Abigail Stoddard – Prime Therapeutics

- How does your industry/stakeholder group interact with the development or movement of pharmaceutical products in Oregon?

> **735.530 Definitions for ORS 735.530 to 735.552.**
> (5)(a) "**Pharmacy benefit manager**" means a person that contracts with pharmacies on behalf of an insurer, a third party administrator or the Oregon Prescription Drug Program established in ORS 414.312 to:
> (A) Process claims for prescription drugs or medical supplies or provide retail network management for pharmacies or pharmacists;
> (B) Pay pharmacies or pharmacists for prescription drugs or medical supplies; or
> (C) Negotiate rebates with manufacturers for drugs paid for or procured as described in this paragraph.
> (b) "Pharmacy benefit manager" does not include a health care service contractor as defined in ORS 750.005.

Answer:

Pharmacy Benefit Managers (PBMs) are defined under current state law as well as their functions at 735.530 to 735.552. A PBM is a health care company that contracts with insurers, employers, and government programs to administer the prescription drug portion of the health care benefit. PBMs work with insurers and employers to ensure high-quality, cost efficient access to prescription drugs for their beneficiaries. We offer a variety of services, including but not limited to claims processing, formulary management, pharmacy networks, drug utilization review and disease management and adherence initiatives to keep the prescription drug benefit affordable. On average, PBMs save plan sponsors and consumers 35% compared to plan sponsors who do not use pharmacy benefit managers.

PBMs have no role in the development or movement of pharmaceuticals in Oregon. We do, however, play a role in how patients access their prescription drug benefit under their health plan. PBMs create pharmacy networks at the direction of our clients and in compliance with state and federal laws and regulations. The goal is to ensure patients have broad access to medications, particularly through local retail pharmacies. Some PBMs own mail service pharmacies and/or specialty pharmacies to help serve patients. These pharmacies are licensed and regulated by the Oregon Board of Pharmacy like any other pharmacy.

- How does your industry/stakeholder group interact with the pricing of pharmaceutical products in Oregon? What pricing mechanisms are utilized?

  Answer:

  PBMs, like health plans, do not have any control over the price the manufacturer sets for a particular drug. We do, however, have some tools to help drive down the cost of the pharmacy benefit. PBMs offer a set of core services to clients designed to contain drug expenditures such as claims administration, pharmacy network management, negotiation and administration of product discounts (which may include manufacturer rebates), as well as mail-service pharmacy and specialty pharmacy services.

- What successes, difficulties or obstacles involving pricing transparency within the pharmaceutical supply chain impact your industry/stakeholder group?

  Answer:

  Innovations in technology, streamlined data sharing, and greater communication and connectivity between patients and all their health care providers – physicians, pharmacy and insurers – can help create a truly seamless system that offers greater transparency and access. The system continues to evolve and the greater use of electronic health records will help prescribers to have expanded visibility into lower cost alternatives at the point of prescribing. By providing access to formulary and cost-sharing information in the prescriber's office, health care providers can identify covered prescription drugs, provide patients with accurate cost-sharing information, and initiate prior authorization all before the patient reaches the pharmacy counter. Greater use of tools such as this by all the players in the health care system will help lower drug costs for patients and improve adherence and outcomes.

  E-prescribing, for example, is an effective tool to help physicians manage patient care by helping avoid adverse drug interactions, improve patient adherence and reduce fraud and abuse.

  Payers and PBMs have no insight as to when, why, and how drug pricing might change for brand name and generic medicines currently on the market.

Oregon
Kate Brown, Governor

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OREGON LEGISLATIVE ASSEMBLY
JOINT TASK FORCE ON FAIR PRICING OF PRESCRIPTION DRUGS

DCBS' ROLE IN THE PHARMACEUTICAL SUPPLY CHAIN
May 18, 2018

Thank you for the opportunity to comment in advance of the first meeting of the Joint Task Force on Fair Pricing of Prescription Drugs. We write this letter on behalf of the State of Oregon Department of Consumer and Business Services ("DCBS" or "we"). DCBS is Oregon's largest consumer protection and business regulatory agency and also serves as the state's insurance regulator. DCBS, through the Division of Financial Regulation, works to protect Oregonians' access to fair products and services through education, regulation, and consumer assistance.

As a result of great work by many stakeholders over the last several years, Oregon's uninsured rate has fallen dramatically so that today 94% of all Oregonians and 100% of Oregon's children have access to health care coverage. Health care costs, however, continue to rise and cause hardship for many and it is not always apparent what is driving these cost increases. HB 4005 takes a first important step towards increased transparency through its reporting requirements and the creation of this Task Force. DCBS looks forward to fulfilling its reporting role as set out in HB 4005 and to contributing to the important work of this Task Force.

1. **How does your industry/stakeholder group interact with the development or movement of pharmaceutical products in Oregon?**

In our role as the state's largest consumer protection agency, DCBS does not directly interact with the development or movement of pharmaceutical products in Oregon. However, the department does currently have two indirect interactions with the those involved in the supply chain and in the gathering of data:

a. *PBM registration*. Pursuant to a state law enacted in 2013, pharmacy benefit managers (PBMs) are required to register with the Department before they may conduct business in Oregon. Registration must be renewed annually. Following adoption of an amendment to this registration law in 2017, DCBS is now required to have in place a process for pharmacists to file a complaint alleging that a PBM has engaged in conduct that could subject a PBM to the loss of its registration. Such conduct includes engaging in dishonesty or fraud or gross negligence in the conduct of business as a PBM.

b. *Manufacturer Reporting*. In addition to creating this Task Force, HB 4005 established a reporting process for prescription drug manufacturers in certain circumstances. Briefly, HB 4005 requires prescription drug manufacturers to submit detailed information about prices and factors that went into determining those prices. Manufacturers must submit

these reports when the prescription drug is (1) $100 for a month supply and the increase in the drug's price is 10% or more in a calendar year. Additional requirements apply when, in the case of new prescription drugs, the price is $670 for a 30 day supply.[1] Insurance carriers filing in the individual and small group will submit more information about drug costs through the rate review process, and Oregonians will also be able to register inquiries about drug prices to the department.

The department will collect all this information, analyze for general trends, and report findings to the public and the Legislative Assembly.

2. How does your industry/stakeholder group interact with the pricing of pharmaceutical products in Oregon? What pricing mechanisms are utilized?

DCBS indirectly interacts with the pricing of pharmaceutical products in Oregon, primarily through:

a. *Review of health benefit rates*. The department utilizes a robust process for the annual review and approval of the rates charged for health benefit plans sold in the individual and small employer markets. As part of the review process, the department does consider the costs paid for medical expenses, including prescription drugs. As part of the "binders" filed by each insurer, the following prescription drug information is submitted:

- The prescription drug formularies offered by an insurer. Insurers may have more than one formulary.
- The tiers of prescription drugs associated with each formulary. For example, generic, preferred, preventive, or non-preferred.
- The cost share for each tier, including the cost of purchasing a 30-day supply, a 90-day supply, purchasing through a mail order pharmacy, or purchasing the prescription drug at an out-of-network pharmacy. Insurers may use either a coinsurance (percent) or a copayment (flat dollar amount).
- The unique prescription drug identification number for each prescription drug covered by the insurer. Insurers submit a concept unique identifier (RXCUI) for each prescription drug.
- The utilization management procedures for each prescription drug, for example step-therapy or prior authorization.

[1] Medicare Part D regulations establish the threshold tier for new specialty drugs; the dollar figure as of 2017 is $670 for a 30-day supply. *See* https://www.cms.gov/Medicare/Health-Plans/MedicareAdvtgSpecRateStats/Downloads/Announcement2017.pdf

Notably, insurers are not required to submit the following additional information:

- The name of the prescription drug.
- The category and class of the prescription drug belongs in. We use a separate tool provided by CMS to determine the category and class of each prescription drug and ensure compliance with prescription drug coverage requirements.
- Which prescription drugs are not covered by the insurer.
- Why an insurer elects to cover one prescription drug over another.

After an initial review of the 2019 rate filings, insurers are indicating that, consistent with prior years, drug costs are rising faster than other costs.

b. *Initial review of drug formularies*. A formulary is a list of medicines, generic and brand name, grouped into cost-sharing tiers. As part of the binder filings we receive for individual/small group market filings, we receive and review the formularies in advance. This review is meant to make sure that the formularies are not designed in a discriminatory manner. However, after approval insurance carriers may alter the formularies. These so-called mid-year tiering changes, which are not required to be submitted to DCBS and are therefore not reviewed, may occur if:

- The plan no longer covers a drug.
- A new drug is added.
- A drug is moved to a different cost-sharing tier.
- A drug is removed from the market.

c. *Setting standards for network adequacy*. Under Oregon law, anyone offering a health benefit plan must also ensure that their networks of providers are sufficient to deliver the coverage the person offers without unreasonable delay. This includes ensuring adequate networks of pharmacies, whether chain or independent, are included in the network. This does not mean, however, that anyone is required to be allowed to join a carrier's provider panel.

d. *Registering pharmacy benefit managers*. Please see discussion in 1(a) above.

e. *Drug manufacturer reporting*. Please see discussion in 1(b) above.

3. What successes, difficulties or obstacles involving pricing transparency within the pharmaceutical supply chain impact your industry/stakeholder group?

a. *Interlocking contracts*. In delving into the interactions between PBMs, pharmacies and insurance carriers, the role of contracts has presented an obstacle to DCBS' full understanding of price setting practices. In fact, the 2016 budget note report to the Assembly from HB 5701 stated that the department "encountered challenges verifying information between parties due to…complexity and limited transparency

in the MAC reimbursement process."[2] One can commonly find non-disclosure clauses in these contracts, which limit our ability to learn how pricing and rebates actually work.

b. *Mid-year price changes*. Price increases are caused by several things and a consumer might not know the exact cause:

- The drug is removed from the tier that it appeared on in the previous plan year (e.g. preferred to non-preferred).
- The drug is moved from one tier to another mid year (from preferred to non-preferred).
- The member has a co-insurance not a copayment. Co-insurance is charged as a percent of the cost of an item (e.g. 10% of the allowed price of a drug) rather than a fixed amount (e.g. $20 for a one month supply of generic drugs). Under a co-insurance scheme, which is common in non-ACA standard plans, if the price of a drug changes from one month to the next the member portion would also change.

