Pharmacy Benefit Management Reporting Task Force Meeting
September 12, 2019
Meeting Notes

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

Department of Managed Health Care Staff Present:
Shelley Rouillard, Director
Pritika Dutt, Deputy Director, Office of Financial Review
Wayne Thomas, Chief Life Actuary, Office of Financial Review

Facilitator:
Yolanda Richardson, CEO, Teloiv Consulting

1. Welcome and Introductions - Agenda

Yolanda Richardson opened the meeting by welcoming the Task Force members and members of the public. She asked the Task Force members to introduce themselves. Ms. Richardson reminded the Task Force members that the Task Force's charge is to determine what additional data elements the Department of Managed Health Care (DMHC) should require health care service plans or their contracted Pharmacy Benefit Managers (PBM) to report in addition to the current data reporting requirements. Ms. Richardson then asked Shelley Rouillard, Director of the DMHC, for her opening remarks.

2. Opening Remarks

Ms. Rouillard welcomed the Task Force members and audience, and thanked the Task Force for the robust discussion at the last meeting. She noted the Task Force members offered a lot of suggestions for things to consider for PBM reporting. However, some of the ideas were outside of the scope of the Task Force. Ms. Rouillard reminded the Task Force members to focus on those data elements that might increase transparency around pharmacy costs and PBM remuneration. Through this process we hope to shed light on PBM payment arrangements.

Ms. Richardson provided an overview of the agenda and asked the Task Force and audience if they had any questions or comments.

3. Current Data Requirements

Pritika Dutt, DMHC Deputy Director in the Office of Financial Review, provided a detailed overview of the data elements collected from the health plans for the DMHC's Prescription Drug Cost Transparency Reporting Template which is required under Senate Bill (SB) 17 (Chapter 603, Statutes of 2017).

Sherri Cherman asked how long the DMHC has been collecting this data and whether there is any analysis performed. She stated a summary of any trends or other information could be useful to the Task Force. Ms. Dutt explained that last year was the first year plans were required to report and the next data submission is due October 1, 2019. Ms. Dutt added the Prescription Drug Cost Transparency Report (SB 17) from the first year is available on the DMHC's website, and the DMHC will be able to begin trending after more data are received.

Nicole Thibeau asked for the makeup of the group that analyzes the data, and whether one of the members is a pharmacist. She remarked that there is a lot of crossover in the list, as some drugs were reported as both generic and as specialty. She asked if it is possible for the same drugs to be reported in multiple areas. Ms. Dutt replied that actuaries and a consulting group analyze the data. The data are reported by the health plans, so it is possible that one plan may list a drug as generic and another plan could list the drug as specialty. The DMHC is considering ways to work through this.

Dr. Neeraj Sood asked what the "total plan spend" is based on and how the plans define what they are paying a pharmacy on behalf of plan members. Ms. Dutt said the reporting instructions include a SB 17 Glossary, which defines each term. Annual plan spending is defined as what the plan paid on all health care services including enrollee copays. In addition to the top 25 drug information, there are two fields on the last page of the template that capture spending information for all prescription drug costs for the year - the total annual plan spending, which includes copays, and the total paid prescription plan costs, which excludes copays. Total paid prescription plan cost shows what the plan paid for prescription drugs. However, it does not factor in any manufacturer rebates.

Dr. Sood asked if the plan reports the list price or the price actually paid to the pharmacy. He commented that the premium should include what the plan is spending plus its administrative costs and profits. Ms. Dutt explained that plans should be reporting what they paid the pharmacy because the goal is to capture the amount of the annual premium attributable to pharmacy costs.

Lisa Ghotbi asked whether this represents an aggregate view of the health plan's entire process. Although the DMHC asks for the list of PBMs, plans are not required to report on the number of members who are covered under each PBM. She suggested this is a potential opportunity for additional data collection. She asked whether the DMHC has

thoughts about asking for the member spend (out-of-pocket) amount. This might add some transparency to what the plan is paying versus what the member is paying. She also noted the definitions need to be clear; some tabs ask for plan paid and some tabs ask for plan spend.

