LPRO: LEGISLATIVE POLICY AND RESEARCH OFFICE

Joint Interim Task Force on Fair Pricing of Prescription Drugs

Report on Transparency Strategies for the Pharmaceutical Supply Chain

November 2018

EXECUTIVE SUMMARY

This report outlines the work and recommendations of the Joint Interim Task Force on Fair Pricing of Prescription Drugs (Task Force). Over a five-month period, 18 members who represent entities in the pharmaceutical supply chain developed a set of transparency recommendations for the Oregon Legislative Assembly. Members each contributed over 100 hours of work completing a number of exercises and surveys to elicit robust feedback on transparency proposals across the supply chain. The recommendations reflect the collective work of the Task Force—striving towards consensus with recognition of the inherent difficulties and complexities of the pharmaceutical supply chain including the unique roles of and interplay between federal and state government.

Background and the Task Force Charge

In 2018, the Oregon Legislative Assembly passed House Bill 4005. This legislation enacted reporting provisions for pharmaceutical manufacturers and insurers and established the Task Force on Fair Pricing of Prescription Drugs. The Task Force was charged with developing a strategy to create transparency for drug prices across the entire supply chain of pharmaceutical products. Additionally, the Task Force was required to include a cost-effective and enforceable solution that exposes the cost factors impacting prices paid by Oregonians for pharmaceutical products and may include recommendations for legislation.

Summary of Task Force Process and Activities

The Task Force first met in May 2018 and completed its work in October 2018. Over the course of six in-person meetings, members engaged in a series of informational presentations and exercises to develop and refine strategies to create transparency for drug prices.

In May, information was provided by each Task Force member describing their industry, role, and perspectives on transparency in the pharmaceutical supply chain. This information provided foundational knowledge among members about the roles of different entities in the supply chain and pharmaceutical market. In June, non-legislative members completed a survey to provide information for a more comprehensive understanding of the prescription drug distribution system in Oregon and identifying cost factors that (1) influence the prices of pharmaceutical's paid by Oregonians, and (2) may benefit from increased transparency or should remain non-transparent.

In August, the survey results were used to finalize a set of cost factors and evaluation criteria to be applied to potential transparency proposals. The cost factors identified and used to develop a set of initial transparency proposals were:

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

The process used by the Task Force to generate cost factor transparency proposals was done by reviewing the June survey results, legislative proposals in other states, and submitting original ideas offered by members at the August meeting. This process led to the development of preliminary transparency proposals.

Prior to the September meeting, members were asked to provide feedback on 32 cost factor preliminary transparency proposals, which was used to refine the transparency proposals. The refined transparency proposals were evaluated through a survey tool using the following criteria: (1) ability to monitor, (2) better decision-making, (3) cost-effective, (4) cost reduction, and (5) enforceability The results were used to inform discussions and further improvement of proposals at the September 25th meeting. The final refinement step involved members suggesting language revisions and engaging in preliminary voting exercise, which staff used to develop the final proposals considered by the Task Force at the October meeting.

Transparency Recommendations for Pharmaceutical Supply Chain

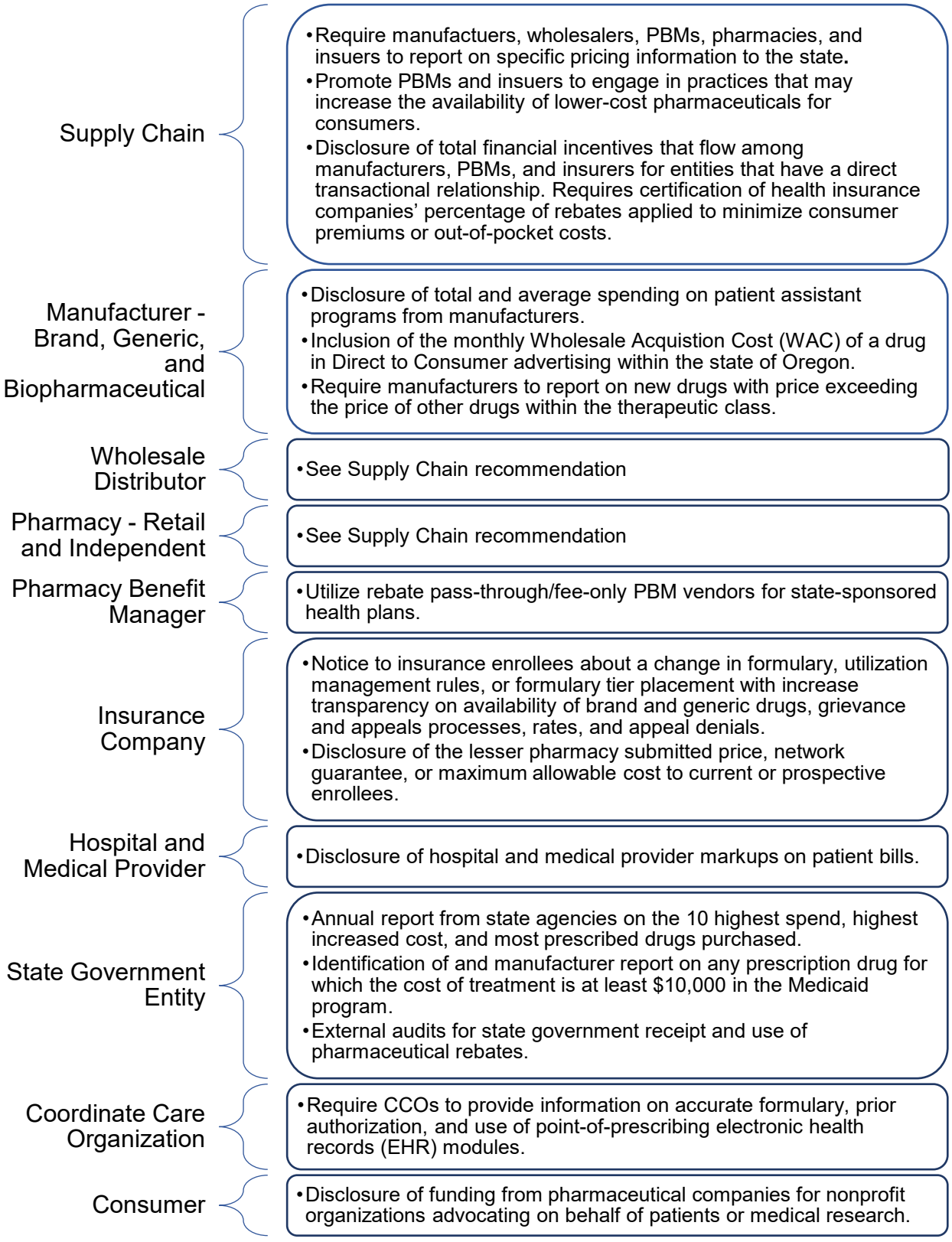
Throughout the process, members provided critical feedback on several transparency proposals considered as part of a transparency strategy for the pharmaceutical supply chain. The proposals are intended to increase transparency on eight cost factors identified by members for increased transparency by individual market participants, and include proposals across the entire supply chain – from manufacturers to consumers. Collectively the transparency proposals reflect the Task Force's work to address the charge to create transparency for drug prices across the entire supply chain of pharmaceutical products. It is the intent that the proposals also offer the legislature a cost-effective and enforceable solution that exposes the cost factors affecting prices paid by Oregonians. The final set of proposals was refined and voted on by the majority of members for recommendation to the legislature.

Figure 1 displays the recommendations the majority (*pending)* of voting members agreed to send to the legislature for consideration. The recommendations are sorted by the pharmaceutical supply chain entity primarily affected by each transparency strategy. Recommended transparency strategies are made in good faith by the majority of members to improve transparency and provide solutions to expose the cost factors affecting pharmaceutical prices paid by Oregonians. Further analyses should be considered to fully understand the impacts and limitations of each transparency proposal.

Additional Considerations and Next Steps

Additional topics related to pharmaceutical policy were identified by members throughout the Task Force work and are summarized in this report. These recommendations represent the completion of the initial charge of the Task Force. The Task Force will continue to work to address pharmaceutical policy through December 31, 2020 at the guidance of the Oregon Legislative Assembly.

Figure 1. Overview of (PENDING) Recommended Transparency Strategies



Source: Legislative Policy and Research Office

TASK FORCE MEMBERS

Senator Dennis Linthicum
Senator Elizabeth Steiner Hayward
Representative Teresa Alonso Leon
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

Report prepared by Cassie Soucy and Oliver Droppers, Legislative Analysts, Legislative Policy and Research Office on behalf of the Joint Interim Task Force on Fair Pricing of Prescription Drugs.