Regardless of the cause, the effect of these changes to the end user (the consumer) is increased costs. The department has no direct ability to regulate mid-year tiering changes, though there are certainly legitimate reasons to change formularies throughout a plan year.

c. *Large group/self-insured regulatory gaps*. Under ERISA, self-insured plans are generally not subject to state laws related to insurance. For example, large group filings do not need to comply with essential health benefit regulations to the same extent as individual/small group filings. As essential health benefit review is the main way in which we review formularies, this means that DCBS does not review formularies for large group coverage. Similarly, many facets of health benefit plans in the large-group market (defined as 50 or more employees) remain outside the rate review process.

d. *Medicaid and Medicare*. These plans, including Medicare Advantage plans, are not regulated by the department.

e. *Too many unknowns*. Borrowing the adage "we don't know what we don't know," our own experiences gathering information about the pharmaceutical supply chain leave as many questions as answers. For example, in 2017 the department called for information from those offering health benefit plans in Oregon concerning prescription drug spending. The particular "data call" sought information from seven insurers about the top 50 drugs by:

[2] *See* DCBS, *2016 Report of the Department of Consumer and Business Services Regarding Pharmacy Benefit Manager Compliance and Recommendations for Statutory and Rule Changes* 6 (2016).

- Aggregate claim costs;
- Utilization based on claim count;
- Utilization by days supply count;
- Higher cost by days supply; and
- Highest annual cost growth.

We received data from 2015 calendar year totals. One data point to emerge compared the difference between the top 15 drugs by allowed amount and the top 15 drugs by claims count. The top 15 drugs by allowed amounts represents the amounts paid by the insurer for the drug, while the claims count simply counts the number of times the reporting carrier paid a claim the prescription drug.

The results concluded that while the top 15 drugs constituted 29% of the amounts reimbursed, they only made up 2% of the claims. See Appendix A for more information.

Because of the way in which gathered the information, carrier-specific findings must remain excluded. We are also limited by the information we can gather. For instance, if a carrier does not cover a prescription within its formularies, we would not have data on pricing.

This data only provides a partial window into the overall pharmaceutical supply chain. We do not currently have data on billed amounts, nor do we know what rebates went into the reimbursement that could have exerted downward pressure on the allowed amount.

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Appendix A. 2017 Data Call Results

Top 15 drugs by Allowed Amount				
Drug Name	**2015 Total Allowed Amount**	**2015 Paid Claim Count**	**% of Annual Totals (Allowed Amount) for Reporting Companies**	**% of Annual Totals (Paid Claim Count) for Reporting Companies**
HUMIRA & HUMIRA PEN	39,277,350	11,854	5.0%	0.1%
HARVONI	36,200,737	1,969	4.6%	0.0%
ENBREL & ENBREL SURECLICK	30,343,191	9,876	3.9%	0.1%
LANTUS & LANTUS SOLOSTAR	20,226,008	40,177	2.6%	0.4%
TECFIDERA	14,618,083	2,623	1.9%	0.0%
COPAXONE	11,794,086	2,291	1.5%	0.0%
HUMALOG & HUMALOG KWIKPEN	11,128,290	24,684	1.4%	0.3%
AVONEX & AVONEX PEN	10,690,583	2,084	1.4%	0.0%
ADVAIR DISKUS	8,877,582	23,604	1.1%	0.3%
METHYLPHENIDATE ER & HCL ER	8,328,421	32,117	1.1%	0.4%
TRUVADA	7,930,970	4,355	1.0%	0.0%
STELARA	7,849,375	677	1.0%	0.0%
SOVALDI	7,618,571	413	1.1%	0.0%
ABILIFY	7,434,008	7,049	0.9%	0.1%
ATRIPLA	7,367,606	2,598	0.9%	0.0%

Data based 2015 calendar year totals.

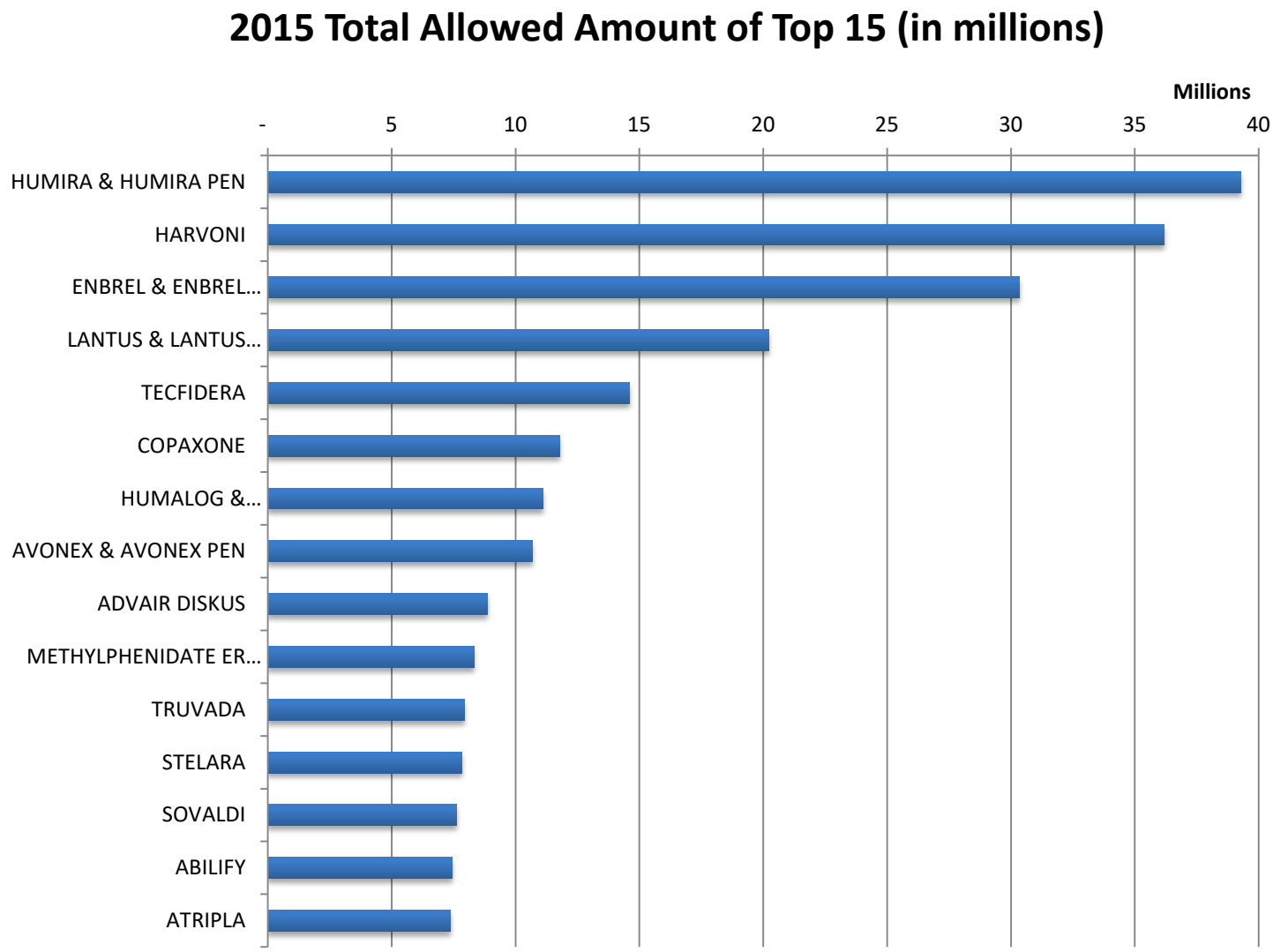
Costs are based on Allowed Amount not billed amount. Allowed Amount is comprised of the amount paid by the insurance company and the individual members cost share.

Each company independently reported their Top 50 drugs, of the top 15 drugs by allowed amount costs 12 were reported by all 7 companies, the remaining 3 were each reported by 6 companies. Drugs were only included on more detailed table when they were reported by at least 6 of the 7 companies.

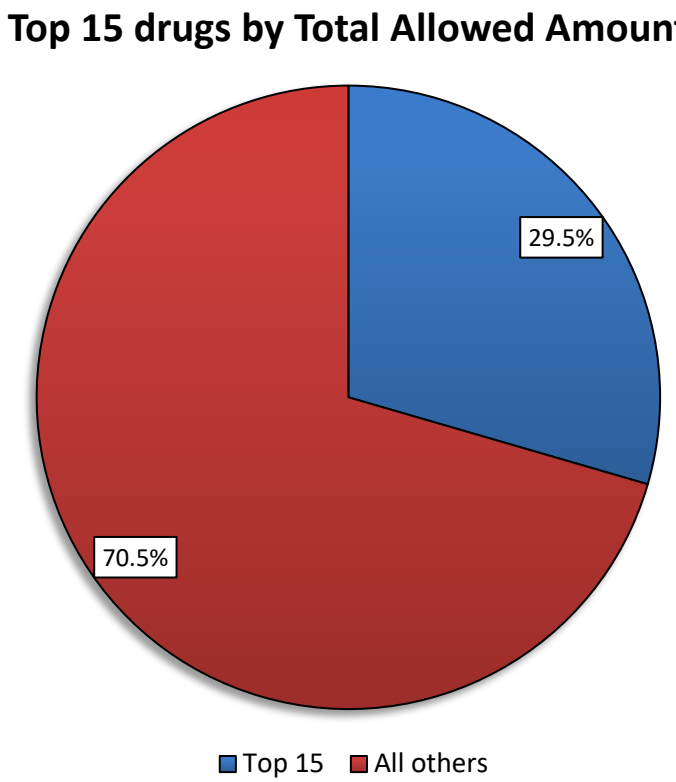
Drugs reported were combined when there were differences in naming conventions and when the same drug had different dispensing methods (example - Humira & Humira Pen).

