Oppose SB 872 Impedes HB 4005—Oregon's Prescription Drug Price Transparency Law &

Ignores Task Force Recommendations

The organizations opposed to SB 872 and the -8 amendments don't often agree on issues at the capitol. We represent a broad, divergent array of stakeholders involved in the health care industry and specifically in the debates on pharmaceuticals. While many of us disagree about how to fix the challenges of increasing health care costs, we all agree that SB 872 is not the answer. SB 872 puts the cart before the horse by circumventing the process established just last session in HB 4005, the Prescription Drug Price Transparency legislation.

In 2018, the Oregon Legislature passed HB 4005, legislation viewed as possibly the most aggressive transparency legislation in the country. This program is barely off the ground and was meant to provide meaningful data to the Legislature, so it could better understand what causes price increases and guide its decision making to address those increases. The announcement launching the HB 4005 Prescription Drug Price Transparency program in March said, "It will help people better understand why drug prices increase, and help legislators make informed decisions on how to control rising costs."

The -8 amendments dramatically exceed many of the recommendations of the HB 4005 Task Force on the Fair Pricing of Prescription Drugs, insert completely new concepts into the discussion, and have had little to no input from the public or from those stakeholders who participated in the Task Force, in the HB 4005 Rulemaking process and who are most directly impacted by the cumbersome new reporting schemes envisioned in the bill.









Biotechnology

Organization













AMBIA









The HB 4005 Task Force on Fair Pricing of Prescription Drugs report to the Legislature included the following statement "...the complexity of the supply chain and the aggressive Task Force timeline presented limitations to engage in a comprehensive analysis of the recommendations. Due to these reasons, the recommendations outlined below will benefit from further analysis to assess their impact on the pharmaceutical supply chain, including the individual market participants impacted by each transparency strategy." As the stakeholders impacted by the recommended strategies, we can assure you, little if any work has been done to assess the impact to our industries and SB 872 goes far beyond the recommendations, which will be detrimental to those of us opposing SB 872.

SB 872 received one public hearing on March 20th. Stakeholders with concerns about the legislation were told the House was handling all of the pharmaceutical bills, and that SB 872 would not be moving, but the companion bill, HB 3093 would be the vehicle. With our efforts focused on the House Bill, a surprising turn of events occurred and instead, SB 872 was passed to Ways and Means with no further policy discussions. The sponsors advised "The sponsors will be seeking amendments to the current bill in an effort to ensure proper implementation of the recommendations. For more information regarding specific language or amendments, please refer to OLIS or contact the offices of the chief sponsors." Although several stakeholders provided amendment suggestions, virtually none of the recommendations were included in the original -2 amendment that was drafted May 28th and distributed to some stakeholders May 30th. The -8 amendment was just released on June 5th, and no amendment to SB 872 has been posted on OLIS.

SB 872 raises significant policy concerns, but the process concerns are overwhelming. Stakeholders were not convened for any substantive discussion until this week. The Ways and Means Committee is meant to discuss fiscal issues, not policy. Yet the proposed amendments to SB 872 introduce brand new concepts with policy implications that were never considered by the actual policy committee and were never part of the Task Force on Fair Pricing of Prescription Drugs recommendations. Further, the Task Force charge was to look at the entire supply chain. It specified manufacturers, insurers and PBMs, who are included in this legislation and who already have transparency components that were included in HB 4005 and the resulting rules. But it also specified distributors, wholesalers and retail pharmacies who do not have any transparency requirements in SB 872. Further, SB 872 includes provisions requiring transparency provisions for hospitals and practitioners who were not named in the supply chain charge.