For more information please contact the Legislative Policy and Research Office,
900 Court St. NE, Room 453, Salem OR, 97301
503-986-1813

November 1, 2018

ACKNOWLEDGMENTS

The Task Force engaged in several exercises and activities to develop the transparency recommendations. Task Force members each contributed over 100 hours of work on exercises and surveys to elicit Task Force member feedback to recommend these transparency proposals. Through this work, many individuals contributed to the development of the exercises, implementation of surveys, and contribution of expertise to the Task Force. The following individuals are acknowledged for their dedicated time to helping the Task Force process, developing transparency proposals, and finalizing the transparency recommendations:

Rick Blackwell, Department of Consumer and Business Services

Jane Horvath, Horvath Health Policy

Devin Howington, ICMresolutions

Sam Imperati, ICMresolutions

Anna Levy, Oregon Health Authority

Jesse O'Brien, Department of Consumer and Business Services

Danielle Ross, Legislative Policy and Research Office

Jeannette Taylor, Oregon Health Authority

Ben Zientara, ICMresolutions

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PHARMACEUTICAL MARKET ENTITIES

The pharmaceutical market involves different types of entities that serve specific purposes to provide pharmaceutical drug products to consumers. These entities interact with each other through complex activities such as the movement of pharmaceutical product, contracting with one or more entities, or providing services for another entity within the pharmaceutical supply chain. Market entities participating or referenced in Task Force deliberations are briefly described below to provide a general overview of their role in the pharmaceutical market and how they interact with the flow and pricing of prescription drugs.[1]

Manufacturers

Pharmaceutical manufacturers research, develop, and produce prescription drugs used to address 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 following the clinical trials and decides whether each drug will be made available on the market to consumers.[2] The manufacturing industry can be separated into three distinct areas with unique characteristics to each – brand, generic, and biopharmaceutical manufacturers.

Brand Manufacturers

Pharmaceutical manufacturers who produce brand-name drugs are often responsible for the initial research and development of a new pharmaceutical product. Brand-name drugs receive patents and exclusivities from the FDA.[3] 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.[4]

Generic Manufacturers

Once a brand-name drug is no longer patent-protected generic manufacturers may begin producing therapeutically equivalent generic drug products. The FDA must give approval for a generic drug application to ensure its equivalence to the branded drug before it can

[1] Please see Appendix A for a glossary of pharmaceutical terms used throughout this report and other Task Force documents.
[2] 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>.
[3] U.S. Food & Drug Administration. *Frequently Asked Questions on Patents and Exclusivity* <https://www.fda.gov/Drugs/DevelopmentApprovalProcess/ucm079031.htm>.
[4] 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.

be produced.[5] Generic drugs comprise the largest portion of the pharmaceutical market, providing approximately 90 percent of all drugs dispensed to consumers.[6]

Biologic Manufacturers

Biologic manufacturers are distinct from traditional brand and generic manufacturers because they produce drug products made from living organisms. Biologic drug products can range from products such as antitoxins to vaccines. Manufacturers of biologic drug products are similarly required to receive approval from the FDA in order to sell their products.[7] Biosimilar drug products may be produced following the expiration of the biologic's patent and other data protections.

Similar to the relationship between brands and generics, biosimilars are required to be extremely similar to approved biologics by having the same strength, dosage form, and route administration (such as injection).[8] Many biologics and biosimilars are categorized as specialty drugs due to their complex structure using living organisms, the storage requirements needed, and the cost and complexity of the administration of the product to the consumer.

Wholesale Distributors

Wholesale distributors purchase and store large quantities of pharmaceutical products directly from manufacturers. They then sell those products to pharmacies, hospitals, and health care facilities. As the wholesale industry has evolved, services offered by wholesalers have increased to include specialty drug distribution, drug repacking, electronic order services, and reimbursement support.[9]

Pharmacies

Pharmacy entities are licensed by the State and dispense pharmaceutical products to consumers. Pharmaceutical products are ordered by the pharmacy and delivered by a wholesale distributor. Licensed pharmacists dispense pharmaceutical products to consumers according to the prescription received by written note or electronic transmission. Pharmacies can be separated into three primary pharmacy types:

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[5] U.S. Food & Drug Administration. *Generic Drugs: Questions & Answers* <https://www.fda.gov/drugs/resourcesforyou/consumers/questionsanswers/ucm100100.htm>.
[6] 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>.
[7] U.S. Food & Drug Administration. *Development & Approval Process (CBER)* <https://www.fda.gov/BiologicsBloodVaccines/DevelopmentApprovalProcess/default.htm>.
[8] U.S. Food & Drug Administration. *Biosimilars: More Treatment Choices and Innovation* <https://www.fda.gov/ForConsumers/ConsumerUpdates/ucm436399.htm>.
[9] Kaiser Family Foundation. *Follow the Pill: Understanding the U.S. Commercial Pharmaceutical Supply Chain,* March 2005. <https://olis.leg.state.or.us/liz/2017I1/Downloads/CommitteeMeetingDocument/148677>.

- Retail – local entities that are open to the public. These can be national corporate chain pharmacies, independently owned individual stores, or regional chains. In Oregon, 1,377 retail pharmacies are licensed by the Oregon Board of Pharmacy.[10]
- 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 as well as high levels of patient or provider support.
- Mail-order – organizations that deliver pharmaceutical products through the mail. These pharmacies can be owned by a wholesale distributor, pharmacy benefit manager, or insurance company.

Pharmacy Benefit Managers

Pharmacy benefit managers (PBMs) are intermediaries between health plans and 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.[11] Additional services a PBM can provide include administration of mail-order or specialty pharmacy services. In Oregon, 55 PBMs are currently registered with the Department of Consumer and Business Services.[12]

Insurance Companies

Health insurance companies provide medical and pharmacy benefits that include a list of pharmaceutical drugs covered by the insurance 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 includes consumer cost sharing – 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 with consumers. Higher formulary tiers have higher consumer cost sharing than lower formulary tiers. Typically, manufacturers negotiate with insurers (or their pharmacy benefit managers) for a drug's formulary tier placement.

Health Care Providers

Health care providers who can prescribe, dispense, or administer drugs to patients in hospitals or in community settings are established by state law. Prescribing health care providers assess patients to diagnose and provide treatment options including prescription medications. Health care providers may prescribe drugs, depending on the health care setting, through written, oral, or electronic communications to a pharmacy.

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[10] Oregon Board of Pharmacy. Active license statistics as of October 1, 2018.
[11] Ibid.
[12] Department of Consumer and Business Services. "Re: Number of PBMs Registered." Email message to Cassie Soucy, October 10, 2018.

Consumers

Consumers receive prescriptions for pharmaceutical drugs from prescribing health care professionals. If a consumer has health insurance coverage, the costs of a prescription may be fully covered or require consumer cost-sharing. An uninsured consumer is often responsible for the total cost of the drug. Consumers are dependent on a prescribing health professional, their pharmacist, and the negotiated agreements between pharmaceutical market entities to establish the cost of prescribed pharmaceutical drugs.

Other Related Entities

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

- Hospitals – Hospitals may purchase large quantities of drugs for inpatient and outpatient use. Many hospitals operate their own pharmacies to dispense the pharmaceuticals products to patients, once prescribed by a qualified health provider.

- Coordinated Care Organizations (CCOs) – CCOs function similarly to managed care companies and are regulated under federal and state Medicaid laws. The majority of Oregon's Medicaid participants are enrolled in CCOs.

- 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 – provides oversight and regulation regarding Medicare and Medicaid programs which purchase pharmaceutical drugs.
    - Oregon Health Authority (OHA) – implements and regulates Oregon's Medicaid program, and oversees Oregon's Prescription Drug Program, a state prescription discount card program.
    - Department of Consumer and Business Services (DCBS) – provides oversight and regulation of commercial health insurers and PBMs, reviews and approves individual and small group health insurance rates and forms, and oversees the Prescription Drug Transparency Program.

- Group Purchasing Organization (GPO) – This is an entity that represents a group of drug purchasers, such as hospitals and health systems. A GPO negotiates with manufacturers on behalf of its clients for either up-front discounts, on-invoice discounts or back-end rebates. GPOs negotiate a purchase-order from which members of the buying group can purchase pharmaceutical products in the quantities needed. GPOs may provide additional client administrative services as well.

- Pharmacy Services Administration Organization (PSAO) - Similar to a GPO, but serves independent retail 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 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 (WAC), the average wholesale price (AWP), actual acquisition cost (AAC), and maximum allowable cost (MAC). 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. 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. 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.

Financial Negotiations by Pharmaceutical Market Entities

Manufacturers determine the initial price of pharmaceutical products based on revenue needs and market conditions such as competition, length of remaining patent, and expected sales, among other factors.[13] This results in the established WAC for a pharmaceutical product. Generic drug prices are generally competitive among manufacturers and can vary daily due to market forces. For generics, the WAC may be significantly different from the generic list price relative to brands, because there is more competition among manufacturers of certain generic drugs.[14]

Wholesale distributors purchase drugs from manufacturers at a slight discount from the list price. Many wholesalers keep track of sales to different purchasers (pharmacies, hospitals) under prices negotiated between the manufacturer and the purchaser. Any differences between the negotiated price paid by the purchaser and the WAC price are charged back to the manufacturer.

