Cost Transparency – Prescription Drug (CTRx)
Workshop 1 – Data Users
3/15/2018
Outline and Summary

CTRx Workshop 1 Outline

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CTRx Workshop 1 Summary

OSHPD Background and Introduction to SB 17

The Office of Statewide Health Planning and Development (OSHPD) has been collecting hospital and skilled nursing annual financial data since 1975. Over the years, OSHPD has collected hospital quarterly financial and patient-level discharge data, nonprofit hospital community benefit reporting, coronary artery bypass graft information, patient-level emergency department and ambulatory surgery data, and more.

In October 2017, OSHPD was charged with the collection and reporting of prescription drug cost information resultant of the signing of California Senate Bill (SB) 17 (Chapter 603, Statutes of 2017) into law. SB 17 seeks to increase prescription drug cost transparency by requiring drug manufacturers to provide advance notification to public and private purchasers before a specified cost increase occurs.

Effective January 1, 2018, drug manufacturers must provide 60-day notice to specified public and private purchasers before a wholesale acquisition cost (WAC) increase takes effect where such increase would exceed 16 percent across the proposed increase and the cumulative increases that occurred within the previous two calendar years prior to the current year.

Beginning January 1, 2019, drug manufacturers must provide additional information to OSHPD related to cost increases that meet the requirements of the 60-day notice, on a quarterly basis. Additionally, manufacturers must provide data regarding new prescription drugs with an initial WAC that exceeds the threshold set for a specialty drug under the Medicare Part D program

(currently $670 per month) within three days after the release of the drug into the commercial market, and with further detail within 30 days after initial notification.

SB 17 allows drug manufacturers to limit information reported to what is in the public domain or otherwise publicly available. Manufacturers that do not comply with SB 17 are subject to a $1,000 per day civil penalty for each day the required information is not reported. OSHPD will publish data received from manufacturers on its website beginning Spring 2019.

In conjunction with the information submitted by drug manufacturers relating to prescription drug cost increases, health plans and insurers must provide information to state health plan and insurance regulators for the 25 most frequently prescribed drugs, the 25 most costly drugs by total annual plan spending, the 25 drugs with the highest year-over-year increase in total plan spending, and any other aggregate data on the impact of drug costs to large group health care plans and health insurance policies by October 1, 2018 and annually thereafter.

CTRx Workshop Synopsis

On March 15, 2018, OSHPD welcomed representatives from health plans, health insurers, pharmacies, pharmacy benefit managers, health care advocates, and public and private purchasers to participate in a CTRx workshop to provide input and feedback related to desired utilization of the data submitted by drug manufacturers.

The public meeting was held at the OSHPD Conference Center and included a panel of invited guests to share their technical expertise as potential data users of information to be published by OSHPD pursuant to SB 17. Invited panel guests were solicited from statewide associations and included representation from OSHPD, the California Department of Managed Health Care (DMHC), Kaiser Permanente, Molina Health Care, Health Access, California Labor Federation, San Diego Electrical Health & Welfare Trust, Blue Shield of California, and the National Academy for State Health Policy.

Attendees from the general public included representatives of the California Life Sciences Association, UNITE HERE International Union, Consumers Union, Magellan Health, Kaiser Foundation Health Plan, Covington & Burling, Nielson Merksamer, and Wilke Fleury, LLP. The California State Senate Committee on Health, the California Department of Insurance, and the California Department of Finance were also in attendance.

Scott Christman, Deputy Director and Chief Information Officer of the Information Services Division at OSHPD, opened the meeting with an overview of the OSHPD organization and a synopsis of SB 17. Ty Christensen, Health Program Audit Manager at OSHPD, provided a summary of the CTRx program and overall workshop objectives. Jim Jones, a pharmaceutical industry subject matter expert and consultant for OSHPD, introduced 11 definitions of terms taken from or related to SB 17 that will be used in drafting regulations to implement the law.

After reviewing definitions, Mr. Christensen and Mr. Jones outlined data elements specified in SB 17, including drug identifiers and cost, supporting information, and cost change rationale. The speakers discussed drug manufacturer data, WAC history data, WAC increase data, and new prescription drug data, as well as the ability for manufacturers to provide supporting documentation related to the structured data that is submitted. Further, OSHPD is in the process of procuring the Medi-Span Electronic Drug File v2. The file is an electronic drug

dictionary of prescription drugs and over-the-counter products that will be used to strengthen reporting and compliance validation.

Following the discussion of data elements, OSHPD solicited input from workshop participants in the form of user stories. The purpose of this exercise was to elicit examples of contextual uses for the data that will be collected. OSHPD reviewed two user story examples to illustrate the story creation process, after which panel guests and public audience members developed individual user stories. Information captured included user role, process, or functionality desired in the data provisioning tool or data set, and the desired result or outcome. Participants were also asked to provide acceptance criteria against which the request can be tested and/or validated, as well as any additional comments to support data provisioning and/or utilization processes.