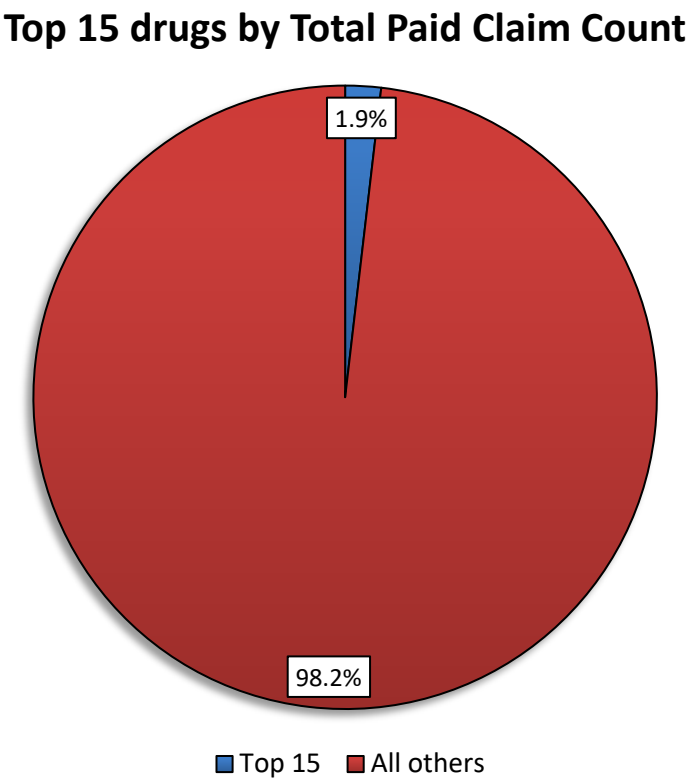
This information is based off the responses of seven insurance companies and their business in the commercial market in Oregon.

Appendix A. 2017 Data Call Results



Appendix A. 2017 Data Call Results





Erin Moller – Yakima Valley Farm Workers Clinic

- How does your industry/stakeholder group interact with the development or movement of pharmaceutical products in Oregon?

  As a Federally Qualified Health Center, which hosts a 340b pharmacy, we are not involved in development of pharmaceutical products. We are however, involved in the dispensing of pharmaceutical products to patients that are currently within our system.

  Our interest is to ensure access to medications for all individuals seeking medical care in our communities. Our only means of accomplishing this is to have access to medications and dispense them at a cost that is affordable for our patients.

- How does your industry/stakeholder group interact with the pricing of pharmaceutical products in Oregon? What pricing mechanisms are utilized?

  Our interaction is when we receive a contract to dispense medications as a network pharmacy. The pricing mechanism is determined by PBM who issues the contract on behalf of the plan.

  We need to ensure that patients that are uninsured are able to continue to receive access to medications. Ensuring that fair and appropriate pricing contracts for medications is vital to Community Health Centers because it allows us to subsidize the cost of medications for our under and uninsured patients.

- What successes, difficulties or obstacles involving pricing transparency within the pharmaceutical supply chain impact your industry/stakeholder group?

  Lack of transparency between contracting agencies and PBM's. This allows the PBM's to increase the cost for both the plan and pharmacy without proof of added value.

Jack Holt - Hi School Pharmacy Services and Northwest Generics

How does your industry/stakeholder group interact with the development or movement of pharmaceutical products in Oregon?

Through our VAWD certified warehouse, Northwest Generics, which is located in Vancouver Washington, we currently supply approximately 700 generic pharmaceutical products to 19 corporately owned and 29 affiliated independent pharmacies in the State of Oregon, the majority of whom are the singular operating pharmacy operating in their rural community. By purchasing directly from the manufacturer we are better able to control the cost of goods, allowing us to sell most items at a lower price than they would be able to find from a traditional wholesaler, while at the same time limiting market disruptions such as product shortages for our group. We piggyback with our traditional wholesaler's (currently McKesson)) courier service to deliver our product on a daily basis (Monday through Friday) to our member stores.

How does your industry/stakeholder group interact with the pricing of pharmaceutical products in Oregon? What pricing mechanisms are utilized?

1. Northwest Generics buys directly from the manufacturer for the items it stocks in its warehouse much like a traditional wholesaler.
    a. Because our overhead costs are much lower to operate (no marketing sales force, highly efficient warehouse operations), and we are able to buy at competitive rates (most traditional wholesalers charge a manufacturer a fee ranging up to 12% of the purchase price just to stock their merchandise in the warehouse) we can consequently sell our inventory at a lower cost than the larger wholesalers to our members.
    b. Also in addition, due to our direct contract terms, specifically price protection guarantees, we are able to mitigate some of the pricing fluctuations that happen in the market place, or at least delay them for a short time.
    c. The traditional wholesalers set their catalog purchase price on generics for most independent pharmacies at an arbitrary number (which varies based upon the region of the country as well as other market conditions such as wholesaler competition in the area, volume purchasing considerations and market share requirements for a wholesaler). The catalog purchase price is

then reduced by a combination of off-invoice discounts and/or earned volume based rebates. At Northwest Generics we sell to our members at a net priced model, with no back-end rebates involved.

2. Hi School Pharmacy Services is the other side of my business which owns and operates 19 retail pharmacies, as well as assisting 29 independent pharmacies in our State by offering vendor and wholesale contracts based upon aggregated purchasing volume. We interact with the pricing of pharmaceutical products in Oregon in several ways:
    a. Purchasing:
        1. We purchase most *branded* pharmaceuticals at a discounted price off of WAC (defined as Wholesale Acquisition Cost). It is the list price paid by a wholesaler, distributor and other direct accounts for drugs purchased from the wholesaler's supplier. Generally, it is the price put by the manufacturer of drug before any rebates, discounts, allowances or other price concessions are offered by the supplier of the product.
        2. We purchase *generic* pharmaceuticals in 4 ways:
            a. From a traditional wholesaler based upon a arbitrarily determined catalog price with off-invoice discounts applied and earned volume rebates
            b. From a traditional wholesaler based upon contracted rates negotiated between manufacturers and Hi School Pharmacy which are loaded as "indirect priced contracts" and are net priced meaning they are not subject to additional discounts or rebates from the wholesaler.
            c. From Northwest Generics warehouse who has negotiated directly with the manufacturers to be able to purchase and resell the items in the same way a traditional large wholesaler does, with the exception that the price is usually much lower than a traditional wholesaler and is "net priced" meaning the price the pharmacy pays for the item is not subject to additional discounts or rebates.
            d. From tertiary national wholesalers such as ANDA and Parmed to name just a couple of sources which are used to source Brand and Generics either due to availability issues in the market place or due to beneficial pricing considerations.

    b. Selling:

1. Approximately 5% of the prescriptions we sell are on a cash basis (referred to as Usual and Customary or U&C) and the retail price is determined by factoring in the true cost of the goods in combination with a market analysis of other retail prices in our region.
2. Approximately 95% of the prescriptions we sell are processed by a Pharmacy Benefit Manager (PBM) on behalf of an Insurance plan such as a Medicare D plan, Oregon Medicaid, Oregon Managed Care and Commercial Insurance plans. The prices adjudicated are based upon one or more of the following pricing mechanisms:
    a. Average Wholesale Price (AWP) which is a benchmark that has been used for over 40 years for pricing and reimbursement of prescription drugs for both government and private payers. The price is calculated and published by companies such as Medi-Span and First Data Bank. It can be applied to both Brand and Generic pharmaceuticals, and all third party contracts discount this price from 16% to 80+% depending on if it is a Branded or Generic medication.
    b. Maximum Allowable Cost (MAC) which is the upper limits that a pharmacy benefit manager ("PBM") or prescription drug benefit plan will pay a pharmacy for generic drugs and brand name drugs that have generic versions available (multi-source brands). The Mac list started in the 80's and was maintained (on the Federal government level) as more of a universal list to control the pricing of generics because the AWP benchmark on generics did not work well for this class of drugs. It was eventually adopted and changed by insurers and PBM's to become what it is today: not a singular list for generic pricing based upon actual market values, but rather a method of pricing generics based loosely upon WAC. A pricing method which can be changed on a daily basis to produce a profit margin desired by the PBM and one in which most plans have multiple MAC lists with which can be applied as needed.
    c. National Average Drug Acquisition Cost (NADAC) which is based on a retail price survey and focuses on the retail community pharmacy acquisition costs for generics. CMS has mandated that Medicaid pharmacy programs reimburse the actual acquisition cost (AAC) of drugs plus a professional dispensing fee. The NADAC represents the average acquisition cost. The pharmacies surveyed include independent retail and community pharmacies and chain pharmacies. The prices are updated and loaded into the WV Medicaid Pharmacy Point of Sale (POS) claims system, operated by

Molina Medicaid Solutions, on a weekly basis. This is the pricing mechanism we interact with Oregon Medicaid.

What successes, difficulties or obstacles involving pricing transparency within the pharmaceutical supply chain impact your industry/stakeholder group?

Successes

a. 340B partnerships
    1. In a few of our stores we have contracted with covered entities as a provider of pharmaceuticals for their Federal 340B program. This has been a success for us in that we have stability in knowing that for each prescription we fill we will earn a set minimum amount that allows to be profitable.