Many stakeholders in this process have been diligently working to comply with HB 4005. Often, participants struggled with concerns about the inclusion of PBM rebates in reporting requirements for insurers because it potentially exceeded statutory authority. There were concerns about requiring all pharmaceutical manufacturers to report to DCBS and pay a fee as part of the program whether or not they had price increases covered. But the program is now up and running, and there will be more information available on manufacturer price increases and insurers handling of pharmaceuticals than ever before. Which is why it is extremely concerning that a number of the provisions of the bill go far beyond HB 4005 and far beyond the Task Force Regulations to specifically increase reporting requirements on the entities covered by HB 4005 and will substantially increase the workload as the DCBS is already trying to complete standup of the current program.

We urge you to Oppose SB 872. The discussion will continue on these issues with or without this legislation. A Task Force already exists that can continue discussions if Legislators believe that's necessary in advance of the information that will soon be provided by DCBS and the HB 4005 program. These decisions should not be made lightly, and they should not be made without a full understanding of how they will actually be implemented. SB 872 and the new and expanded concepts it would implement need a lot more work, and a lot more input from those who will be required to comply.

HB 4005 Timeline

- July 31, 2018 February 1, 2019 Rulemaking: Stakeholders participated in a labor intensive, time consuming process that included several revisions of the draft rules and extensive comments from all affected parties.
- March 15th New Drug Reports: DCBS began accepting reports for new drugs that enter the market above \$670. This will be a rolling process requiring manufacturers to submit a report no later than 30 days after a drug enters the market.
- May 13th Insurers Report Drug Costs: As part of their rate filings, insurers are required under HB 4005 to report to DCBS the top 25 drugs in three tiers including those that were most frequently prescribed, the most costly and causing the greatest increase in plan spending for the previous year, including any effect rebates or price concessions may have on premiums.
- **Mid-June New Drug Reports Expected:** The first reports from DCBS for the Prescription Drug Price Transparency program will be available in the next few weeks, but are not yet. This will be the first time the public and legislators see any results from the landmark HB 4005 transparency legislation.
- **July 1**st **Annual Price Increase Reports Due:** Manufacturers will report on drugs that had a net yearly increase of 10% or more for all drugs that cost \$100 or more for a one month supply or course of treatment.
- Fall, 2019 Insurer and Price Increase Reports Available: DCBS has indicated they will likely release these first reports from insurers and manufacturers at some point in the Fall. This will be the first time information about increases in pharmaceutical costs will be available through this program. The reporting requirements are more aggressive than any other state.
- **Fall, 2019 Public Hearing:** DCBS will hold their first annual public hearing on prescription drug prices and information reported to the department by pharmaceutical manufacturers, health insurers, and consumers who are able to report drug price increases to the new program.
- Dec. 15, 2019 First Annual Report Due: On or before this date, the information collected by the program and any recommendations for legislative changes to contain the cost or reduce the effect of prescription drugs will be available.
- March 15, 2020 Annual Price Increase Reports Due: In the second year of reporting, the timeline moves to and will remain in March.
- **December 31, 2020 Task Force on Fair Pricing of Prescription Drugs Sunsets:** HB 4005 also created a task force to examine transparency across the supply chain. The task force was required to submit a report to the Legislature by November 1, 2018 that **MAY** include recommendations for legislation, but also kept the task force operational until the end of 2020, after the first report is expected from the new program.

Specific Stakeholders Concerns on SB 872 and Amendments

It is important to note that there is not uniform agreement amongst all of the stakeholders on each of the points below. However, there is widespread agreement that the current rules that were put into place by HB 4005 should stay in place, and the Legislature should not pass a bill this session to change them. There is further agreement that SB 872 goes far beyond both the scope of the Task Force and the actual recommendations of the Task Force. Many of these issues have not been discussed in great detail and in the legislative context as it relates to the pharmacy supply chain, words really matter. This bill is in no way ready to be passed and cannot be modified this session to pass. The new policies would be extremely challenging to implement and could have serious unintended consequences and detrimental impacts. It would also likely overload DCBS and make the work they are doing on HB 4005 more challenging.

