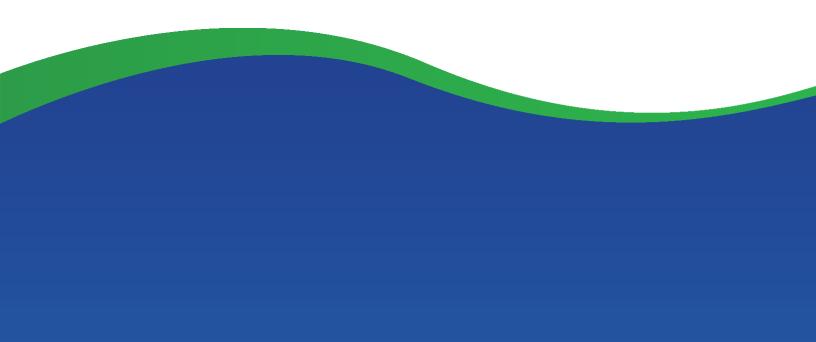


Task Force on Pharmacy Benefit Management Reporting

Report to the Legislature

February 2020



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I. Executive Summary

The California Department of Managed Health Care (DMHC) protects consumers' health care rights and ensures a stable health care delivery system. As part of this mission, the DMHC licenses and regulates health care service plans (health plans) under the Knox-Keene Health Care Service Plan Act of 1975. The DMHC regulates the vast majority of commercial health plans and products in the large group, small group, and individual markets, including most of the health plans that participate in Covered California.

Assembly Bill (AB) 315 (Wood, Chapter 905, Statutes of 2018), as codified in Health and Safety Code section 1385.007, required the DMHC to convene a Task Force on Pharmacy Benefit Management (PBM) Reporting. The purpose of the Task Force was to determine "what information related to pharmaceutical costs, if any, the [DMHC] should require to be reported by health care service plans or their contracted pharmacy benefit managers." The Legislature recognized that any recommendation would be in addition to information already reported pursuant to Senate Bill (SB) 17 (Hernandez, Chapter 603, Statutes of 2017) reporting requirements.

From July to December 2019, the DMHC facilitated a series of public Task Force meetings to develop the recommendations contained in this report and presented below.

Task Force Recommendations

In order to increase transparency and understand how PBMs impact the cost of prescription drugs, the Task Force recommends requiring PBMs to report data related to the services PBMs provide for commercial health plans directly to the DMHC. PBMs would be required to report drug-specific data as well as aggregated information on PBMs, including revenue and expense information.

At the drug level, the Task Force recommends requiring PBMs to report the following:

- A list of the 100 most costly drugs, the 100 most frequently prescribed drugs, and the 100 highest revenue-producing drugs, grouped by generic, brand, specialty, and other.
- For each drug that falls into the above categories:
 - The pharmacy type used to fill the drug prescription, such as integrated, chain, independent, specialty, and mail order pharmacies.
 - Pricing and rebate information, including the amount of rebate the PBM receives from the manufacturer, the amount of rebate the PBM passes to the health plan, the amount the health plan pays the PBM, and the amount the PBM pays the pharmacy.

At an aggregated level, the Task Force recommends gathering information on PBMs, including revenue and expense information, to determine PBM market impact and the value PBMs provide to consumers. This information would include reporting on the following:

- The health plans with which the PBM contracts, the scope of services provided to the health plan, and the number of enrollees served by the PBM.
- PBM revenue, including revenue from manufacturers, health plans, pharmacies, and other revenue.
- PBM expenses, including payments to pharmacies, claims processing, special programs, administration, and other expenses.