Difficulties/Obstacles

a. MAC Pricing
    1. It is a moving target which can be easily changed on a daily basis without warning or explanation
    2. The multiple lists are either not published or if they are they are difficult to access.
    3. There is no transparency in how the MAC lists are determined and calculated
    4. Appeals to the MAC pricing levels are most often denied but no documentation is provided as to why or where it could be purchased within the State for the MAC price
    5. When prices go down in the market place the reimbursement goes down quickly, often within a week, but when the price goes up it often take 30-90 days to be adjusted by the PBM.
b. DIR Fees
    1. These are fees that are being applied by PBMs on Medicare claims currently but are starting to pop up on some commercial plans. They can be a set dollar amount or a percentage of the claim processed and the fees are taken back retroactively often 3-6 months later, which makes all but impossible to project cash flow or profitability.
    2. Initially created to reduce patient's costs and reward good pharmaceutical care by pharmacies, they are being set as a minimum "claw back" of reimbursements for good pharmacies and then are increased for pharmacies that do not meet PBM arbitrary metrics.

3. Pharmacies are rated on performance metrics that they have little to no control over.

c. Gag rules
    1. Many of our contracts prohibit us from discussing pricing issues and/or presenting options to our customers. It can sometimes be cheaper for patients to pay cash out of pocket verses some of the co-pays the PBM's require us to collect. In addition there are alternate medications that could be dispensed that are less expensive which are just as effective, but we can be threatened to have contract termination if we pursue too many of these options
d. Inability to decline to fill a prescription if we are paid below cost.
    1. Our contracts require us to fill all prescriptions presented whether we are profitable or not.
e. PBMS are not required to "act in the best interest of patients"
    1. Branded pharmaceuticals can be required to be dispensed even if there is a less expensive generic alternative. This often a result of being paid rebates from a manufacturer directly to the PBM to get their drug on the PBM formulary.
    2. Patient co-pays are inflated to be more than the cost that the pharmacy is to be ultimately be paid, which results in higher patient costs and more profits to the PBM
f. Inadequate Dispensing fees
    1. There are multiple dispensing studies showing that a retail pharmacy needs to be paid an adequate dispensing fee in order to remain viable. When our pharmacies are filling prescriptions with the drugs being discounted to actual costs (or below) with 10 cent dispensing fees, we are being faced with closing our doors.
g. Lack of transparency
    1. This affects our overall health care costs in Oregon, as well as the profitability and viability of our community pharmacies.
        a. There is little or no transparency into how and at what rates PBMs reimburse community pharmacies
        b. There is little or no transparency into the higher rates that PBMs charge health plan sponsors
        c. There is little or no transparency for the difference (commonly referred to as the "Spread") retained by PBMs for reimbursing low and charging high.

Jason Kirby - Walgreens

- **How does your industry/stakeholder group interact with the development or movement of pharmaceutical products in Oregon?**

Pharmacists play an important role in helping people on their path to better health by improving access to care and lowering costs for patients. Pharmacists are often on the front lines of health care and do much more than fill prescriptions. At the core, pharmacists provide medication counseling to help patients better understand their prescription medications that improve adherence for patients with chronic diseases. Pharmacists can answer questions about prescription drugs, help identify lower-cost alternatives or recommend pharmacy services, such as automatic refills or script consolidation programs that result in fewer trips to the pharmacy. Our pharmacists also provide medication reviews to check for potential unsafe interactions between different medications and to ensure that the patient's medication regimen is appropriate. Additionally, pharmacists deliver disease management services by providing disease and lifestyle management support to patients living with chronic diseases like diabetes and heart disease as well as more complex, chronic conditions requiring specialty therapy. Pharmacists also administer immunizations to help prevent a range of ailments and diseases, including seasonal flu, meningitis, chicken pox, and many others. Pharmacists are specially trained to provide vaccine services, offering patients a safe and convenient way to stay current and protected with all recommended vaccines. Finally, pharmacists may prescribe certain medications. In some states, namely Oregon, pharmacists are able to prescribe hormonal contraceptives, giving patients greater access to convenient care.

OREGON LEGISLATIVE ASSEMBLY

JOINT TASK FORCE ON FAIR PRICING OF PRESCRIPTION DRUGS

MAY 18, 2018 – WALGREENS

- **How does your industry/stakeholder group interact with the pricing of pharmaceutical products in Oregon? What pricing mechanisms are utilized?**

Most often, patients have their first encounter with the stark reality of high out-of-pocket drug costs right at the pharmacy counter. This is especially pronounced in an era of high deductibles and high coinsurance. It's a challenging atmosphere for pharmacists because they are in an environment where these out-of-pocket costs are a number one health issue that can especially impact medication adherence. As health care providers on the front lines, pharmacists know that helping patients afford their medications contributes to driving adherence. Our pharmacy care teams help find ways to make medications more affordable. We do everything we can to conduct a complete review of benefits with primary and any secondary insurance providers and explore potential benefit options, coordinate with the doctor and insurance company to facilitate prior authorizations, explore less expensive generics, biosimilars and other therapeutic alternatives, match patients with manufacturer, copay, and discount programs that may help cover the cost of medications not covered by insurance, or help with co-payments that may still be too much to afford. Specifically, we'll discuss financial need, identify programs patients may be eligible for, and coordinate applications for assistance.

OREGON LEGISLATIVE ASSEMBLY

JOINT TASK FORCE ON FAIR PRICING OF PRESCRIPTION DRUGS

MAY 18, 2018 – WALGREENS

- **What successes, difficulties or obstacles involving pricing transparency within the pharmaceutical supply chain impact your industry/stakeholder group?**

Americans spend more on prescription drugs than anyone else in the world—with an average cost of about $1,100 per person per year, with much of the cost stemming from advancement in medicine and greater utilization of life-saving products. Policymakers are looking for solutions from the drug supply chain and the roles we can play in driving down costs for patients and the healthcare system. There are many dynamics within the supply chain, far removed from pharmacists, which can impact the price of drugs. Many patients are unaware of the impact of manufacturer list price changes, drug formulary placement, and other market forces that set the price of a drug at the point-of-sale and patients' cost sharing amounts. As a pharmacy-led health and wellness company, we know that drug therapies produce value and cost savings for our nation's health care system through improved outcomes for patients. Walgreens is well positioned to continue to drive down the cost of drugs for our patients and the health care system through programs that support medication adherence, financial and copay assistance, utilizing less expensive alternatives, and discounting medications through our value-priced prescriptions savings club. Walgreens is part of the solution and supports efforts to bring more transparency to the drug supply chain and to lower patient out-of-pocket drug costs, including policies that drive value and quality outcomes. Still, the greatest contribution pharmacy makes to healthcare is to help patients do well on their therapy. The cost to our healthcare system from medication nonadherence reaches nearly $300 billion. Pharmacist can be one of the most influential voices in helping patients take their medications as directed. Recognizing them as providers and fully leveraging pharmacists as key professionals in healthcare delivery maximizes a valuable resource while producing savings across the entire healthcare system. Oregon should be commended for their leadership in this effort through the expansion of the scope of pharmacists, giving patients greater access to convenient care.

OSPIRG
Standing Up To Powerful Interests

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To: Task Force on Fair Pricing of Prescription Drugs

From: Jesse Ellis O'Brien, OSPIRG Policy Director

Re: May 18, 2018 Task Force meeting

OSPIRG greatly appreciates the opportunity to represent the interests of Oregon consumers and contribute to the critical work of this Task Force. Here are our brief answers to the questions posed to Task Force members in advance:

- How does your industry/stakeholder group interact with the development or movement of pharmaceutical products in Oregon?

Consumers are the end users of pharmaceutical products more or less by definition, but whether we rely on prescription drugs ourselves or not, all Oregonians ultimately pay the price for prescription drugs through health insurance premiums, taxes and costs passed on in the prices of consumer goods and services by employers that provide health coverage.

Consumers have a role in the movement of pharmaceuticals to the extent that they choose which drugs and what drug coverage to purchase, when and where. Today, consumers are too often forced to make those decisions—which can be enormously consequential to their health and financial security—in the dark, with imperfect information at best about how much they will pay and no assurance whatsoever that prices are reasonable or provide good value for their money.

- How does your industry/stakeholder group interact with the pricing of pharmaceutical products in Oregon? What pricing mechanisms are utilized?

Consumers have little to no say in prescription drug pricing and are generally forced to accept prices negotiated in secret between a range of industry stakeholders that they cannot trust to have their best interests at heart.

The portion of drug spending that consumers have some control over is their own out-of-pocket spending, which comes in the form of some combination of copays, coinsurance and deductibles set by the consumer's health plan. But even with regard to out-of-pocket spending, consumers rarely have many options to contain their exposure to high drug costs. Consumers can choose to go without prescribed medications, or use less than they should, but doing so may risk dire health consequences.

Consumers have essentially no way of limiting their own exposure to the underlying cost of drugs that is passed along in premiums, taxes and other costs.

- What successes, difficulties or obstacles involving pricing transparency within the pharmaceutical supply chain impact your industry/stakeholder group?

Coinsurance and deductibles are often difficult to navigate for consumers due to the opacity of drug pricing. It is essentially impossible for consumers to know what to make of, e.g., a 25% coinsurance rate for a drug in the absence of comprehensive price transparency. This is not simply an issue of consumers failing to understand the intricacies of insurance—even the most savvy consumer will not be able to calculate their 25% share of a price that is not made available to them. Consumers struggle with this kind of opacity both when seeking to use their current coverage to purchase a drug and when shopping for a health plan.

The opacity of the drug pricing system also makes it hard to know exactly how consumer-facing costs like premiums and out-of-pocket charges interact with the very complex industry dynamics between manufacturers, distributors, pharmacy benefit managers, health plans and pharmacies. For example, it is essentially impossible to know the extent to which consumers really benefit in the form of lower premiums and out-of-pocket costs from manufacturer rebates, and whether the entire system of behind-the-scenes rebate negotiations redounds to the benefit of consumers.

Consumers are also increasingly concerned about the rising cost of drugs for our health care system, which we are all paying for in a wide variety of ways. As big drug price hikes have grabbed the headlines in recent years, I have heard from many Oregonians who simply want to know where all that money is going, and what, if anything, can be done to contain rising drug costs.