Below are a few of the concerns we have:

- There are changes to the reporting requirements, reporting windows and triggers that were just finalized in February for HB 4005. We should not make changes any of the reporting requirements or details covered by HB 4005 until we actually see allow HB 4005 to go into effect and can review the information.
- HB 4005 was limited to drugs that increased a net of 10% to avoid drugs that increased, then went back down. The goal is to focus on the drugs that increase by 10% or more as a starting point and we should not change the standards.
- SB 872 eliminates the ability for PEBB, OEBB, OPDP or CCOs the contract with a PBM unless it is on a fee-only basis and the pharmacy benefit manager passes through rebates, incentives or discounts offered by the manufacturer. The Task Force specified that state sponsored health plans should evaluate the utilization of these types of contracts with PBM's but was also very clear that if a state sponsored plan can demonstrate it can obtain greater savings with the shared rebate model they should be able to do so. SB 872 ignores the recommendation and simply requires the policy without any evaluation of the current arrangements of CCOs and others today.
- Net increase was a term debated at length in HB 4005 rulemaking. We should not revisit in now. To examine results year over year, you need consistency in determination about what you are measuring. Net should stay in statute as it is now defined in rule.
- The patient assistance reporting requirements are also expanded beyond HB 4005 which is inappropriate at this time. We should not revisit HB 4005 at this time when we have not received even one report with information yet.
- DCBS had extensive rulemaking on HB 4005 and required all manufacturers to pay DCBS a fee to cover the cost of the current program even if they aren't subject to submitting a report because their drug prices have increased. SB 872 requires manufacturers to formally register with DCBS and allows them to be assessed additional fees. We need to let the process in place work before making changes.
- There are broad allowances for DCBS to request additional information from manufacturers, even those who are not subject to current reporting requirements laid out in HB 4005. This would only increase the workload for DCBS and take their focus away from processing and understanding the information submitted by those manufacturers who have increased their prices by 10% or more.
- Providing blanket immunity to the department, it's officers, employees and agents for disclosure of trade secrets gives no protection that trade secrets will be kept as such. This provision is not responsible and would be susceptible to legal challenge.

- Much of the information requested of insurers to post will be challenging or confusing to consumers.
- Amendments regarding notices of formulary changes were not made consistently across all health insurance markets.
- There should not be a separate filing for insurers to DCBS with a narrative about how we develop our formulary. We already submit a significant amount of information through our rate filing.
- There is no systematic way to populate the information related to the requirement to list and keep up to date for each brand drug whether a generic alternative is available.
- Provisions of the website posting requirements for insurers would potentially require manual review and editing and would certainly be expensive technology projects for each insurer.
- Similar to concerns about changes to HB 4005 reporting for manufacturers, changes should not be made for insurers at this time either. There is no justification for increasing the number of drugs insurers will report on from 75 to 200. There has not even been a report out yet on the current insurer reporting and DCBS needs time to implement the current system before making changes.
- Health plans do not instantaneously receive rebates from manufacturers. They are often received 2-3 years after the drug is filled which makes the new reporting requirement challenging at best.
- There are reporting requirements for manufacturers related to PBMs that would be impossible for a manufacturer to report accurately.
- Any changes to the HB 4005 reporting process will add administrative burden to insurers, additional
 work for DCBS when they should focus on the highest cost drugs at this point. We need to give HB
 4005 time.
- We do not know, necessarily, the "price" of a drug and are unclear what "price" actually refers to.
- SB 872 has insurers reporting to DCBS "Any drug for which the price is \$10,000 or more..." That language would suggest every insurer in Oregon report to DCBS all drugs that cost more than \$10,000. Insurers do not set the prices and should not be reporting prices to DCBS, especially in such a duplicative way that has no relation to our formulary.
- Out of pocket costs can vary widely based on the health plan that the enrollee is in and whether the drug is subject to a flat copay or a coinsurance that varies with the price of the drug. This information would likely not be helpful.
- There is confusion about what is covered in SB 872 when there has been a separate group meeting on HB 2185. The language is not consistent at all.
- The average cost paid by the carrier to a PBM or TPA will not be discernable on a drug by drug basis
 if the carrier pays the PBM or TPA on a fee only basis (which is required by other sections of the bill
 for state sponsored plans.
- Reporting costs paid to a PBM for drugs that are discernable on a drug-by-drug basis, this reporting
 would be equivalent to requiring a carrier to report its contracted rates to ever doctor in its network.
 The information is highly proprietary and trade secret but would also provide little, if any, usable
 information on the cost of drugs to consumers.

