year, a majority (at least 50%) of their rebates were passed through to enrollees at the point of sale. This language was included in one of the preliminary proposals but was significantly diluted in the final proposal, missing an opportunity to provide direct relief to patients at the point of sale. Biopharmaceutical companies provide hundreds of billions of dollars in rebates, paying out \$153 billion in 2017 alone. While PhRMA voted against the specific proposal as constructed, for the reasons specified above, aggregate rebate disclosure by PBMs with appropriate confidentiality protections is a policy the state of Oregon should pursue.

Proposal Code: Supply Chain 1

Although this proposal did not pass, we believe that any such reporting should be at the aggregate level, and not at the product or NDC-9 level so not to violate confidential contractual agreements.