Clint Hopkins asked if the DMHC validated the plan's data through an audit. Ms. Rouillard replied the plans attest under penalty of perjury that the data they submitted are accurate, but that the DMHC has not audited the data.

Dr. Sood suggested the DMHC collect drug level rebate information.

Patrick Robinson asked whether the Task Force could recommend changes to any of this reporting and should they use the SB 17 template as the basis for what should be collected. Ms. Rouillard responded the Task Force members should be recommending data that would supplement what the DMHC already collects, and that the Department is happy to take the Task Force members' recommendations on the SB 17 template.

Ms. Ghotbi remarked that diabetic testing strips and other supplies are also a significant cost to health plans, and just collecting the brand/generic/specialty omits this cost. She also suggested all the forms include an "other" category.

Ms. Thibeau commented it is interesting that specialty drugs are a huge cost to the health plans, but the lowest percentage cost to the patient. This creates a lack of transparency to the patient of the actual cost of specialty drugs and brand name drugs which may create an incentive for patients not to use generics because the out of pocket cost to the patient is higher.

Scott Christman, Deputy Director and Chief Information Officer, Office of Statewide Health Planning and Development (OSHPD), presented on OSHPD's requirements under SB 17 and the ongoing work that is being done around Assembly Bill (AB) 1810 (Chapter 34, Statutes of 2018) relative to the Healthcare Payments Database (HPD). He stated OSHPD's functions include collection of data related to hospital-based cost transparency and hospital financial disclosure data. Mr. Christman recommended the Task Force:

- Collect data elements by 11-digit National Drug Code (NDC)
    - Separate 11-digit NDC into 3 data elements:
        - 5-digit Labeler Code, 4-digit Product Code, 2-digit Packaging Size Code
    - Separate Product Description into 4 separate data elements:
        - Drug name, dosage strength, dosage form, packaging size
    - Total units sold/reimbursed in previous year
    - Total rebate previous year
    - Portion of rebate kept previous year
    - Total amount actually paid to pharmacies in previous year
    - Total amount received/reimbursed by health plan

Mr. Robinson commented that the Food and Drug Administration (FDA) is running out of NDC numbers and OSHPD might plan for a different type of NDC number.

Dr. Sood asked whether the DMHC can require reporting from self-insured plans under the Employee Retirement Income Security Act (ERISA). Ms. Rouillard answered no because these plans are not under the DMHC's jurisdiction.

Ms. Ghotbi asked whether pharmacy rebates were to be collected under AB 1810. Mr. Christman answered the legislation mentions rebates, but the statute is fairly short and basically directs OSHPD to write a legislative report.

Ms. Cherman asked whether, regarding the total amount actually paid to pharmacies in the previous year, OSHPD gave any thought to parsing the data out further by vertically integrated pharmacies versus non-integrated pharmacies. She stated there is a huge discrepancy in the amounts pharmacies receive. Mr. Christman said he appreciated the suggestion, but it had not been considered.

Public Comments

Danny Martinez, California Pharmacists Association (CPhA), asked if manufacturers are complying with the 60-day advance notice reporting required by SB 17 and how OSHPD would know if a manufacturer was not complying. Mr. Christman answered there is no enforcement language in the statute.

4. California Landscape: Health Plans and PBMs

Bill Head, Pharmaceutical Care Management Association (PCMA), presented on the contractual relationships between health plans and PBMs, and the functions that health plans can delegate to PBMs.

Mr. Head addressed several of the questions raised by the Task Force at the last meeting, including the disclosure of the spread on generic drugs and the different fees associated with rebates. Mr. Head said generics drive down the price of prescription drugs and there are no rebates on generics. He stated any administrative fees are received from manufacturers. The Task Force noted that there are no rebates on generics to beneficiaries/patients, but there may be other rebates involved in the supply chain.

Dr. Sood asked how PBMs make money based on their services. Mr. Head replied PBMs are generally paid on a per member per month (PMPM) basis.