Pharmacies purchase pharmaceutical drug products from wholesale distributors. Pharmacies interact with other pharmaceutical market entities such as PBMs to negotiate for inclusion in their pharmacy networks. Pharmacy networks include agreements on reimbursement guarantees from the PBM and health insurance company for dispensed pharmaceuticals. Pharmacies also charge a dispensing fee for the professional services delivered to the insurance company.

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[13] Kaiser Family Foundation. *Follow the Pill: Understanding the U.S. Commercial Pharmaceutical Supply Chain,* March 2005. <https://olis.leg.state.or.us/liz/2017I1/Downloads/CommitteeMeetingDocument/148677>

[14] Ibid.

PBMs interact with manufacturers, pharmacies, and health insurers regarding the pricing of prescription drugs. PBMs are contracted by health insurance companies to manage the health plan's pharmacy benefits through contractual administrative services which may include processing claims, maintaining pharmacy network adequacy, and formulary management. Rebates from manufacturers are typically negotiated by PBMs on behalf of their clients and can determine a manufacturer's inclusion or placement on the drug formulary. 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. These rebates can be retroactively distributed back to the health insurance company from the PBM, which retains a portion of the rebate.

Health insurance companies determine the cost-sharing for enrolled consumers. Cost-sharing for prescription drug benefits can include set copayment prices, specific percentages of coinsurance, or payment of a deductible amount before receiving coverage for costs. Consumer's prescription drugs cost-sharing is determined by their health plan or they can pay the cash price if they are uninsured. 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.

Changes in Prescription Drug Pricing

The price of a prescription drug is initially set by the manufacturer but the price and/or the cost may change by discounts and other price negotiations as the product goes through the supply chain. The discounts, rebates, and fees that accrue throughout pharmaceutical market entities can impact the costs to consumers for prescription drugs. 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.[15]

[15] Congressional Research Service. *Frequently Asked Questions About Prescription Drug Pricing and Policy*. April 2018. <https://olis.leg.state.or.us/liz/2017I1/Downloads/CommitteeMeetingDocument/149350>.

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.[16] In Oregon, pharmaceutical legislation has addressed several topics, including transparency within the pharmaceutical supply chain. In Oregon, over the past decade there have been multiple pieces of introduced legislation. For the purposes of this report, three pieces of legislation are highlighted as they specifically sought to address pharmaceutical transparency in Oregon.

House Bill 3486 (2015)

Oregon began examining pharmaceutical price transparency in 2015 with House Bill 3486.[17] This bill would have required manufacturers of prescription drugs with a WAC of $10,000 or more to file an annual report with the Oregon Health Authority (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.[18] The second bill, Senate Bill 793, would have required pharmaceutical manufacturers to report to the Department of Consumer and Business Services annually on the prices of prescription drugs sold in Oregon and price increases for prescription drugs.[19] Both bills received public hearings and were not moved out of committee upon adjournment of the legislative session.

House Bill 4005 (2018)

During the 2018 legislative session, House Bill 4005 was enacted into law as the *Prescription Drug Price Transparency Act*.[20] House Bill 4005 has several provisions requiring pharmaceutical manufacturers and insurance companies to report specific information to the Department of Consumer and Business Services (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 course of the previous calendar year. Any manufacturer required to report on a

[16] National Conference of State Legislatures. *Statewide Prescription Drug Database | 2015 – Present*.
[17] House Bill 3486 (2015)
[18] Senate Bill 792 (2017)
[19] Senate Bill 793 (2017)
[20] House Bill 4005 (2018)

prescription drug 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 Centers for Medicare and Medicaid Services 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 Fair Pricing of Prescription Drugs to examine and develop a transparency strategy for prescription drug prices across the pharmaceutical supply chain.

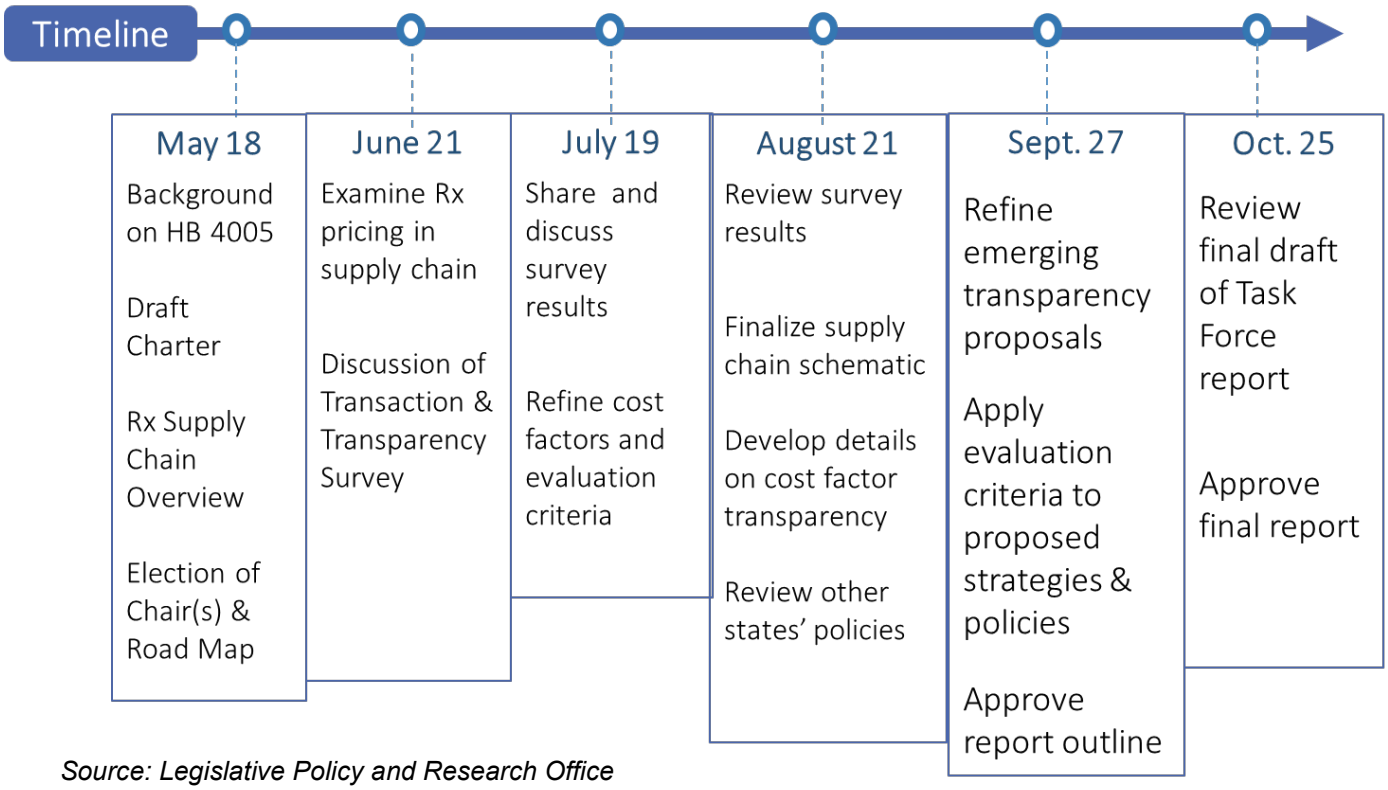
TASK FORCE OVERVIEW AND PROCESS

The Joint Task Force on 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.[21]

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 represented different stakeholders of the pharmaceutical supply chain from manufacturer, PBMs, state agencies to consumer representation.[22] 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.

[21] HB 4005

[22] Joint Interim Task Force on Fair Pricing of Prescription Drugs. *Updated Roster*. September 2018. <https://olis.leg.state.or.us/liz/2017I1/Downloads/CommitteeMeetingDocument/150804>.

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.

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.[23]

An official charter was adopted outlining responsibilities and expectations of Task Force members including[24]:

- 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 Legislature. The Task Force unanimously elected Dana Hargunani, Chief Medical Officer, OHA, and Andrew Stolfi, 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 by voting "one", "two", or "three". If a consensus on a recommendation was still not reasonably likely, the votes of those present at the meeting were to be taken and recorded as a Majority - Minority vote. Majority is defined as at least 51 percent, eight voting members. Those with minority viewpoints were responsible for providing rationale, proposing alternative solutions, or suggesting approaches to resolve differences. All minority positions were documented under the specific transparency recommendations for which the Task Force member was unsupportive.

A public comment period was held at each meeting. This provided members of 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.[25]

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[23] ICMResolutions. *Mediation* <https://www.mediate.com/icm/>.
[24] Joint Interim Task Force on Fair Pricing of Prescription Drugs. *Charter and Operating Procedures,* 06/21/2018 <https://olis.leg.state.or.us/liz/2017I1/Downloads/CommitteeMeetingDocument/149545>.
[25] Joint Interim Task Force on Fair Pricing of Prescription Drugs. *Committee Overview* <https://olis.leg.state.or.us/liz/2017I1/Committees/JFPRX/Overview>.