II. Introduction/Background

AB 315 was enacted in 2018 with the goal of increasing oversight and transparency regarding Pharmacy Benefit Managers (PBMs). PBMs are health care companies that contract with health plans to manage pharmacy benefits and negotiate manufacturer rebates. Notable provisions of AB 315 include:

- Pharmacists must inform a consumer at the point of sale if the retail price for a covered prescription is less than the consumer's cost-sharing. This responds to concerns that PBMs include "gag clauses" in their contracts with pharmacies that prohibit pharmacists from providing this information.
- Establishes contracting and disclosure requirements for PBMs and purchasers. A PBM must notify a purchaser of any conflict of interest and must disclose any material changes in contract terms to a contracted pharmacy. When requested by a purchaser, PBMs must make confidential disclosures on a variety of issues, including rebates, fees, and utilization discounts.
- Codification of the existing standard that health plans are ultimately responsible for the delivery of pharmacy benefits, even when such benefits are delegated to a PBM. The bill added a variety of Knox-Keene Act provisions with specific requirements for contracts between health plans and PBMs.
- PBMs must register with the DMHC. However, this requirement does not give the DMHC the authority to regulate PBMs directly in the way that the DMHC regulates health plans.
- Establishes a three-year pilot project, in Riverside and Sonoma counties, to prohibit a health plan from limiting the quantity of a prescribed medication an enrollee can receive at a retail pharmacy if a larger quantity is available via mail order.

In addition to the provisions described above, AB 315 required the DMHC to establish a Task Force on PBM Reporting and provide a report to the Legislature with the Task Force's findings. The purpose of the Task Force was to determine what information, if any, health plans or their contracted PBMs should report to the DMHC. The bill required the DMHC to select Task Force members and convene a meeting by July 1, 2019. The Task Force was to consider recommendations of additional data elements, including:

- Wholesale acquisition costs of pharmaceuticals.
- Rebates obtained by the health plan or PBM from pharmaceutical manufacturers.
- Payments to network pharmacies.
- Exclusivity arrangements between health plans or contracted PBMs and manufacturers.

The Task Force was required to consider information already being reported by health plans to the DMHC pursuant to SB 17. SB 17 requires commercial health plans to report annually on the following:

- The 25 prescription drugs most frequently prescribed to health plan enrollees.
- The 25 most costly prescription drugs by total annual health plan spending.
- The 25 prescription drugs with the highest year-over-year increase in total annual health plan spending.
- The overall impact of prescription drug costs on health care premiums.

The DMHC annually aggregates and summarizes the information submitted by health plans pursuant to SB 17 in its *Prescription Drug Cost Transparency Report*. The DMHC's most recent *Prescription Drug Cost Transparency Report* demonstrated the significant impact of prescription drug costs on health plan premiums.¹ For example, health plans paid nearly \$9.1 billion for prescription drugs in 2018, an increase of more than \$400 million from 2017. Health plans also reported that manufacturer drug rebates totaled approximately \$1.058 billion or about 12 percent of the \$9.1 billion spent on prescription drugs in 2018.

Although the *Prescription Drug Cost Transparency Report* includes information on manufacturer rebates, the report contains limited information on the role PBMs play in the prescription drug market.

¹ *Prescription Drug Cost Transparency Report*, Measurement Year 2018, available at: <u>http://dmhc.ca.gov/Portals/0/Docs/DO/2018SB17PrescriptionDrugTransparencyReport</u>.<u>pdf</u>

III. The PBM Task Force and Summary of Meetings

Pursuant to the requirements of AB 315, in early 2019 the DMHC began the recruitment and selection process for Task Force members. Eight members, representing pharmacies, health plans, consumers, and non-profit organizations, were selected. The Task Force members are:

- Sherri Cherman, PharmD, President and CEO, Elements Pharmacy.
- Shane Desselle, RPh, PhD, FAPhA, President, Applied Pharmacy Solutions.
- Lisa Ghotbi, PharmD, Director of Pharmacy Services, San Francisco Health Plan.
- Clint Hopkins, PharmD, Owner and CEO, Pucci's Pharmacy.
- Patrick Robinson, RPh, MBA, Pharmacy Manager, Sutter Health Plus.
- Neeraj Sood, PhD, Professor and Vice Dean for Research at the USC Price School of Public Policy.
- John Stenerson, Deputy Executive Officer, Self-Insured Schools of California.
- Nicole Thibeau, PharmD, AAHIVP, Director, Pharmacy Services, Los Angeles LGBT Center.