John Stenerson asked about a new drug on the market called Duexis, which is a combination of Ibuprofen and Pepcid. Separately, these drugs are available for pennies but Duexis is very expensive. He asked why a PBM managing a benefit for a purchaser would include this drug on the formulary. Mr. Head answered he was unaware of this specific drug and stated it is up to the physician to prescribe.

Ms. Ghotbi commented there is a U.S. Government Accountability Office (GAO) report that says generic spread is the major revenue source for PBMs and health plans don't have access to this information.

Ms. Cherman asked for clarification on what fees were included in the chart titled "Where the Rx Dollars Go." Mr. Head responded that he would find out.

Ms. Ghotbi asked for more information on Direct and Indirect Remuneration (DIR) fees. Mr. Head responded that DIR is a Medicare program that created incentives for patients around medication adherence. Ms. Ghotbi asked whether this model is being applied to commercial insurance and if there is any reporting around what is paid to pharmacies versus what is recouped from pharmacies. Mr. Head responded that he is not aware of any public reporting. Ms. Ghotbi replied that those programs are leading to claw-backs for pharmacies and it is unclear to the pharmacy why the claw-backs are being applied.

Public Comment

Mr. Martinez, CPhA, asked where the dollars go when there is an error, correction, or claw-back related to performance guarantees and audit rights that protect the plans. Mr. Head responded the audit rights are between the plan and the PBM, so the plan knows what the pharmacy paid the PBM.

Mr. Martinez also asked about the slide titled "Pharmaceutical Supply Chain Profit Margins." He noted Dr. Sood created this graph and asked whether Dr. Sood feels it is an accurate representation of the industry. Dr. Sood answered the data are based on U.S. Securities and Exchange Commission (SEC) filings of the publicly traded firms and the figure represents publicly reported profit margins. There are a lot of caveats. For example, for manufacturers, one would need to separate out the U.S. business versus foreign business, among other considerations. This is a 30,000-foot view of the industry, and there are a lot of assumptions involved.

5. Information the DMHC Should Consider for PBM Reporting: A Facilitated Discussion with Task Force Members

Ms. Richardson summarized data elements suggested by the Task Force during the meeting:

- Plan spend versus plan paid
- Rebate information by drug
- Consistent definitions and instructions for specialty, brand name, and generic drugs, and the addition of an "other" category
- Costs related to specialty drugs and how they differ from generics
- Vertically integrated versus independent pharmacy prices and how they differ

Dr. Sood reminded the Task Force not to ask for data for the sake of the data but to define the questions to be answered and build the recommendations based on that.

Task Force members recommended additional data elements:

- How rebates for specialty and brand name drugs relate to the formulary
- Collect data separately for preferred and non-preferred drugs, and generic versus authorized generic
- Data related to coupons and impact on consumer costs
- How payment methodologies are changing medication practices
- Whether rebates lead to increased list prices
- The data that are collected by PBMs should be disaggregated
- The difference between a rebate collected from a manufacturer versus a DIR fee paid by a pharmacy
- Differential reimbursement by vertically integrated, independent, 340B, etc.
- The basis for setting a Maximum Allowable Cost (MAC) price and how the PBM knows that it's appropriate
- Pricing for a 30-day supply of a brand name versus generic drug at a retail pharmacy compared to a 90-day supply at a mail order pharmacy. This should also include a comparison by vertical and specialty pharmacies
- The ultimate price paid for a drug after claw-backs
- On-invoice and off-invoice pricing, including the impact of claw-backs; and what is invoiced versus what is paid

Public Comment

Mr. Martinez, CPhA, made a recommendation for consideration related to the DMHC's existing power over PBMs. He noted Mr. Head mentioned a list of current laws but didn't mention MAC appeals to PBMs. The big problem with SB 17 is there's no enforcement mechanism. He believes the DMHC has existing authority to oversee the health plans and should have indirect access to the PBM since it is the responsibility of the plan to oversee its delegates.

Dr. Sood suggested cross-checking the rebates PBMs and health plans get by asking for the same information from both parties.

6. Closing Remarks

Next meetings are scheduled for October 14, 2019, and December 4, 2019.