Before the first meeting, Governor Brown submitted a letter to the Task Force describing the importance of transparency to consumers purchasing from the pharmaceutical supply chain.[26] 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 the 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 the 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

[26] 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/2017I1/Downloads/CommitteeMeetingDocument/148672>.

Task Force Perspectives on the Pharmaceutical Supply Chain

Beginning in May, the Task Force collected information to help inform the 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.[27] 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 was the complex interactions and negotiations that occur within the system. Transparency was also discussed by members with differing viewpoints about types of transparency that may benefit consumers and the limitations of transparency throughout the 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 the Oregon Health Authority (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.[28] All voting Task Force members and one invited participant completed the survey prior to the July 19th meeting.[29]

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[27] Joint Interim Task Force on Fair Pricing of Prescription Drugs. *Task Force Member Responses to Questions, Combined.* 05/18/2018 <https://olis.leg.state.or.us/liz/2017I1/Downloads/CommitteeMeetingDocument/148672>

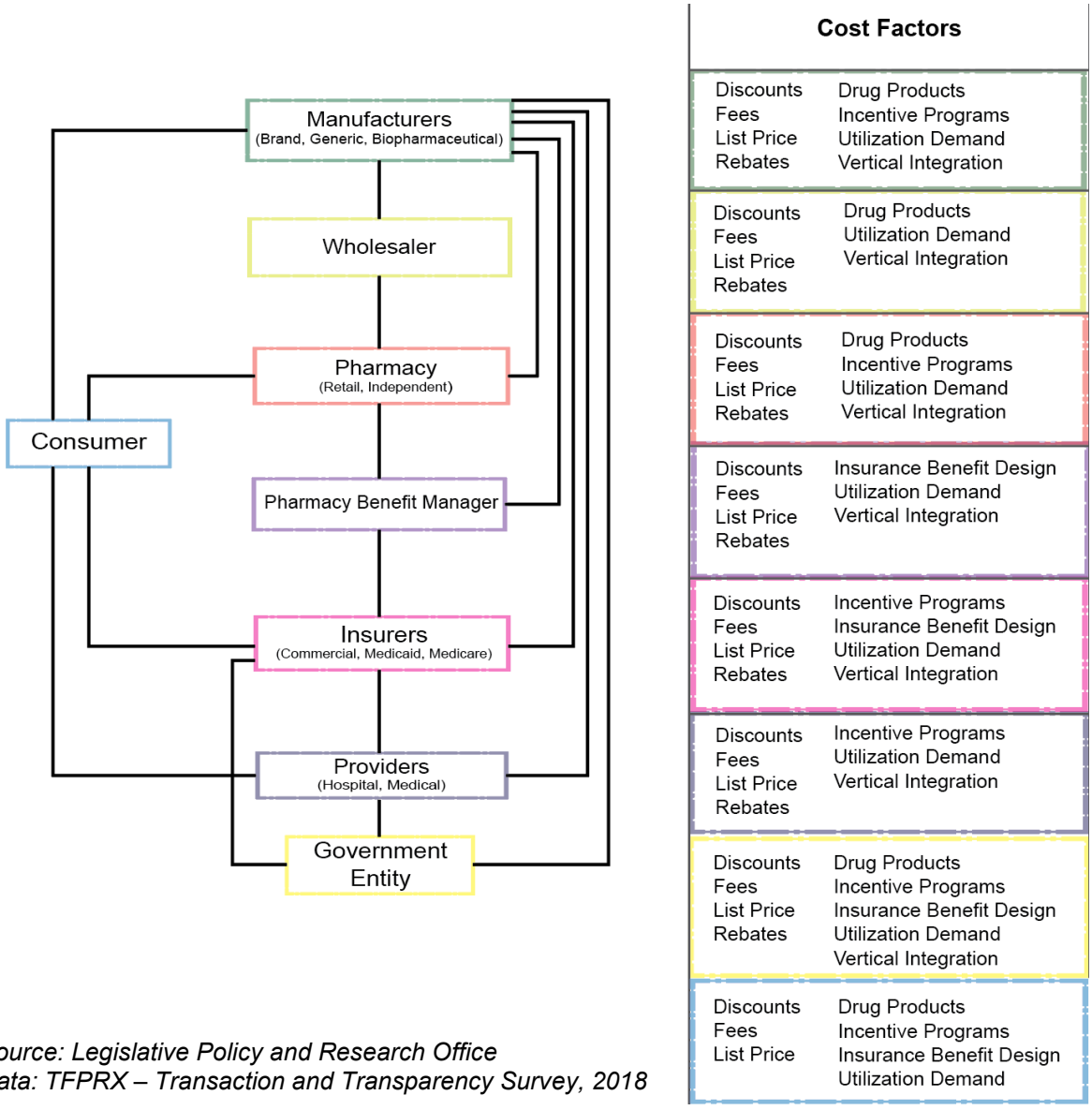
[28] Joint Interim Task Force on Fair Pricing of Prescription Drugs. *Transaction and Transparency Survey*. 7/19/2018. < https://olis.leg.state.or.us/liz/2017I1/Downloads/CommitteeMeetingDocument/149715>

[29] Please see the Transparency and Transaction Summary of Survey Results for further information.

Survey Results

Task Force members were asked to identify all stakeholders with whom they had direct transactional relationships.[30] 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). 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

[30] 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).

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 that can 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: [31]

- 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 also provided their perspectives on which of the factors should or should not have greater transparency, with the opportunity to suggest other cost factors for transparency.[32] Certain cost factors were selected for both the ability to increase or decrease price as well as whether there should or should not be greater 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.[33]

The results of the Transparency and Transaction Survey provided unique data specific to Oregon for future 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 Transparency and Transaction 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

Members discussed the proposed cost factors and suggested including markups and pharmacist gag clauses as cost factors for consideration. Each cost factor was defined in the glossary to establish a common understanding of these terms.[34] Task Force members accepted the following cost factors and their definitions for consideration in transparency proposals:

[31] Please see the Transparency and Transaction Summary of Survey Results for further information.
[32] Ibid.
[33] Ibid.
[34] Please see Appendix A for the Glossary of Pharmaceutical Terms.

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

LPRO and facilitation staff evaluated the frequency of evaluation criteria proposed by members throughout the survey to develop list for Task Force consideration. Additional evaluation criteria were included based on the statutory charge for "cost effective and enforceable solutions".[35] Similar to the cost factors, each evaluation criterion was defined within the glossary to establish a common understanding amongst members.[36]

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 ideas brought forward from academic pharmaceutical research and legislative concepts from other states

Pharmaceutical Policy and Research

The Task Force was presented 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.

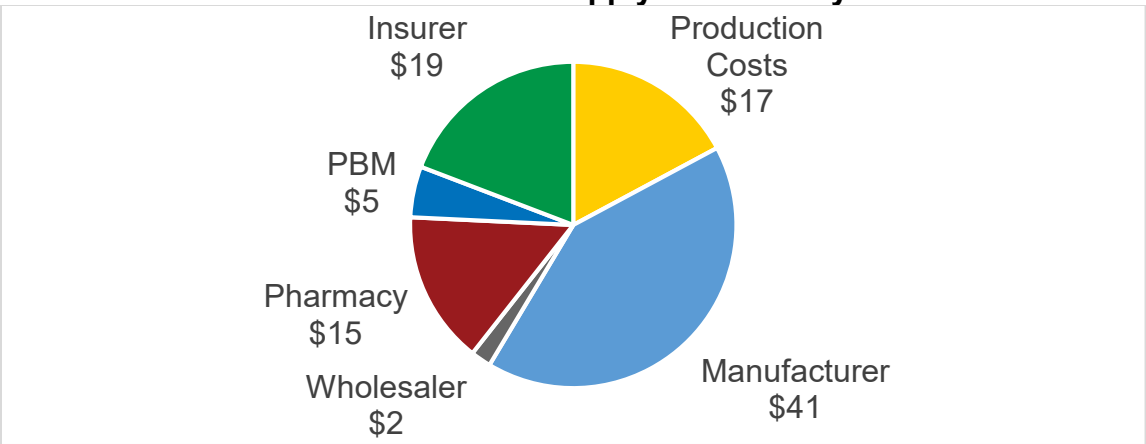
Flow of Money in the Pharmaceutical Supply Chain

Dr. Neeraj Sood of the University of Southern California was invited to present on research about the flow of money in the pharmaceutical supply chain.[37] 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 SEC filings to estimate the gross and net profits and illustrate the flow of money for a drug

[35] HB 4005
[36] Ibid.
[37] Sood, N. et. al. *The Flow of Money Through the Pharmaceutical Distribution System*, June 2017 <https://olis.leg.state.or.us/liz/2017I1/Downloads/CommitteeMeetingDocument/149980>

purchased. The result of these estimates found entities in the supply chain retaining the following from a $100 prescription drug expenditure (Figure 4).