From July to December 2019, the DMHC held a series of Task Force meetings. Early meetings focused on educating Task Force members and interested stakeholders on the legislative mandate before the Task Force. Assembly Member Jim Wood, the author of AB 315, presented at the first Task Force meeting and described the impetus for the bill and the need for greater PBM transparency.

The Task Force heard presentations from a variety of sources, including DMHC staff, the California Office of Statewide Health Planning and Development (OSHPD), the Pharmaceutical Care Management Association (PCMA), the California Association of Health Plans (CAHP), the California Pharmacists Association, and representatives from pharmacies and the life sciences.

The Role of and Concerns Regarding PBMs

Throughout the Task Force meetings, various presenters discussed the role of PBMs in the complex pharmaceutical supply chain. It was noted that PBMs play no role in the physical distribution of prescription drugs. Rather, drugs move from the manufacturer, to the distributor, to the pharmacy, to the consumer. PBMs help health plans manage their drug benefits through negotiating or contracting with manufacturers and/or pharmacies on behalf of their contracted health plans.

It was established there is a lack of transparency regarding the value PBMs bring to the health care industry and how they help to reduce prescription drug costs. There is also a lack of transparency regarding how PBMs make money and how much money they make.

Sources of PBM revenue, and associated concerns, include:

- PBMs receive rebates from manufactures for certain prescription drugs. The "retained rebate" is the amount of rebate the PBM receives but does *not* pass along to the plan. Even health plans are often unaware of the amount of the PBM's retained rebate. Additionally, rebates may offer perverse incentives, as higher cost drugs could mean higher rebates for the PBM.
- PBMs pay pharmacies on behalf of health plans. "Spread pricing" is the difference between the payment the PBM negotiates with the health plan and the amount the PBM pays the pharmacy. When a PBM pays the pharmacy less than the health plan pays the PBM, the PBM makes money on the difference (the "spread"). As with retained rebate amounts, the "spread" is often known only to the PBM and may contribute to rising prescription drug costs.
- PBMs receive negotiated payments (or fees) from manufacturers to reimburse pharmacies and cover the PBM's administrative expenses. The amount of these fees is unknown. PBMs may also receive per member per month payments from the health plans with which they contract.
- Another way PBMs earn revenue is via "post-transaction fees", including "clawbacks" from, and audits of, pharmacies. These post-transaction fees occur when the PBM retroactively takes back the entire amount or a portion of the amount it paid the pharmacy for dispensing a drug. These fees are often assessed due to minor infractions that do not rise to the level of violations of state or federal law. For example, a PBM may take back fees (or offset future claims) because a prescription lacks a physical address and therefore does not meet the standards established in the contract between the PBM and the pharmacy. Advocates suggest PBMs may focus these post-transaction fees on expensive drugs in order to recoup the largest amount of money possible.

The PBM marketplace appears to be highly concentrated, with the top three PBMs representing approximately 75% of covered lives in California. Some suggest that this concentration is evidence of a stable and functioning market, whereas others believe it is evidence that the largest PBMs have a stranglehold on the market and therefore wield too much negotiating power. Stakeholders attending the Task Force meetings asserted that dominant PBMs may negotiate higher rebates only to keep the bulk of the rebate. By not passing the rebate on to health plans, consumers may be adversely affected by higher costs.

Market concentration is seen not only across the marketplace, but also vertically within the supply chain. Some PBMs own their own pharmacies, referred to as an "integrated pharmacy." This may result in misaligned incentives, as a PBM may favor an integrated pharmacy even if competing pharmacies have lower costs. Additionally, the Task Force heard from pharmacy representatives who stated PBMs may improperly utilize prescription information to steer patients who are prescribed high-cost drugs to the PBM's integrated pharmacies. Some PBMs and health plans have common ownership which could lead to PBMs increasing drug costs to rival health plans.

While much of the discussion at the Task Force meetings focused on the potentially negative impact of PBMs, the Task Force also sought to hear from diverse viewpoints.

For example, they heard comments and presentations from the PCMA, which represents PBMs. PCMA claims PBMs add value by aggregating the buying power of millions of enrollees, thereby getting better contract terms and lower drug prices. PBMs may also help with utilization management, ensuring adherence and decreasing medication error.