The transparency provisions of HB 4005 are a great first step, and the additional transparency this Task Force will be exploring could be an important next step, but ultimately, Oregon consumers will likely need more than transparency to ensure fair pricing for prescription drugs. Consumers need real accountability for the industries all up and down the drug supply chain to ensure that there are mechanisms to keep prices reasonable, and that drug pricing serves the public interest.

Thank you for your time and consideration.

JOHN SANTA, OREGON HEALTH POLICY BOARD (OHPB).

OHPB is the policy and oversight board of the Oregon Health Authority (OHA). OHPB has been working alongside OHA to design and implement a comprehensive health reform plan for our state. In 2010, OHA put forth the first Action Plan for Health. The plan used strategies and a timeline to address urgent health care issues in the state. The 2010 Action Plan aimed at addressing issues of cost, quality and access to health care through innovation. The launch of Oregon's coordinated care organizations (CCOs) is a reflection of this aim. In 2016 OHPB asked OHA to update the Action Plan. The 2017 Action Plan refresh is a response to that request. It uses the guiding principles to target basic strategies that drive system change and policy action in 2017-2019. Strategies relevant to the Joint Task Force include:

- Pay for outcomes and value
- Increase access to health care
- Improve health equity
- Engage stakeholders and community partners
- Measure progress

Improving the process, outcomes and value of prescription drugs is a high priority for OHPB. The CCOs and multiple community partners have identified prescription drugs as the highest priority when it comes to cost and a high priority when it comes to access, equity, engagement and measurement. In 2017 OHPB created a High Cost Prescription Drugs Committee to engage stakeholders in these issues. The work of that committee has been put on hold pending the work of the Joint Task Force. OHPB appreciates being included in the Joint Task Force.

- How does your industry/stakeholder group interact with the development or movement of pharmaceutical products in Oregon?

OHPB advises OHA especially about matters involving CCOs and other coverage options for Oregonians (PEBB, OEBB, state agencies, health exchanges). OHPB is aware of the importance of pharmaceutical products and their impact on the cost, outcomes (benefits and risks), and value. The Board's goal is to productively engage stakeholders and community partners around these issues to maximize access and value. The Board is especially focused on CCOs and the patients they serve as Oregon prepares for CCO 2.0, a new 5 year contract for CCO services.

- How does your industry/stakeholder group interact with the pricing of pharmaceutical products in Oregon? What pricing mechanisms are utilized?

OHPB provides policy guidance to OHA. As a result we are interested in the pricing mechanisms used by OHA contractors and by other state agencies. A variety of pricing mechanisms are used. Multiple strategies are possible that would affect those mechanisms. As an OHPB member I believe value could be significantly increased via improved pricing options

- What successes, difficulties or obstacles involving pricing transparency within the pharmaceutical supply chain impact your industry/stakeholder group?

OHPB, like many stakeholders, is able to evaluate only portions of the pharmaceutical supply chain because of the lack of transparency at multiple levels, especially related to prices. While the Board understands the benefits of confidentiality in some cases, multiple stakeholders and community partners have reported frustration with the lack of transparency especially around high cost drugs. This is especially true when it comes to individual consumer/patients having a credible sense of the cost/price of a pharmaceutical product, the benefit/risk of that product and the overall impact that product may have on the community.

Joseph Schnabel - Salem Hospital

- How does your industry/stakeholder group interact with the development or movement of pharmaceutical products in Oregon?

  Hospital pharmacies purchase pharmaceutical products from drug wholesalers, manufacturers, compounding pharmacies, and repackagers. Hospital pharmacies, including Salem Hospital, participate in clinical research involving drugs that are not yet approved for marketing by the FDA.

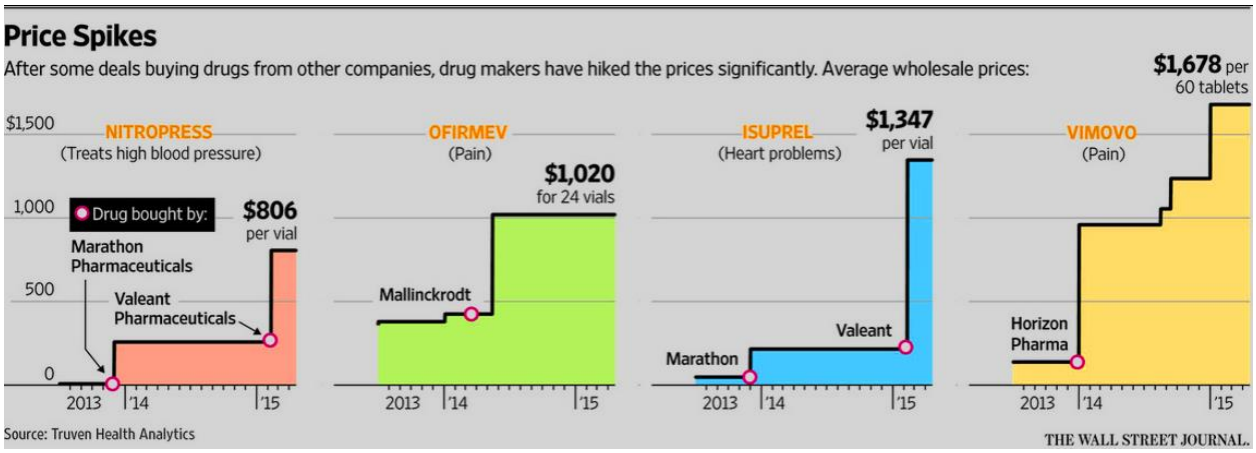
- How does your industry/stakeholder group interact with the pricing of pharmaceutical products in Oregon? What pricing mechanisms are utilized?Hospital pharmacies purchase pharmaceutical products primarily from drug wholesalers (McKesson, Cardinal, AmerisourceBergen, FFF Enterprises), but also directly from manufacturers and compounding pharmacies. Drug pricing is complex and hospital pharmacies purchase pharmaceutical products on various pricing tiers: Group Purchasing Organization (GPO); Manufacturer's List Price; Wholesale Acquisition Cost (WAC), and; 340B (if the hospital is eligible).
  Hospitals that participate in the Federal 340B pricing program most commonly utilize a replenishment model for drug purchasing, so that the price of the drug is determined after it is used. If an outpatient drug is used in a 340B-eligible situation, it can be replaced at the 340B price. If it is used in a 340-B ineligible situation, it must be purchased at Wholesale Acquisition Cost. Thus, the cost of a prescription drug on the shelf is not determined until after it is used.

OREGON LEGISLATIVE ASSEMBLY

JOINT TASK FORCE ON FAIR PRICING OF PRESCRIPTION DRUGS

- What successes, difficulties or obstacles involving pricing transparency within the pharmaceutical supply chain impact your industry/stakeholder group?

  Prices can fluctuate wildly based on unstable market forces. When prices change, there is generally no warning or explanation as to why the product is suddenly much costlier. Below are examples of dramatic price increases that affected hospital pharmacies for medications that had previously been relatively inexpensive.



  When dramatic price increases occur, pharmacists work with physicians to determine if there are alternative medications or alternative means of providing them. For example, Salem Hospital decreased the use of nitroprusside (Nitropress®) by over 90% and reduced the use of isoproterenol (Isuprel®) by 50% utilizing alternative products when their prices spiked in 2015.

  Many newer drugs do not have suitable alternatives and the high prices cannot be avoided. Often these agents provide better clinical outcomes than older medications and high prices generally persist until there are more competitors in the market.

Leah Lindahl - Healthcare Distribution Alliance

- How does your industry/stakeholder group interact with the development or movement of pharmaceutical products in Oregon?

  The Healthcare Distribution Alliance (HDA) represents primary pharmaceutical wholesale distributors — the vital link between the nation's pharmaceutical manufacturers and more than 200,000 pharmacies, hospitals, long-term care facilities, clinics and others nationwide. Specific to Oregon, our members serve nearly 4,000 points of care across the state.

  The nation's primary pharmaceutical wholesale distributors play a vital role in the healthcare system. Every day HDA members work around the clock to safely and efficiently ship 15 million healthcare products (medicines, medical supplies, durable medical equipment, et al) to pharmacies, hospitals and other healthcare providers in order to keep their shelves stocked with the medications and products they need to treat and serve their patients. Distributors are unlike any other supply chain participants – their core business is not engaged in manufacturing and they do not prescribe medicines or dispense to patients. Their key role is to serve as a conduit for medicines to travel from manufacturer to patient while making sure the supply chain is fully secure, fully functional, and as efficient as possible.

  Primary distributors purchase pharmaceutical products from brand and generic manufacturers. They store, handle, pick, pack and ship those products, delivering them to virtually every pharmacy setting in the country. Furthermore, wholesale distribution has evolved over the last decade from simply managing warehouses and shipping goods. This is no longer an industry focused solely on moving products from point A to point B. Rather, pharmaceutical distributors provide a wide array of supporting services that enable the pharmaceutical supply chain to function efficiently and safely, delivering significant value to manufacturers and healthcare providers — and ultimately to patients.