Figure 4. Estimated Amount of $100 Prescription Drug Expenditure 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.[38] 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 information from research done by the Pharmaceutical Researchers and Manufacturers of America[39] and the Association of Accessible Medicines[40] to illustrate the different perspectives on how money flows through the pharmaceutical supply chain (Figure 5). Task Force members utilized this combined document to discuss the cost factors identified in the Transaction and Transparency Survey and their potential influence on the flow of money.[41]

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[38] 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/2017I1/Downloads/CommitteeMeetingDocument/149981>

[39] 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/2017I1/Downloads/CommitteeMeetingDocument/150035>

[40] 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>.

[41] Joint Interim Task Force on Fair Pricing of Prescription Drugs. *Flow of Money Through the Pharmaceutical Supply Chain – Discussion Draft.* August 2018. <https://olis.leg.state.or.us/liz/2017I1/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		
Actual Total	$83	$84	$116	$408	$4272.5	$101	$100				
Consumers			$40 Co-payment	$408 Deductible	$612 Coinsurance				Coinsurance Copayment Premiums	Coinsurance Copayment Deductible	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)	Discounts Fees Incentive Progam/Kickbacks Insurance Benefit Design List Price Rebates	Copay assistance Drug development Market exclusivity Patents	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 acquistion 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)		Higher cost-sharing tiers	Share of rebates and fees	Rebates Service contract Utilization management
Providers											
Government Entities											

Other States' Pharmaceutical Policies

Task Force members were also presented information on pharmaceutical policies other states have proposed or enacted to help begin development of the Task Force recommendations. The National Conference of State Legislatures (NCSL) reports that since 2015, states have introduced over 3,500 "pieces of legislation" relating to pharmaceutical policy in the United States.[42] 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 pharmacy benefit managers (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.[43] 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 Refinement

Task Force members were given the opportunity 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

[42] National Conference of State Legislatures. *Statewide Prescription Drug Database | 2015 – Present*.
[43] Joint Interim Task Force on Fair Pricing of Prescription Drugs. *Other States' Prescription Drug Legislative Proposals (2015-2018) – Discussion Document.* <https://olis.leg.state.or.us/liz/2017I1/Downloads/CommitteeMeetingDocument/150038>

staff collected and reviewed the feedback provided by Task Force members to edit the cost factor transparency proposals.[44] Task Force members provided LPRO staff with:

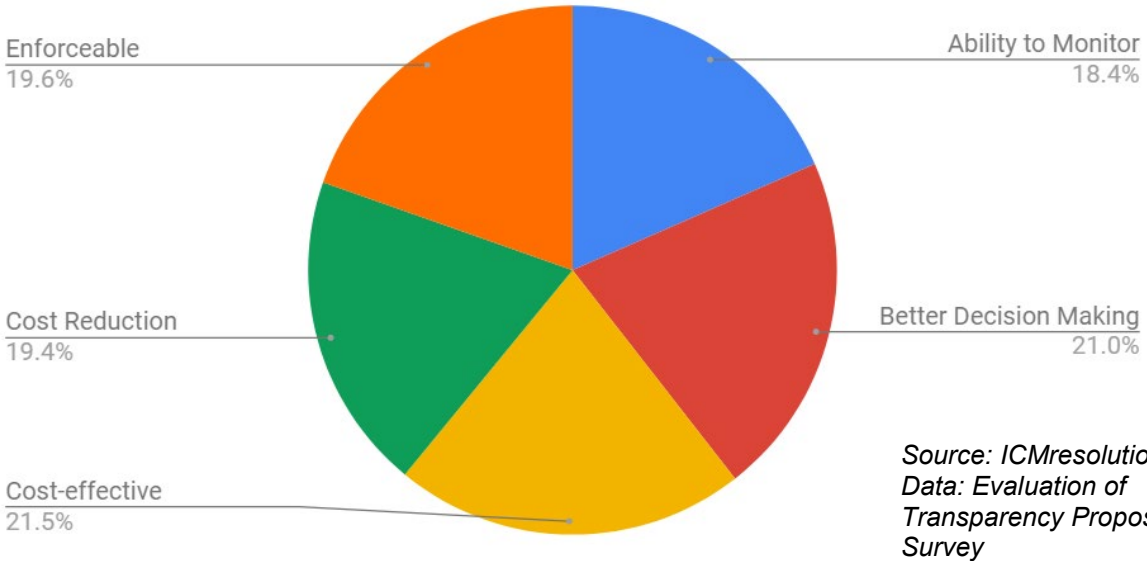
- Revisions to thirty of the thirty-two individual proposals, and
- Thirty-three "new" proposals, several of which were similar or nearly identical to each other.

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.[45] These refined proposals were used in the Evaluation of Transparency Proposals Survey for members to apply the evaluation criteria to draft transparency proposals.

Evaluation of Transparency Proposals Survey

The Evaluation of Transparency Proposals Survey was designed and implemented by ICMresolutions staff using the refined cost factor transparency proposals described above.[46] Using the finalized evaluation criteria, members were asked to weight each evaluation criteria based on how important they thought it was in assessing transparency proposals. The aggregate results of weighing the evaluation criteria are displayed in Figure 6.

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



Source: ICMresolutions Data: Evaluation of Transparency Proposals Survey

[44] Joint Interim Task Force on Fair Pricing of Prescription Drugs. *Transparency Proposal Exercise.* September 2018. <https://olis.leg.state.or.us/liz/2017I1/Downloads/CommitteeMeetingDocument/150473>

[45] Joint Interim Task Force on Fair Pricing of Prescription Drugs. *Proposal Exercise Responses Comparison Table.* September 2018. <https://olis.leg.state.or.us/liz/2017I1/Downloads/CommitteeMeetingDocument/150403>

[46] Joint Interim Task Force on Fair Pricing of Prescription Drugs. *Evaluation Factors Survey.* <https://olis.leg.state.or.us/liz/2017I1/Downloads/CommitteeMeetingDocument/150931>

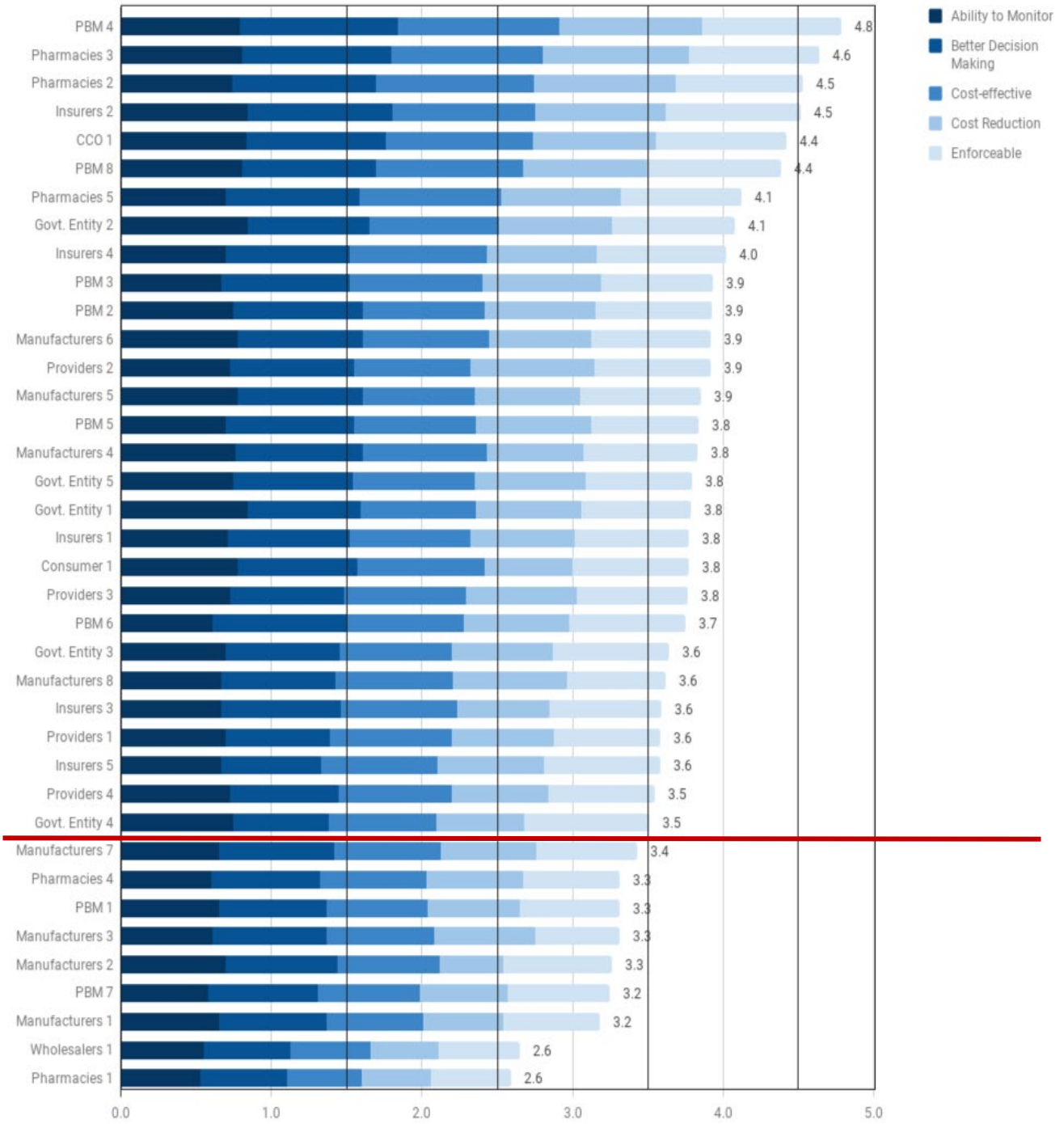
The highest weighted evaluation criteria for assessing transparency proposals was cost-effective followed by better decision-making, enforceable, cost reduction, and ability to monitor. These results demonstrate that Task Force members weighed the evaluation criteria relatively equal to the other evaluation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