- There are limited confidentiality protections in the new provisions of SB 872 reporting for insurers because it's separated from our current filing that is done through the rate filing process.
- It's unclear why providers and hospitals are established at a 3-month reporting requirement when all others are reporting yearly.
- We do not believe the provider or hospital would have access to the "price" to report the 50 most expensive drugs they prescribed.
- It is unclear who actually does this reporting for a medical provider. Are the reports for each provider? By facility? This section has not been explored in detail and is confusing.
- If these drugs are just prescribed to patients, it makes no sense that the medical provider would report the amount billed to an insurer.
- Independent specialty practice providers would be overly burdened by these new regulations and reporting requirements and should not be included in the bill.
- The data independent providers would submit would not be helpful to the discussion of drug prices.
- Health professionals don't typically sell drugs, they administer or dispense. Because pharmacists are able to prescribe now, they might be caught in an unintended situation as a result of this section.
- The definition of health professional is so broad, a pharmacist could be in "independent practice" and fall under the definition.
- There are several places throughout the bill where terms such as "most expensive" or "highest priced" which are unclear. They could mean purchase price or volume.
- Definition of "rebate" is not a commonly recognized or agreed upon definition.
- The report specified rebates should be aggregated. SB 872 ignores that advice.
- The release of rebate information would be competitively disastrous and protection of information is uncertain as noted above.
- Rebate information becoming public will likely drive prices up, not down.
- Insurers using a PBM will have information publicly available that other insurers potentially will not.
- Even aggregate reporting an individual PBM's rebate information can be problematic because some PBMs have only one insurer as a client in Oregon, meaning the rebate info would be directly tied to that insurer.
- PBMs should not be reporting Wholesale Acquisition Costs to DCBS. PBMs do not set the WAC and manufacturers are already required to report WAC to DCBS. DCBS would have multiple entities reporting the exact same information which is a waste of time for everybody.
- SB 872 requires insurers to report the "average cost" paid by the insurer to a PBM. It's unclear what this means. Another example of the wording challenges throughout the bill.
- There remains significant concerns related to SB 872's failure to protect manufacturer identified and propriety company information as required by state and federal law, which the -2 and -8 amendments exacerbate.

- Across the entire bill, there are different reporting requirements at different levels for different parts of the system that should not exist. If the state is required to report 10 and CCOs are required to report 10, medical providers and insurers should report 10. The timelines should all line up and be consistent so that trends can be identified.
- There is literally no strategy around the goal of this legislation. Simply requiring a massive amount of reporting by everybody across the spectrum will not help lower drug prices and could in fact increase them. Inundating DCBS with additional information is only going to make their analysis of HB 4005 data slower and less productive. SB 872 should not pass this session given the concerns expressed by disparate interests across the spectrum of this issue.

Please oppose SB 872

For additional information contact:

Elise Brown:	503.970.1235
Fawn Barrie:	503.580.5487
Shawn Miller:	503.558.7738
Rocky Dallum:	503.830.5098
Matt Markee:	503.510.3371
Jim Gardner:	503.740.7002
Kelsey Wilson:	503.351.6699
Vince Porter:	503.896.8643
Elizabeth Remley:	503.841.3862
Anne Murray:	503.508.3448
Hasina Wittenberg:	503.708.8079