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The primary pharmaceutical distribution industry is a very high volume, yet very low profit margin industry, with the industry margin just over one percent on average in 2016. In fact, overall profitability for the primary distribution sector shows little notable change over the past several years, even during recent market volatility.[1] Three recent studies validated the pharmaceutical distribution industry's low profit margin. The Pharmaceutical Research Manufacturers of America (PhRMA) published a report entitled "Follow the Dollar," illustrating the financial flow of a drug in the supply chain, with a wholesaler retaining 0.005 percent on the drug cost in each of the three examples.[2] A study conducted by the Berkeley Research Group in 2017 concluded that the pharmaceutical wholesale distributor profit on overall branded drug costs was just under one percent.[3] Finally, an article published in USA Today entitled "How Prescription Drug Middlemen Make Their Money," demonstrates that from the overall cost of

[1] Data obtained from annual HDMA/HDA industry *Factbook* Publication, compiled and compared across multiple years.
[2] Follow the Dollar, Understanding How the Pharmaceutical Distribution and Payment System Shapes the Prices of Brand Medicine - http://phrma-docs.phrma.org/files/dmfile/Follow-the-Dollar-Report.pdf.
[3] The Pharmaceutical Supply Chain: Gross Drug Expenditures Realized by Stakeholders; 2017; Table 2 http://www.thinkbrg.com/media/publication/863_Vandervelde_PhRMA-January-2017_WEB-FINAL.pdf.

a $250 drug, the wholesale distributor retained a net profit of $2.50 – the smallest profit margin in the entire drug supply chain.[4]

Traditional pharmaceutical wholesale distributors purchase pharmaceuticals from manufacturers based on the Wholesale Acquisition Cost ("WAC"), a publicly available figure reported for each pharmaceutical product by the manufacturer to various compendia. Manufacturers (pharmaceutical, biologic, generic, etc.) set the WAC price for their products. Wholesale distributors are not privy to how such WAC pricing decisions are made. Wholesale distributors typically purchase pharmaceuticals from manufacturers and sell pharmaceuticals to downstream customers based on WAC. Distributors also charge manufacturers distribution fees related to their services. These service fees, which are not passed down to the subsequent purchaser, typically underwrite the cost of warehousing, ordering, special product handling services (e.g. refrigerated products) and transporting products to the thousands of ship-to points each distributor serves every day. This fee-for-service model reduces demand volatility – aligning order patterns more closely to actual patient demand and, eliminating artificial demand spikes, allowing for a supply chain that operates more smoothly and predictably.

It should be noted that without HDA members, each manufacturer would be responsible for ensuring that patients get the medicines they need when they need them, employing substantial financial, logistical and staff resources at the company level to provide medicines and supplies to hundreds of thousands of dispensing sites. Without distributors, the supply chain would be much less efficient, less reliable and less secure, which could hinder the ability of patients to get the medicines they need in a timely fashion and add significant costs to our healthcare system – approximately $42 billion each year.

Additionally, due to anti-trust constraints the association is precluded from being privy to, or providing a venue for any discussion about prices and/or the

[4] "How prescription-drug middlemen make their money", USA Today, October 3, 2016; https://www.usatoday.com/story/news/2016/10/03/how-prescription-drug-middlemen-make-their-money/91461918/.

components of prices among members. As members may not discuss pricing, pricing formulas, policies or the terms of their purchase and sales contracts in any HDA sponsored venue, the organization is unable to provide any comments or answer questions about specific drug products, classes of product, their prices or negotiations that take place between member companies and their suppliers and/or customers. We simply have no visibility into these topics.[5]

- What successes, difficulties or obstacles involving pricing transparency within the pharmaceutical supply chain impact your industry/stakeholder group?

  The pharmaceutical supply chain is a complex and interconnected system, with distributors working on a national and regional scale. State-level policies can and will often impact downstream partners depending on the scope and detail of such policy. Due to these complexities, policy solutions under consideration often can lead to unintended consequences or not achieving the anticipated results. HDA commends the Oregon legislature for convening the Task Force on Fair Pricing of Prescription Drugs in order to have a detailed conversation with all supply chain representatives to understand their specific role in, and influence on, medication delivery and cost.

  Traditional pharmaceutical wholesale distributors' goal in the pharmaceutical supply chain is a simple one: add efficiency, security and timely delivery of products so providers can concentrate on patient care and ensure their patients have regular access to the medications they need. Historically, pharmaceutical wholesale distributors have effectively achieved this goal and have therefore had a positive effect on the supply chain and patients while having minimal influence on the overall cost of drugs.

[5] HDA's antitrust policy strictly prohibits any discussions which constitute or imply an agreement or understanding between or among its members concerning: 1) prices, discounts, or terms or conditions of sale; 2) profits, profit margins or cost data; 3) market shares, sales territories or markets,; 4) allocation of customers or territories; 5) selection, rejection or termination of customers or suppliers; 6) restricting the territory or markets in which a company may resell products; 7) restricting the customers to whom a company may sell; or 8) any matter which is inconsistent with the proposition that each members company of HDA must exercise its independent business judgment in pricing its services or products, dealing with its customers and suppliers and choosing the markets in which it will compete.

Legislative Joint Task Force on Fair Pricing of Prescription Drugs

Insurance Companies

Robert Judge, Director of Pharmacy Services
Moda Health

May 18, 2018

About Moda

- Northwest-based health insurer offering dental, medical and pharmacy insurance and administrative services.
  - Operate in Oregon, Washington and Alaska
- Administer pharmacy programs for more than 1.2 million individuals in the Pacific Northwest.
- Administer the Oregon Prescription Drug Program (OPDP), which includes:
  - Oregon Educators Benefits Board (OEBB)
  - Public Employee Benefits Board (PEBB)
  - SAIF
  - Eastern Oregon Coordinated Care Organization
  - Other self-insured, government and facility programs statewide,
  - 300,000+ residents using OPDP discount card

Question 1:

How does your industry/stakeholder group interact with the development or movement of pharmaceutical products in Oregon?

Impact the development or movement of pharmaceuticals by…

- Pay for the costs of delivering healthcare, including prescription drugs, on behalf of clients and members.
- We have a primary mission to manage costs and protect consumers against rising drug costs.
- We have a high degree of transparency required by state regulation and oversight: file health plan designs with DCBS each year.
  - Transparent filing that includes prescription drugs (documents are public, actuarial analysis and public hearings) and requires approval by DCBS for the premium rates.
  - Once filings and premiums are approved by DCBS, they cannot be changed during the plan year.
  - All cost increases from drug manufacturers during the course of the plan year must be absorbed and reflected in premiums.

Question 2:

How does your industry/stakeholder group interact with the pricing of pharmaceutical products in Oregon? What pricing mechanisms are utilized?

Impact the pricing of pharmaceutical products by...

- The power in setting the price of drugs is skewed towards manufacturers.
- We do not set prices for prescription drugs, pharmaceutical manufacturers do.

Pricing mechanisms include...

- Develop and manage formularies and prescription drug benefits
  - Formularies (Preferred Drug Lists) identify drugs that offer the greatest overall value (safety, effectiveness and price)
  - Prescription drug benefits as part of our health plans that help consumers pay for prescription drugs

Pricing mechanisms include...

- Manage the impact of uncontrolled increases in prescription drug prices on clients and members by:
  - Contracting directly, or through a PBM, with retail, mail and specialty pharmacies to dispense medications to members
  - Contracting directly, or through PBM or 3rd party aggregators, for rebates that offset the cost of medications that have been selected to be on formulary
    - The net impact of rebates are included in the actuarial analysis and public rate setting process
- These tools only assist us with controlling the effect of manufacturer price increases. They do not offset these effects.

Question 3:

What successes, difficulties or obstacles involving pricing transparency within the pharmaceutical supply chain impact your industry/stakeholder group?

Difficulties or obstacles involving pricing transparency within the pharmaceutical supply chain…

- Continuous manufacturer price increases—multiple times within a plan year and cumulative year-to-year impact
- Legislative efforts to place limits on payers' ability to manage drug formularies
- Patent extensions and / or delays with generic and biosimilar alternatives
- Direct to Consumer advertising

Difficulties or obstacles involving pricing transparency within the pharmaceutical supply chain…

- Prescribers and consumers not knowing or understanding the real cost of drugs
- FDA drug approval process that does not require drug companies to prove that their new products are better than existing products
- Increasing availability of manufacturer copay coupons and other third party schemes

Successes involving pricing transparency within the pharmaceutical supply chain…

- House Bill 4005 – A first step towards greater drug price transparency and containing drug costs
- Pharmacy & Therapeutic committee decisions – that evaluate medications to determine therapeutic efficacy and manage drug use
- Formularies and use of drug tiers – which incent members to select most therapeutically effective options
- Prior authorizations and Utilization Management efforts – that keep drug plan costs down by requiring lower-cost medications before moving to higher-costing alternatives
- Rebate analyses – used to select drug preferences based on the lowest net cost drug for clinically similar alternatives

Ryan Dunlap - MolecularMD

- How does your industry/stakeholder group interact with the development or movement of pharmaceutical products in Oregon?

Oregon's biopharmaceutical industry is primarily made up of small start-up to midsized companies that research, develop, and manufacture medical products and technologies to treat patients afflicted with serious diseases, to delay the onset of these diseases, or to prevent them in the first place. In that way, our industry's novel therapeutics, vaccines, and diagnostics yield not only improved health outcomes, but also reduced health care expenditures due to fewer physician office visits, hospitalizations, and surgical interventions.

These companies are typically needing to raise capital to move to the next phase of development or manufacturing of their innovative products, which can be increasingly difficult when faced with political headwinds given the efficiency of the capital markets and the unlimited investment options available to the venture capitalists and other investors in other, less risky industries.

Some of these companies must also bargain directly with pharmacy benefit managers, distributors, pharmacies and others in the overall supply chain, at times giving major discounts on products despite an already risky and unprofitable stage of its business, which can hinder their ability to enter or compete effectively in the market.

- How does your industry/stakeholder group interact with the pricing of pharmaceutical products in Oregon? What pricing mechanisms are utilized?

On the most basic level, manufacturers establish a list price for pharmaceuticals. However, what purchasers and patients pay is much more complicated than just established list prices. Manufacturers of biotechnology and biomedical products provide discounts or rebates to purchasers in government programs based upon federal or state law, including but not limited to Medicare, Medicaid, 340B, and state employee health plans. Our industry also provides discounts and rebates to private commercial purchasers based upon volume and competitive market-based negotiation. However, insurers also affect how much patients pay out of pocket for these services.

Pharmaceutical Benefit Managers (PBMs) frequently take a share of the rebates negotiated on behalf of their clients, which can force the client to pay more for prescription drugs than the manufacturer offers. Additionally, PBMs do not pass these rebates or shares of the rebates on to the patient, forcing the patient to pay more out of pocket. Moreover, PBMs frequently require gag clauses in their contracts that prevent pharmacists from telling the patient they may be able to obtain a drug a lower price than their copayment if they were to otherwise purchase the drug outside of their insurance plan.