Task Force members were then asked to apply the evaluation criteria to assess the refined 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 the 38 transparency proposals evaluated.[47] Figure 7 below displays all the transparency proposals evaluated by total score with the red line indicating the 3.5 score cutoff.[48]

[47] Joint Interim Task Force on Fair Pricing of Prescription Drugs, *TFPRX – September Survey Results,* <https://olis.leg.state.or.us/liz/2017I1/Downloads/CommitteeMeetingDocument/150807>

[48] Please see Appendix B 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

Additional Transparency Proposal Refinement

Using the results of the Evaluation of Transparency Proposals Survey, Task Force members 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 rationale about the proposed changes submitted to LPRO staff. Feedback and rationale were integrated for into a revised set of transparency proposals.[49]

Task Force members were asked following the discussion of each transparency proposal whether the revisions to the transparency proposal would increase, decrease, or maintain their initial scoring of each proposal from the Evaluation of Transparency Proposals Survey. 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, Task Force members were asked to provide their preliminary votes on the transparency proposals by indicating one of the following:

- "One" indicates full support for the proposal as stated.
- "Two" indicates you agree with the proposal as stated, but prefer to have it modified in some manner in order to give the proposal full support.
- "Three" indicates your refusal to support the proposal as stated, but suggested revisions will move your support from a 3 to either a 2 or 1.

All transparency proposals but one received a majority (eight or more members) preliminary vote of agreement (votes of 1 or 2) from Task Force members. A number of proposals received at least one preliminary vote of disagreement (vote of 3). Only one proposal received a majority preliminary vote of disagreement. The results from the preliminary vote exercise were used to inform the final considerations of the transparency proposals.

[49] Joint Interim Task Force on Fair Pricing of Prescription Drugs. *Preliminary Vote and Member Feedback*.

TASK FORCE RECOMMENDATIONS

The Task Force engaged in a thoughtful series of iterative exercises to provide feedback on and revise a set of transparency proposals to create transparency for drug prices 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 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.

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 will benefit from further analysis to assess the impact of transparency on the pharmaceutical supply chain including the individual market participants impacted by each transparency strategy.

During the process, members who disagreed with a majority recommendation were provided the opportunity to provide their comments or alternative suggestions. This information is summarized below the corresponding majority transparency strategy recommendation.[50] Table 2 below displays the cost factors identified by Task Force members and corresponding transparency recommendations that address each cost factor.

[50] Please see Appendix C for full feedback from Task Force members voting in the minority for a specific transparency proposal.

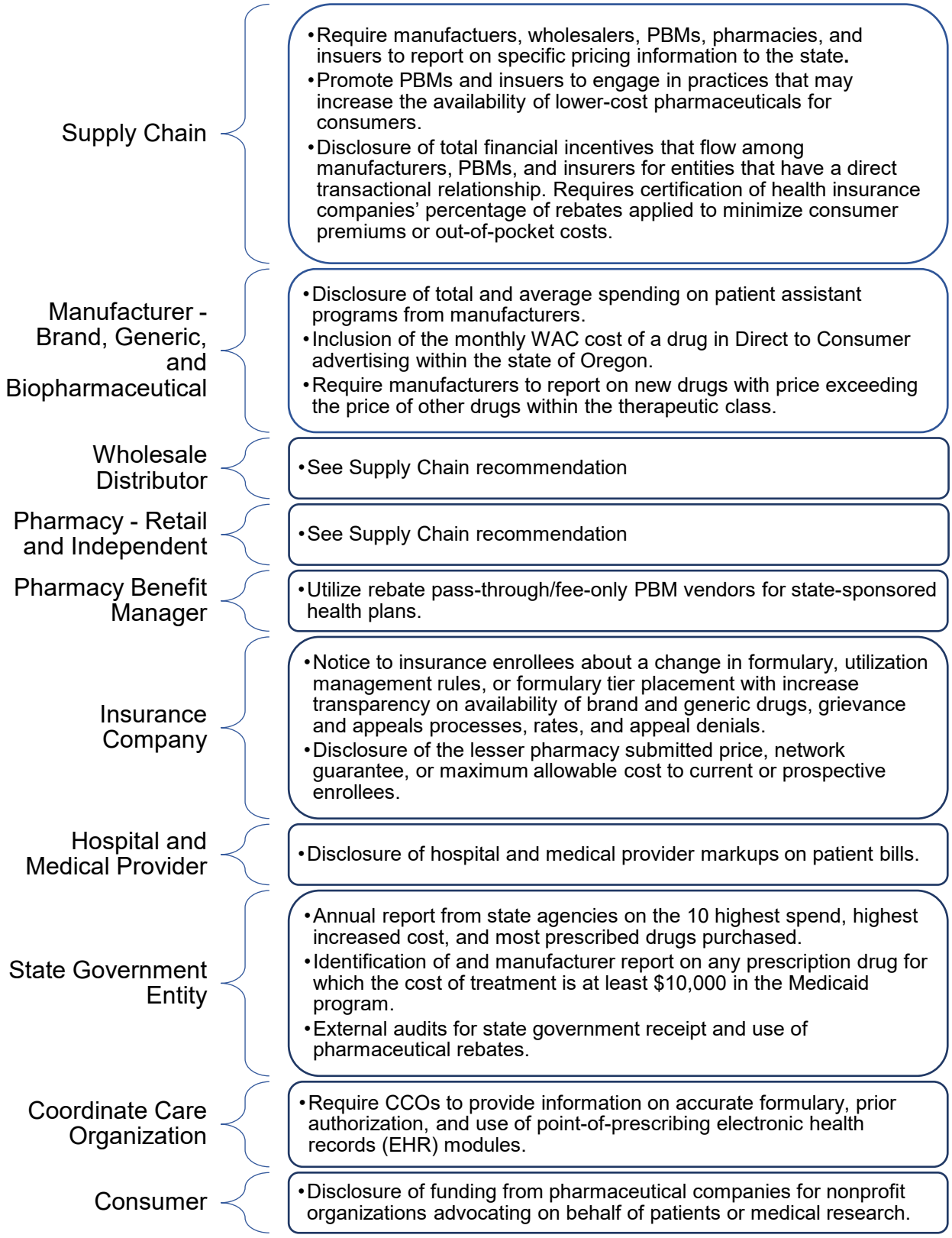
Table 2. Cost Factors Addressed in Transparency Recommendations

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

Source: Legislative Policy and Research Office

Recommendations in this report are sorted by the pharmaceutical supply chain entity primarily affected by the described transparency strategy. Figure 8 displays an overview of the recommendations the majority of Task Force members agreed to present to the legislature for consideration.

Figure 8. Task Force Transparency Strategies and Recommendations



Source: Legislative Policy and Research Office

PENDING SUPPLY CHAIN RECOMMENDATIONS

Several of the transparency proposals separated out by different pharmaceutical entities provided similar recommendations. These recommendations were consolidated into a singular proposal when possible to eliminate duplication of transparency strategy recommendations. One recommendation involves requiring several pharmaceutical supply chain entities to disclose specific pricing information. Another combined recommendation aims promote 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 following cost factors: discounts, fees, insurance benefit design, list price, pharmacist gag clause, and rebates.

Supply Chain Recommendation #1 - Require identified supply chain entities to report on specific pricing information to the state.

The pharmaceutical supply chain involves different entities who interact, compete, and supply consumers with pharmaceutical products. Information regarding pricing and payment or pharmaceutical products is complex and often not well understood by other supply chain entities or consumers. The Task Force discussed developing an overall supply chain transparency recommendation to improve transparency of specific pricing information on identified cost factors to the State of Oregon.

Market participants identified below will be required to submit any reports and information listed to the Department of Consumer and Business Services (DCBS) annually with conditional exemptions from public disclosure under ORS 192.345 as a trade secret. Reporting will be limited to any prescription drug that is $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.