PCMA cited a 2018 Office of Inspector General (OIG) report indicating that, despite rebates for brand name drugs, utilization of brand name drugs in Medicare Part D decreased between 2011 and 2015.² Generic drugs, which make up the majority of the drugs dispensed, are generally not eligible for rebates. PCMA also cited a U.S. Government Accountability Office (GAO) report finding that 99.6% of rebates for Medicare Part D prescriptions are passed on to plan sponsors and, ultimately, consumers.³ Finally, PCMA stated there are 66 PBMs active in California which shows the market is not overly concentrated.

While PBMs were the focus of the Task Force, PCMA suggested the Task Force should consider the impact of Pharmacy Services Administrative Organizations (PSAOs) on prescription drug costs. PSAOs contract with independent pharmacies to pool their purchasing power and improve negotiations with payors. Similar to the concern over lack of PBM transparency, PCMA suggested a concern over lack of PSAO transparency.

The Task Force also heard from a representative from CAHP, who encouraged the Task Force to consider that health plans need flexibility to negotiate contracts with PBMs on behalf of their members. CAHP suggested that gathering additional data elements could have the unintended consequence of chilling contracting. CAHP also asked the Task Force to ensure that additional reporting requirements consider the confidential nature of health plan contracts.

² Increases in Reimbursement for Brand-Name Drugs in Part D, Office of the Inspector General, available at: <u>https://oig.hhs.gov/oei/reports/oei-03-15-00080.pdf</u>

³ Medicare Part D: Use of Pharmacy Benefit Managers and Efforts to Manage Drug Expenditures and Utilization, Government Accountability Office, available at: <u>https://www.gao.gov/assets/710/700259.pdf</u>

IV. Task Force Recommendations

The presentations and public comments made to the Task Force stressed the need for additional PBM transparency to help understand what is driving prescription drug cost increases and determine how consumers can be better protected. The Task Force discussed the need for PBM data at the drug level to determine whether and how PBMs impact specific drug prices. It was suggested PBMs may target specific drugs for posttransaction fees and may steer consumers who are prescribed high-cost drugs to the PBM's integrated pharmacy. The Task Force also discussed the need for information on PBM revenue and expenses, as this information is opaque not only to the consumer, but also to the health plans, pharmacies, and manufacturers with which the PBM works. Gathering data on the sources of revenue and expenses will help demonstrate the value PBMs bring to the marketplace.

As noted earlier, existing law (SB 17) requires health plans to report information on the 25 most costly drugs, the 25 most frequently prescribed drugs, and 25 drugs with the highest year-over-year increase in the categories of generic, brand, and specialty drugs. The Task Force recommends requiring PBMs to submit similar categories of drug-specific data. The Task Force determined PBM reporting requirements should align with current health plan reporting requirements under SB 17 whenever possible.⁴

Require PBM Reporting on Drug Specific Information

To promote transparency, the Task Force recommends requiring PBMs to submit the following drug-specific information:

- Require PBM reporting of the top 100 most costly, 100 most frequently prescribed, and 100 highest revenue-producing drugs. Requiring PBMs to report on the top 100 of these categories would allow for comparison with the health plan data reported under SB 17 and would also allow for better trend analysis year-over-year. PBM reporting on the highest revenue-producing drugs would help demonstrate whether and to what extent there is a correlation between drugs that produce the highest revenue for PBMs and drugs that are most frequently prescribed, most costly, or have the highest year-over-year increase.
- Require PBMs to report drugs by the categories of generic, brand, specialty, and "other." Separating the drugs by generic, brand and specialty would align PBM reporting with health plan reporting under SB 17. Adding a new category of "other" would capture supplies and other covered services related to prescriptions. For example, diabetic testing strips would fall into the category of "other." These are generally covered as a health plan prescription drug benefit and often generate rebates.