- What successes, difficulties or obstacles involving pricing transparency within the pharmaceutical supply chain impact your industry/stakeholder group?

Specifically, in regards to HB 4005, our industry will have significant difficulty in understanding how to aggregate, or even identify some of the information called for in the bill, and the information required by the bill lacks context with respect to the entire portfolio of programs (i.e. cost of failed programs) and other related risks that ultimate drive the required return on investment. In addition, without protections for both trade secrets and other intellectual property, our members could be at significant compliance and business risk simply by complying with HB 4005. Finally, the type of data required to be disclosed could create legal risks for members related to allegations of price signaling or other antitrust claims under state and federal law.

Meaningful transparency would help patients get the information they need to make informed choices. It would help patients understand what medicines are covered by their health plans and what kind of cost-sharing is required, such as copays, deductibles and coinsurance. It would also shine light on the role of insurers and pharmacy benefit managers who ultimately decide what patients pay out of pocket for prescription drugs.

Specific example highlighting the need for increased transparency with respect to other players in the supply chain:

One small biotechnology and pharmaceutical manufacturer attempting to launch and commercialize a new pharmaceutical product to compete with existing products offered by

much larger organizations began the process of contracting with channel partners and pharmacy benefit managers, only to realize that the rebate needed to satisfy the PBMs was over twice that charged to the larger competitors (over 50% in many cases), creating a barrier to competition that precluded any ability to lower the list price of the drug to put competitive downward pressure on the prices in the market. Moreover, after one particular negotiation of a rebate in excess of 50% with one of the nation's largest PBMs, the rebate charged to that company, which prior to the negotiation was ~$70,000, jumped to over $700,000 the very next month, with no increase in prescription volume. Upon further investigation, is was discovered that a vast majority of the rebate increase related to a small handful of existing patients, seen by existing doctors, all ordering the prescriptions through one single specialty pharmacy. Further research, including contact with the specialty pharmacy, revealed that these rebate claims stemmed from a "pharmacy benefit administrator", which had no visible website presence to verify it's validity, who apparently had purchased prescription data from this pharmacy, and turned around and somehow sold that data to the PBM who then claimed these prescriptions as falling under their plan, thus causing the astronomical increase in the rebate. After filing a grievance with the PBM, the charges were subsequently removed, but there was no explanation, certainly no apology, for the "mixup". It's unlikely that this was an isolated incident, and more likely points to a hidden inefficiency in the supply chain, one that seems without purpose and should be strongly considered as transparency efforts progress.

Saumil Pandya - Pharmaceutical Research and Manufacturers of America

- How does your industry/stakeholder group interact with the development or movement of pharmaceutical products in Oregon?

We are the Pharmaceutical Research and Manufacturers of America (PhRMA), a trade association of more than 30 biopharmaceutical companies throughout the country that develop new and innovative brand name medicines that help to save and improve lives. Our member companies invest significant amounts of time and money in research and development (R&D), devoting between 10 to 15 years at a cost of $2.6 billion on average to create a new medicine that improves patient health. The PhRMA board of directors felt so strongly in this commitment to R&D that last year they conducted a comprehensive review of our membership criteria to ensure the association represents companies that are dedicated to researching and developing new, cutting-edge therapies for patients. The result of that review was a requirement that companies maintain a three-year average global R&D to global sales ratio of 10 percent or greater **and** three-year average global R&D spending of at least $200 million per year to be eligible to remain in or join the association. Most PhRMA member companies invest significantly more in R&D than required by the new criteria. On average, PhRMA members invest 20 percent of their revenue in R&D, and the biopharmaceutical sector accounts for 17 percent of all domestic R&D funded by U.S. businesses – far more than the software (11 percent), automobile (6 percent) and aerospace (4 percent) industries.[1] Since 2000, PhRMA member companies have invested more than half a trillion dollars in the search for new treatments and cures, including an estimated $65 billion in 2016 alone.

[1] PhRMA analysis of National Science Foundation, National Center for Science and Engineering Statistics, data. Table 2. Funds spent for business R&D performed in the United States, by source of funds and selected industry: 2015. In: Wolfe RM. Businesses spent $356 billion on R&D performed in the United States in 2015. InfoBrief. NSF 17-320. https://www.nsf.gov/statistics/2017/nsf17320. Published August 2017. Accessed May 2018.

Developing innovative new medicines is a risky endeavor. Only a small fraction of potential new medicines succeeds, with less than 12 percent of candidate medicines that reach phase 1 clinical trials eventually obtaining approval by the FDA. This statistic does not include the thousands of products that fail during preclinical testing, and thus never make it to the clinical trial phase. Of those that obtain approval, only about 1 in 5 produce revenues that exceed the average cost of R&D. Setbacks are inherent in the process and researchers use knowledge gained from the failures to better inform research on other medicines in development. For example, between 1998 and 2014, 167 medicines failed in clinical trials for lung cancer and 10 received approval, and in Alzheimer's disease123 unsuccessful candidate medicines paved the way for 4 new approved medicines.

Once a medicine is finally brought to market, our companies work with wholesalers to transport those medicines to the many points of distribution including retail, mail-order, and hospital pharmacies. After our companies sell and ship their medicines to the wholesaler, they cease to have physical possession of those products. The remaining interactions involving our companies primarily include contract negotiations with insurers. Insurers typically do not take physical possession of medicines. For them, the process of the distribution of medicines only involve financial transactions.

- How does your industry/stakeholder group interact with the pricing of pharmaceutical products in Oregon? What pricing mechanisms are utilized?

Biopharmaceutical manufacturers set the list price, or Wholesale Acquisition Cost (WAC), for branded medicines. However, there are many factors that influence the setting of list prices. Recouping R&D costs for medicines that make it to market and for those who fail are part of that calculus, but are not the only considerations. Among other factors, medicines that make it to market and generate positive revenue must support an entire ecosystem that includes the pipeline costs of medicines that are still in development. Furthermore, most new medicines are entering therapeutic classes where existing competitors are already present. Those competitors have existing contractual arrangements with insurers that strongly influence the level of rebating that will be required for a new medicine entering that therapeutic class to get formulary access. Existing medicines have all the market share in that therapeutic class. For a new medicine to gain market share, it not only has to demonstrate clinical value for patients, but provide financial value for insurers. Thus, factors that go into the setting of list prices for medicines are not arbitrary, but reflect a variety of complex business considerations.

Much of the public debate about the cost of medicines has focused on list prices, which do not account for the significant rebates and discounts Pharmacy Benefit Managers (PBMs) and health plans commonly negotiate with manufacturers in exchange for preferred patient access via formulary placement on lower cost sharing tiers. For certain medicines used to treat chronic conditions like asthma, high cholesterol, hepatitis C, and diabetes, discounts and rebates paid by manufacturers can reduce list price costs to insurers by as much as 30% to 70%.[2]

[2] QuintilesIMS Institute. Estimate of Medicare Part D Costs After Accounting for Manufacturer Rebates. October 2016; Gronholt-Pedersen J, Skydsgaard N, Neely J. Novo Nordisk Defends U.S. Diabetes Drug Pricing. *Reuters*. November 4, 2016. http://www.reuters.com/article/us-novo-nordisk-prices-idUSKBN12Z184 ; Silverman E. What

A point that is often overlooked is that the amount a patient pays for a medicine is determined by their insurance benefit design, not by the list or net price of a medicine. After accounting for all discounts, prices for brand medicines have grown at rates in the low single digits for the past five years, yet many patients have experienced rapidly increasing out-of-pocket costs as insurers have steadily raised co-payments and deductibles, and employed use of percentage-based co-insurance to be paid by patients. Over the past 10 years, there has been an increase in patient cost-sharing as compared to health plan costs. For workers with employer sponsored health insurance, out-of-pocket spending in the deductible phase increased by 230% and coinsurance payments increased by 89%, compared to a 56% increase in payments by health plans.[3]

For medicines, savings negotiated between manufacturers and PBMs are generally not shared with patients at the time that they fill a prescription. Insurers often use the rebates and discounts they receive to help reduce plan costs or premiums, though they are not required to do so (except in Medicare Part D). That means patients who are in the deductible phase of their insurance benefit, or whose cost-sharing is based on coinsurance are typically charged based on the undiscounted list price, even though the PBM may have negotiated a rebate with the manufacturer that significantly lowered the medicine's final net price to the insurer.[4,5] Sometimes a patient's cost-sharing amount may exceed the price the insurer pays for a medicine or exceeds what the patient would pay at the pharmacy counter without using insurance (i.e. by paying in cash). Language in PBM contracts may discourage or prohibit pharmacists from informing insured patients about the lower cash price, at the risk of the pharmacy being excluded from the PBM's network.

Manufacturers are also required to provide sizable statutory rebates, discounts, and fees to government programs, which have increased in recent years due to changes such as an increase in the Medicaid rebate required by the Affordable Care Act, closing of the Medicare Part D "donut hole" and expansion of the 340B program. These mandatory payments grew by more than 40% between 2013 and 2015, increasing from $29.6 billion to $41.8 billion.[6]

The Oregon Medicaid program, along with the Federal government, receive significant rebates that lower the net price for medicines dispensed to Medicaid beneficiaries in the state. In 2016, these rebates totaled more than $350 million, representing a 51 percent discount returned to the state and the Federal government.[7]

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the 'Shocking' Gilead Discounts on its Hepatitis C Drugs Will Mean. *Wall Street Journal*. February 4, 2015. https://blogs.wsj.com/pharmalot/2015/02/04/what-the-shocking-gilead-discounts-on-its-hepatitis-c-drugs-will-mean/
Barrett P, Langreth R. The Crazy Math Behind Drug Prices: Intermediaries that Negotiate to Lower Prices May Cause Them To Increase Too. *Bloomberg Businessweek*, June 29, 2017. https://www.bloomberg.com/news/articles/2017-06-29/the-crazy-math-behind-drug-prices

[3] Claxton G, Levitt L, Long M, et al. Increases in cost-sharing payments have far outpaced wage growth. Peterson-Kaiser Health System Tracker. October 4, 2017. https://www.healthsystemtracker.org/brief/increases-in-cost-sharing-payments-have-far-outpaced-wage-growth/

[4] Hopkins JS. You're overpaying for drugs and your pharmacist can't tell you. Bloomberg. February 27, 2017. https://www.bloomberg.com/news/articles/2017-02-24/sworn-to-secrecy-drugstores-stay-silent-as-customers-overpay.