For this recommendation, Task Force members voted on each pharmaceutical supply chain entity component separate from the other components. This recommendation found the following results when the Task Force members voted on each component separate from the overall transparency recommendation:

The table below summarizes the information the identified supply chain entities would be required to disclose to DCBS by 9-digit NDC:

Table 3. Information Required to be Reported by Supply Chain Entity

	Manufacturers	Wholesalers	Pharmacies	PBMs	Insurers
Required Information to be Reported	Average chargeback paid to wholesaler	Average price paid to manufacturer	Average price paid to wholesaler	Average rebate from manufacturer	Impact of rebates on premium expressed as a percent
	Average fee paid to wholesaler	Average fees received by manufacturer	Average fees paid to wholesaler	Average fees received from manufacturer	Average price paid per prescription minus prescription dispensing fee
	Aggregate rebate paid to PBM	Average chargeback received from manufacturer	Average rebate from manufacturer	Average product reimbursement made to pharmacies	Average product reimbursement
	Average administrative fee paid to PBM	Average pharmacy payment	Average product reimbursement from PBM or insurer	Average product reimbursement from insurer	
		Average administrative fees or other fees paid by top 3 chain pharmacy customers by sales			

Source: Legislative Policy and Research Office

Minority Feedback for Supply Chain #1

Summary of any minority feedback.

Supply Chain Recommendation #2 (Pharmacist Gag Clause) - Promote supply chain entities to engage in practices that may increase the availability of lower-cost pharmaceuticals for consumers.

Pharmacies and pharmacy benefit managers contract with one another to determine terms such as reimbursement for pharmaceutical products. Some contracts include clauses that prohibit pharmacists from telling customers that they could save money by paying cash for prescription drugs rather than using their health insurance. The Task Force recommends 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 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.
- 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 drugs, unless "dispense as written" is on the prescription, (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 price and report to a pharmacy the lower of that price or the contracted co-pay; 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 copayment amount; or
    (2) the pharmacy's retail usual and customary 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, and utilize a pharmacy benefit design that requires customer cost sharing that exceeds the amount the pharmacist will be reimbursed.

Minority Feedback for Supply Chain #2

Summary of any minority feedback.

Supply Chain Recommendation #3 (Rebates) - 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.

Pharmacy benefit managers negotiate on behalf of insurance companies with pharmaceutical manufacturers for formulary placement. This involves negotiations between the manufacturers and pharmacy benefit managers for pricing and placement within the formulary. All commercial health insurers licensed in the State get approval for their premium rates every year. Part of the premium rate justification can include information about how the cost of drugs and manufacturer price concession affect the premium request. Information about drug rebates is considered proprietary and not released to the public. The Task Force recommends the following for manufacturers, pharmacy benefit managers, and insurance companies regarding rebates:

> **Manufacturers** are required to disclose the total 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 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 clients 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.
>
> **Health insurers** are required to certify through their annual filing documents the percent of rebates (at least 50%) that were applied to directly offset the consumers' premiums, out-of- pocket costs, and/or directly benefit the consumer. Health insurers to report where any percent of rebates was 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.

Minority Feedback for Supply Chain #3

Summary of any minority feedback.

PENDING MANUFACTURER RECOMMENDATIONS

The Task Force examined several proposals that address other areas of transparency on topics such as patient assistant programs, financial incentives, direct-to-consumer advertising, and pricing information. Four proposals are outlined below as recommendations to the Legislature to improve transparency of pharmaceutical drugs regarding manufacturers. These recommendations address cost factor transparency for discounts, fees, list price, and rebates.

Manufacturer Recommendation #1 - Disclosure of total and average spending on patient assistant programs from manufacturers.

Patient assistant programs are typically programs in which pharmaceutical manufacturers may provide financial assistance or free drug 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. The Task Force recommends requiring manufacturers to report for 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 NDC); and,
- Financial assistance (if any) provided to pharmacies, government agencies, and patient groups (other than rebates or discounts) for the purchase of pharmaceuticals reported separately.

Minority Feedback for Manufacturer #1

Summary of any minority feedback.

Manufacturer Recommendation #2 - Inclusion of the monthly WAC cost of a drug in Direct-to-Consumer advertising within the state of Oregon.[51]

Direct-to-Consumer advertisements are marketing tools used by pharmaceutical manufacturers to inform consumers of the availability of their drug products. These advertisements appear on the television, radio, internet, and in printed materials such as newspapers. The Task Force recommends requiring pharmaceutical manufacturer Direct to Consumer (DTC) 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.

[51] The Centers for Medicare and Medicaid Services announced on October 16, 2018 the proposed regulation to require television direct-to-consumer drug advertising include the WAC under certain conditions.

Minority Feedback for Manufacturer #2

Summary of any minority feedback.

Manufacturer Recommendation #3 - Require manufacturers to report on new drugs with price exceeding the price of other drugs within the therapeutic class.

Every new drug or biologic needs approval from the U.S. Federal Drug Administration (FDA) before being sold to consumers. The New Drug Application (NDA) or the Biologics License Application (BLA) include information on the clinical trials, effect on humans, and logistics such as manufacturing, processing, and packaging. The Task Force recommends requiring manufacturers to provide to DCBS justification for a price that exceeds the price of other drugs in the class for new drugs and biologics licensed under a NDA or BLA, that are not first-in-class or a biosimilar.

For each report, a manufacturer is required to report the rationale for the price, including the specific considerations that explain 95% of the 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).

Minority Feedback for Manufacturer #3

Summary of any minority feedback.

PENDING WHOLESALER RECOMMENDATION

Wholesale distributors are typically the first purchaser of a pharmaceutical drug product from manufacturers and resell to other distributors and health care providers.

There was only one recommendation that the Task Force considered regarding pharmaceutical price transparency relating to wholesalers. This recommendation was combined into the overall supply chain recommendation #1 as described above. Cost factors identified within the proposal are fees and list price.

PENDING PHARMACY RECOMMENDATIONS

Several transparency proposals were examined by the Task Force that directly or indirectly affect pharmacies. Two recommendations emerged involving pharmacies. These recommendations were combined with other similar recommendations to prohibit any pharmacist limitations to informing consumers about the cash price of pharmaceutical products and allow pharmacists to share information regarding the availability of generics or biosimilars to a consumer.[52] These recommendations address cost factor transparency for discounts, fees, list price, and the pharmacist gag clause.

[52] Please see Supply Chain Recommendation #2 for more information.

PENDING PHARMACY BENEFIT MANAGER RECOMMENDATION

The Task Force has one recommendation involving pharmacy benefit managers. Additionally, there are three of the supply chain recommendations for improving transparency through disclosure of specific information from the PBM to DCBS and allowing pharmacists to provider information on lower-priced therapeutically equivalent drugs. The PBM recommendations collectively address the cost factors of discounts, fees, insurance benefit design, pharmacist gag clause, and rebates.

Pharmacy Benefit Manager Recommendation #1 - Utilization of rebate pass-through/fee-only PBM vendors for state-sponsored health plans.

The Oregon Public Employees Benefit Board (PEBB) and the Oregon Educator's Benefit Board (OEBB) currently contract with PBMs to manage their pharmacy benefits. States such as Ohio and Montana require their state-sponsored health plans to contract with PBMs on a fee-only basis – meaning PBMs pass all manufacturer rebates to the state health plans and payments saved by PBMs are solely based on fees paid. The Task Force recommends requiring state-sponsored health plans (e.g., PEBB/OEBB, CCOs) to evaluate rebate pass-through/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.

Minority Feedback for Pharmacy Benefit Manager #1

Summary of any minority feedback.

PENDING INSURER RECOMMENDATIONS

Several of the transparency strategies proposed for health insurance companies had overlapping policy elements with each other. These transparency strategies have been combined to eliminate redundancies. 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.

Several insurance companies have publicly available information regarding the health plan's insurance benefit design. To improve transparency regarding pharmacy benefits within a health plan, the Task Force recommends that insurers are required to have easily accessible website information on pharmacy benefit – 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 formulary tier,
- Member's cost share amount pursuant to their health plan benefits that includes information on when enrollees will be charged the lesser of Pharmacy U&C or "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.

Minority Feedback for Insurer Recommendation #1

Summary of any minority feedback.

Insurer Recommendation #2 - **Disclosure of the lesser pharmacy submitted price, network guarantee, or maximum allowable cost to current or prospective enrollees.**

Health insurance companies in Oregon are currently not required to disclose the exact amount of money a consumer may pay at a pharmacy due to co-insurance or other negotiated cost sharing mechanisms. 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 price, or coinsurance amount to pay.

Minority Feedback for Insurer Recommendation #2

Summary of any minority feedback.

PENDING HOSPITAL AND MEDICAL PROVIDER RECOMMENDATION

There was only one pharmaceutical transparency strategy for hospital and medical providers that emerged regarding 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 #1 - Disclosure of hospital and medical provider markups on patient bills.