⁴ SB 17 Glossary available at:

http://dmhc.ca.gov/Portals/0/Docs/DO/091219PBMReportingTaskForceMeetingNotes. pdf?ver=2019

- Require PBM reporting on the pharmacy source for each drug reported. Pharmacy source refers to the type of pharmacy used by enrollees to obtain a prescription drug. Pharmacy source includes integrated, chain, independent, specialty, and mail order pharmacies. PBM reporting on pharmacy source would demonstrate the volume of prescription drugs filled at different types of pharmacies, whether certain types of pharmacies are dominating the market and how these market dynamics ultimately impact costs. This data could also shed light on how enrollees access pharmacies and their relationships with pharmacists.
- Require PBM reporting on specific cost-related information for each drug reported, specifically the amount of rebate the PBM retains and whether the savings are passed on to the health plan or enrollee. Such data would include the following:
 - The amount of rebate the PBM receives from the manufacturer,
 - The amount of rebate the PBM passes to the health plan,
 - The amount the health plan pays the PBM, and
 - The amount the PBM pays the pharmacy.

Require Aggregated PBM Reporting, Including Reporting on Revenue and Costs

The Task Force recommends gathering additional information from the PBMs not tied to particular drugs. The Task Force's first recommendation was to require reporting additional information on the health plans with which the PBM contracts, the scope of services provided to the health plan, and the number of enrollees served by the PBM. This information should be provided for the most recent 5-year period. This data will demonstrate how many and what types of services PBMs provide to health plan enrollees and whether there has been market consolidation of the PBM industry over the course of the last five years.

The Task Force recommends PBMs report their revenue and expenses to help demonstrate the value PBMs bring and the role they play in the increasing cost of prescription drugs. Under existing law, health plans report and meet standards for medical loss ratio. Medical loss ratio for health plans is used to assess how much premium dollar is used to pay for actual medical expenses versus administration costs and profit. The Task Force recommends gathering similar revenue and expense information from PBMs to better understand PBM profits and whether these profits contribute to the rising cost of prescription drugs.

The Task Force recommends collecting the following sources of PBM revenue:

- Revenue from manufacturers, including administration fees and rebates.
- Revenue from health plans, including claims processing fees, special program fees, and administrative fees.
- Revenue from pharmacies, including transaction fees and post-transaction fees by category, e.g., integrated, chain, independent, specialty, and mail order.
- All other revenue.

The Task Force recommends collecting the following PBM expenses:

- Payments to pharmacies.
- Claims processing costs.
- Costs for special programs, including adherence and medical management programs.
- Administrative expenses.
- All other expenses.

Potential Challenges

The Task Force recommendations are comprehensive and would require the DMHC to gather a large amount of data from PBMs. Health plans and PBMs have expressed concerns regarding the administrative burden of reporting this data, which may be more challenging for smaller PBMs. There may also be challenges for national PBMs to provide data only on their California commercial market. Confidentiality of the collected data, especially payment rates and contract terms between health plans and PBMs, was also a significant concern.

In order to minimize administrative burden, existing resources should be leveraged to ensure the DMHC is not collecting data that is already available from another source, such as the data submitted for the *Prescription Drug Cost Transparency Report*, OSHPD's Healthcare Payments Database, and health plan rate filings. To address confidentiality concerns, the DMHC notes that all data reported in its *Prescription Drug Cost Transparency Report* is aggregated and no specific health plan or PBM data is shared. The Task Force recommends this level of confidentiality be extended to all Task Force recommendations.

V. Conclusion

The Task Force meetings confirmed that additional information is needed to more fully understand the cause of rising prescription drug costs and to increase transparency. To that end, the Task Force recommends requiring PBMs to report data directly to the DMHC.

PBMs would report drug-specific data as well as aggregate information on PBM revenue and expenses. At the drug level, reporting by PBMs would be comparable to the data already submitted by health plans pursuant to SB 17. PBM reporting requirements should include the highest revenue-producing drugs as well as information on the impact of integrated pharmacies and the value of rebates. The Task Force believes this type of data will help bring transparency to concerns related to spread pricing and retained rebates.

The Task Force also recommends gathering information from PBMs that demonstrates the value that PBMs are bringing to health plan enrollees by focusing on PBM revenue and expenses.