[5] Feeley J, Hopkins JS. CVS Health is sued over 'clawbacks' of prescription drug co-pays. August 9, 2017. https://www.bloomberg.com/news/articles/2017-08-08/cvs-health-is-sued-over-clawbacks-of-prescription-drug-co-pays.

[6] Berkeley Research Group. The Pharmaceutical Supply Chain: Gross Drug Expenditures Realized by Stakeholder. January 2017

[7] The Menges Group, analysis of FY 2016 CMS 64 reports and State Drug Utilization files.

There are two components to Medicaid rebates on branded medicines: the basic rebate and an additional rebate that holds the state harmless for any price increases taken by the manufacturer that exceed inflation based on the Consumer Price Index (CPI-U). For brand medicines the basic rebate is the greater of a) a flat rate (currently 23.1%) of the Average Manufacturer Price (AMP) or b) the difference between AMP and the best price (lowest net price) offered to most customers. For example, if a manufacturer offers an insurer a price for a drug in a particular quarter that is greater than 23.1% below its AMP, that price would set a "best price" for every state, in other words, every state Medicaid program in the country would get that same discount. Manufacturers also negotiate supplemental rebates with the state in addition to these mandatory rebates.

Claims from PBMs, payers, and others about the skyrocketing prices of medicines almost always focus solely on list prices, which are not reflective of actual spending trends. The magnitude of manufacturer price concessions is material. Total rebates and discounts paid by manufacturers have increased by 107% from $74 billion in 2012 to $153 billion in 2017.[8]

- What successes, difficulties or obstacles involving pricing transparency within the pharmaceutical supply chain impact your industry/stakeholder group?

While patients face real challenges affording their medicines, state transparency bills do not directly help patients, and at the same time ignore the complexities of drug development and pricing. Some transparency bills seem to suggest that the price of a medicine should be set based on input costs, such as R&D and marketing expenditures. This minimizes the important role that private health plans play in managing the cost of medicines. Plans are increasingly consolidated, and just three pharmacy benefit managers control 70 percent of the marketplace. Proposed mergers would further increase this consolidation. Because of the consolidated negotiating power of these purchasers, net prices of brand medicines increased only 1.9 percent in 2017, compared to a 6.9 percent increase in list prices.[9]

Further, such bills seem to assume that this type of transparency will promote competition on the market, but as the Federal Trade Commission (FTC) has previously noted, "Too much transparency can harm competition in the market."[10] The FTC has expressed concern "when information disclosure allows competitors to figure out what their rivals are charging, which dampens each competitor's incentive to offer a low price, or increases the likelihood they can coordinate on higher prices."

This does not mean all transparency is bad. In fact, meaningful transparency that helps patients make better, more informed health care choices is what patients want and what will make the system operate more efficiently. For example, a recent survey found that patients want tools to help them determine their out-of-pocket costs for health care.[11] The Network for Excellence in Health Innovation reviewed existing literature and convened patient and

[8] Drug Channels, April 2018 http://www.drugchannels.net/2018/04/the-gross-to-net-rebate-bubble-topped.html
[9] IQVIA Institute. Medicine Use and Spending in the U.S.: A Review of 2017 and Outlook to 2022. April 2018.
[10] T. Koslov and E. Jex, "Price Transparency or TMI?" Federal Trade Commission, July 2, 2015.
[11] K. Fengler, J. Estupiñán, and K. Chan, "What Consumers Most Want from Health Insurers' Technology," strategy+business, June 29, 2016.

consumer groups as well clinicians and other thought leaders to develop recommendations for transparency that would help consumers. They recommended that consumers need information in three areas: choosing a plan, choosing a provider, and making treatment decisions. The FTC has said it is possible to provide these types of information "while avoiding broad disclosures of bids, prices, costs and other sensitive information that may chill competition among health care providers."

Payers and manufacturers have also supported modernizing FDA rules to allow more open communications in contract negotiations and to help with payer formulary planning.[12] Such changes could help to improve information sharing within the supply chain, without the potential for increasing market prices.

[12] AMCP Partnership Forum: Enabling the Exchange of Clinical and Economic Information Pre-FDA Approval. J Manag Care Spec Pharm. 2017;23(1):105-12.

Dana Hargunani – Oregon Health Authority

Joint Task Force on Fair Pricing of Prescription Drugs:
Pharmaceutical Supply Chain Responses:

Oregon Health Authority

5.17.18

How does your industry/stakeholder group interact with the development or movement of pharmaceutical products in Oregon?

State agency is a purchaser of pharmaceuticals.

1. Runs the **Oregon Prescription Drug Program (OPDP),** a program to make prescription drugs available at the lowest possible cost to participants in the program. The OPDP uses bulk purchasing leveraged through partnership with the Washington Prescription Drug Program in the formation of the NW Prescription Drug Consortium. This partnership enables Oregonians to benefit from more aggressive prescription drug pricing that has resulted from pooling our drug purchasing. Since 2007, groups that joined the Consortium have benefited from savings on their pharmacy benefit programs and benefitted from more aggressive prescription drug prices, 100% pass-through pricing on drug costs and manufacturer rebates, lower administrative costs and complete program transparency. The Consortium is available to any purchaser in these states and today serves over 1,000,000 individuals and purchasers in excess of $800 million in drugs each year.

2. **Medicaid Fee For Service (FFS) Pharmacy Program**:
   - The Medicaid pharmacy program is a State/Federal program that includes payment of medications for Oregon Medicaid beneficiaries. The state Medicaid program also manages the Practitioner Managed Prescription Drug Plan (PMPDP, or Preferred Drug List) via recommendations from the Pharmacy and Therapeutics Committee and supported by OHA's contractor the Oregon State University College of Pharmacy. Oregon contracts with a Pharmacy Benefit Administrator (DXC) to administer the pharmacy benefit for the FFS program, including mental health drugs, which are carved out of managed care.
   - Oregon participates in the Sovereign States Drug Consortium, which negotiates supplemental rebate agreements with the pharmaceutical industry on behalf of 12 states. These rebates are in addition to federally required rebates and reduce the net cost to the Medicaid agency.

3. **Utilize Minnesota Multistate Contracting Alliance for Pharmacy (MMCAP) and OPDP GPO purchasing options:** Joining national Group Purchasing Organizations to access special class of trade pricing for eligible institutions. Today, state facilities, public health and other state and local entities participate in our GPO arrangements and purchase in excess of $50 Million annually. We continue to explore new and innovative ways that Oregon can leverage the value of pooling our resources in order to extract greater benefit from buying in bulk from suppliers.

How does your industry/stakeholder group interact with the pricing of pharmaceutical products in Oregon? What pricing mechanisms are utilized?

Medicaid FFS:

- Federal rebates and supplemental rebates (negotiated through state and CCO pharmacy benefit managers) are transparent to the state (i.e., 100% of federal and supplemental rebates get paid directly to the states). These rebates are shared with the federal government according to state's Federal Medical Assistance percentage (FMAP).
- *Federal rebates* are set by the Medicaid Best Price Law, enacted in 1990, which requires drug manufacturers to charge the Medicaid program the lowest price they negotiate with any other buyer.
- Oregon participates in the Sovereign States Drug Consortium, which negotiates *supplemental rebate agreements* with the pharmaceutical industry on behalf of 12 states. These rebates are in addition to federally required rebates and reduce the net cost to the Medicaid agency.

OPDP:

- Contracts with a pharmacy program Master Administrator as part of our Co-administration of the Northwest Prescription Drug Consortium
- The current contract is with MODA. MODA contracts with Pharmacy Benefit Manager (PBM, MedImpact) and Group Purchasing Organizations to secure pharmacy discounts on behalf of the Northwest Prescription Drug Consortium.

What successes, difficulties or obstacles involving pricing transparency within the pharmaceutical supply chain impact your industry/stakeholder group?

Medicaid Drug Rebate Program, authorized by Section 1927 of the Social Security Act:

- Requires drug manufacturers to enter into a national rebate agreement with HHS in exchange for state Medicaid coverage of most of the manufacturer's drugs. Manufacturers are responsible for paying a rebate on those drugs for which payment was made under the state plan; these rebates are shared between states and the Federal government.
- Requirement of state to provide a pathway to coverage for nearly all FDA-approved drugs limits the states' leverage of market competition to get lowest pricing

Limited Manufacturer Incentives:

- Oregon participates in the Sovereign States Drug Consortium, which negotiates supplemental rebate agreements with the pharmaceutical industry on behalf of 12 states. These rebates are in addition to federally required rebates and reduce the net cost to the Medicaid agency. However, there is little incentive for a manufacturer to offer supplemental rebates unless there are other cost-effective treatments on the market.

Limited tools to limit low efficacy, high cost drugs:

- The Medicaid program also faces new challenges as a result of an increase in innovative treatments coming quickly to market under the 21st Century Cures Act. Products with limited evidence of efficacy and high price tags are being approved by the

FDA. Due to the Federal Medicaid Rebate Program, Medicaid programs are required to provide a pathway to coverage for these drugs.

340B Pricing and Entities:

- As the Medicaid Agency we forgo rebate on all claims that are presently marked as 340B. This is not an issue for FFS Medicaid as much as it is for Managed Medicaid. Currently 340B entities are not obligated to share 340B pricing with CCOs, and 340B entities appreciate a revenue from this side of the Medicaid program