Hospitals and medical providers may mark up the price of pharmaceutical products and not disclose the markup on the bill received by the patient. The Task Force recommends requiring hospitals and medical providers to disclose markups by providing an itemized bill to patients that separates the drug acquisition cost and the fees for medication preparation, dispensing, and administration.

Minority Feedback for Provider Recommendation #1

Summary of any minority feedback.

PENDING 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 oversight of pharmaceutical transparency measures. Oregon's Medicaid program is administered by the OHA which includes pharmacy benefits. The Pharmacy and Therapeutics (P&T) Committee for OHA provides analysis of the utilization, quality, medical appropriateness, and cost of prescribed medication through evaluation of claims data; develops policy recommendations and maintains the Oregon Preferred Drug List. The Task Force recommends two strategies to improve transparency on list price and rebates within state government entities purchasing pharmaceutical products.

Government Entity Recommendation #1 - Annual report from state agencies on the 10 highest spend, 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 Oregon Health Authority and other state agencies such as Oregon Youth Authority and Correctional Department are payers or purchasers of pharmaceutical products for individuals enrolled in the Medicaid program or within their care in the correctional system. The Task Force recommends requiring the following:

- State agencies paying for pharmaceuticals to report annually on the top ten most prescribed, top ten highest cost, and top ten highest increased cost of state program prescription drugs.
- Oregon Health Authority though the Pharmacy and Therapeutics Committee to 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.

Minority Feedback for Government Entity Recommendation #1

Summary of any minority feedback.

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

Pharmaceutical rebates are provided by manufacturers to entities that control the formulary and reimburse for products dispensed. The level of rebate is typically contingent on the ability of the payer to move market share. 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.

Minority Feedback for Government Entity Recommendation #2

Summary of any minority feedback.

PENDING COORDINATED CARE ORGANIZATION RECOMMENDATION

Coordinated Care Organizations (CCOs) are health insurance entities contracted by the Oregon Health Authority to deliver health care benefits to Oregon's Medicaid population. The strategy outlined below requires CCOs to improve transparency for insurance benefit design.

Coordinated Care Organization Recommendation #1 - Require CCOs to provide information on accurate formulary, prior authorization, and use of point-of-prescribing electronic medical records (EMR) modules.

Insurance benefit design and utilization management tools are used by health insurance carriers use to control costs. The Task Force recommends requiring CCOs to declare on 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.

Minority Feedback for CCO Recommendation #1

Summary of any minority feedback.

PENDING CONSUMER RECOMMENDATION

Consumers pay for pharmaceutical products when prescribed by a health care provider and do not play a direct role within the pricing of pharmaceutical products within the supply chain. Groups that advocate for support of specific diseases and patients with those diseases can be supported by the pharmaceutical industry and that support can be substantial. The Task Force recommends one transparency strategy for consumers advocacy groups addressing incentives received by other pharmaceutical supply chain entities.

Consumer Recommendation #1 - Disclosure of funding from pharmaceutical companies for nonprofit organizations advocating on behalf of patients or medical research.

Patient advocacy organizations represent a number of health care interests and are thought to provide a critical patient perspective on health care policy topics. The Task Force recommends requiring nonprofit organizations with an annual budget of more than $50,000 and that advocate on behalf of patients or medical research 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% 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.

Minority Feedback for Consumer Recommendation #1

Summary of any minority feedback.

ADDITIONAL CONSIDERATIONS AND NEXT STEPS

Through the course of Task Force deliberations on transparency, many other topics related to pharmaceutical policy were discussed when examining other states' pharmaceutical legislation in August.[53] The National Conference of State Legislatures (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.[54] 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 related. 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 and copay accumulator programs

Next Steps

The recommendations in this report represent the Task Force's work to address transparency throughout the pharmaceutical supply chain and recommendations 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.

[53] Joint Interim Task Force on Fair Pricing of Prescription Drugs. *Other States' Prescription Drug Legislative Proposals (2015-2018) – Discussion Document.* <https://olis.leg.state.or.us/liz/2017I1/Downloads/CommitteeMeetingDocument/150038>

[54] National Conference of State Legislatures. *Statewide Prescription Drug Database | 2015 – Present*.

APPENDIX

I. Appendix A – Glossary of Pharmaceutical Terms

II. Appendix B – Transparency Proposals Scoring Less than 3.5

III. Appendix C – Minority 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:

Biologic	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."
Biosimilar	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
Brand product	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."
Drug Product	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, e.g., same active ingredient, route of administration) and that compete the with branded product after patent or exclusivity expiry. 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	These are known as ‘biologics’ – and contain live active ingredients. They are infused or injected and are not typically self-administered.
Limited Distribution Drug	Limited distribution drugs (LDD) are medications that have been restricted by the manufacturer to selected 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.
Small Molecule products	Non-large molecule drugs, such as chemically synthesized compounds. such as are capsules, tablets, powders, ointments, sprays.
Specialty Drug	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

Specialty Pharmacy	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), 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 make such a determination. There is lack of consistency as to how a drug is determined to be a specialty drug and who determines that. (Erin Moller)
Wholesaler	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. Healthcare providers place orders with distributors for the medicine and products they need, and the distributors process and deliver the orders daily.

Administrative Organizations in the Supply Chain & Administrative Services

Data-sharing Agreements	The contractual agreement between two entities to share information collected on specified topics or groups of people with each other.
Group Purchasing Organization (GPO)	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.
Pharmacy Benefit Manager (PBM)	PBMs handle some or all the pharmacy benefit for health plans (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.
Pharmacy Services Administration Organization (PSAO)	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

Actual Acquisition Cost (AAC)	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.
Average Wholesale Price (AWP)	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.
List Price	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.
National Average Drug Acquisition Cost (NADAC)	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.
Wholesale Acquisition Cost (WAC)	The price the wholesaler or other direct purchasers pay the manufacturer, without factoring in any rebates or discounts, discounts,

	or other price reductions. Generally considered the ‘list’ price, this price is asset by a manufacturer and are 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.
Coupons	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.

Discounts	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.
Incentive Programs/Kickbacks	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.
Markups	An increase in the amount paid by purchasers of pharmaceutical products as determined by the entity selling the pharmaceutical product.
Rebates	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).
Shadow Pricing	Pricing that is determined by certain assumptions that are not easily quantifiable.

Medicaid Rebate Terminology

Average Manufacturer Price (AMP)	Used in Medicaid, AMP is calculated by the manufacturer and provided to CMS, 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.
Best Price (BP)	BP 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% off of the AMP for brand medicines or 13.1% off of AMP for generic medicines, all state Medicaid programs will get the BP rebate. BP is confidential and not publicly available.
CPI Penalty	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 (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

340B Program	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.
Administrative Fee	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.

Average Sales Price (ASP)	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.
Clawback	Practice of charging co-payments 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.
Dispensing Fee/Professional Fee	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.
Fees (general)	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.
Insurance Benefit Design	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 co-pays, deductibles, premiums and co-insurance. 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).

Maximum Allowable Cost (MAC) and Federal Upper Limits (FUL)	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 multi-source drugs to which a MAC is applied is also at the discretion of the payer.
Pass-through Pricing Model	This alternative contracting approach requires that the PBM pass through the price they pay for medications and earn a negotiated administrative fee.
Pharmacist Gag Clause	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.
Price Protection	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.
Reference Price	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 choses 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.

Some percentage of Average Wholesale Price (AWP)	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%.
Spread Pricing Model	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.

Task Force Evaluation Criteria

Ability to Monitor	Enables a regulatory body the oversight of specified entities or cost factors within the pharmaceutical supply chain.
Better Decision Making	Improves the ability for purchasers or regulators of pharmaceutical products to make informed decisions based on accurate information regarding selection and payment for pharmaceutical products.
Cost-effective	A strategy or policy within a positive impact relative to the needed expenditure.
Cost Reduction	Exposes factors that may inform strategies to reduce cost to purchasers of pharmaceutical products.
Enforceable	The ability for a regulatory body or an entity in the pharmaceutical supply chain to enforce a strategy or policy

Appendix B – Transparency Proposals Scoring Less than 3.5

Task Force members provided feedback on preliminary transparency proposals throughout the Task Force meetings. Following the evaluation survey, Task Force members determined to limit deliberations to proposals scoring about 3.5. The following tables outline the proposals that scored less than 3.5 in the evaluation survey.

Proposal	Language	Score
Manufacturers 7	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	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	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	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 U.S. FDA-approved drugs marketed in the state by that manufacturer.	3.3
PBM 7	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 C – Minority Viewpoints from Task Force Members on Transparency Recommendations

Task Force members provided their final vote on the transparency recommendations during the October meeting. Members who voted against specific transparency recommendations were given the opportunity to provide their feedback and rationale to the Task Force. This appendix outlines the minority feedback received by transparency recommendation.

Minority viewpoints will be included following the October meeting.