In closing, Mr. Christman opened the floor for input from members of the general public with each speaker allotted one minute for comment. Two public comments were made regarding support for the law and gratitude at the opportunity to have access to prescription drug cost data.

CTRx Workshop Definitions

OSHPD solicited questions and comments from panel guests as definitions were introduced. A summary of each definition, participant questions or comment, and discussion resolution (where applicable) is provided in the table below:

Phrase	Definition	Public Question/Comment
Prescription Drug	A drug prescribed by a doctor, bought at a pharmacy, prescribed for and intended to be used by one person, and regulated by FDA. **SOURCE:** fda.gov	• Need to alter definition to make broader; law is intended to encompass all prescription drugs regardless of whether administered by nurse in clinic, by physician in inpatient setting, or sold in outpatient pharmacy. • Plans are required to compare pharmacy cost spend; definition limits prescription drugs related to pharmacies specifically as opposed to specialty drugs for chemotherapy. • Should take into account all applicable prescribers and use term “Licensed Health Care Official” to be inclusive for doctors, nurse practitioners, physician assistants, PharmDs, etc.
Breakthrough Therapy Designation	Applies when a drug is: (1) intended alone or in combination with one or more drugs to treat a serious or life-threatening disease or condition and (2) preliminary clinical evidence indicates that the drug may demonstrate substantial improvement over existing therapies.	• The intent of using the FDA designation for breakthrough therapy is to track prescription drugs that were granted this designation and the definition should perhaps be updated to include this.

Phrase	Definition	Public Question/Comment
	SOURCE: fda.gov	
Drug Product	A finished dosage form, as in a tablet, capsule, or solution, that contains a drug substance, generally, but not necessarily, in association with one or more other ingredients. **SOURCE:** Code of Federal Regulations, Title 21, 314.3	• No comments provided
Single Source Drug	A covered outpatient drug that is produced or distributed under an original New Drug Application (NDA) approved by FDA. **SOURCE:** United States Code, Title 42, Section 1396r-8(k)(7)(A); Code of Federal Regulations, Title 42, 447.502	• Not intended to be limited by outpatient drug, need biologics, etc.; however, this is specifically meant for Medicaid designations as opposed to FDA designations and is causing some confusion.
Multiple Source Drug	For a rebate period, a covered outpatient drug for which there is at least one other drug product which meets the following criteria: (1) Is rated as therapeutically equivalent as reported in the FDA's "Approved Drug Products with Therapeutic Equivalence Evaluations" (2) Is pharmaceutically equivalent and bioequivalent, as determined by the FDA (3) Is sold or marketed in the United States during the rebate period. **SOURCE:** United States Code, Title 42, Section 1396r-8(k)(7)(A); Code of Federal Regulations, Title 42, 447.502	• What is considered the "rebate period" and how does this apply? Consider taking that language out? • What about drugs sold in the US and not "during the rebate period"? • Strictly applies to Medicaid; OSHPD tried to provide definitions as they understood them to be interpreted.
Innovator Multiple Source Drug	A multiple source drug that was originally marketed under an original new drug application (NDA) approved by FDA. **SOURCE:** United States Code, Title 42, Section 1396r-8(k)(7)(A); Code of Federal Regulations, Title 42, 447.502	• No comments provided
Noninnovator Multiple Source Drug	(1) a multiple source drug that is not an innovator multiple source drug or a single source drug; (2) A multiple source drug that is marketed under an abbreviated antibiotic drug application; (3) A drug that entered the market before 1962 that was not originally marketed under an NDA;	• No comments provided

Phrase	Definition	Public Question/Comment
	(4) Any drug that has not gone through an FDA approval process, but otherwise meets the definition of covered outpatient drug. **SOURCE:** United States Code, Title 42, Section 1396r-8(k)(7)(A); Code of Federal Regulations, Title 42, 447.502	
Manufacturer	Any entity that holds the National Drug Code (NDC) for a drug or biological product and is engaged in the production, preparation, propagation, compounding, conversion, or processing of drug products; or is engaged in the packaging, repackaging, labeling, relabeling, or distribution of drug products and is not a wholesale distributor of drugs or a retail pharmacy licensed under State law. **SOURCE:** Code of Federal Regulations, Title 42, 447.502	• No comments provided
National Drug Code (NDC)	The numerical code maintained by the FDA that includes the labeler code, product code, and package code. A drug's NDC number is typically expressed using 11 digits in a 5-4-2 format (xxxxx-yyyy-zz) where the first five digits identify the manufacturer, the second four digits identify the product and strength, and the last two digits identify the package size and type. **SOURCE:** Code of Federal Regulations, Title 42, 447.502	• No comments provided
Wholesale Acquisition Cost (WAC)	A published catalog or list price for a drug product to wholesalers as reported by the manufacturer. **SOURCE:** First Data Bank, Drug Pricing Policy (http://www.fdbhealth.com/policies/drug-pricing-policy)	• No comments provided
Medicare Part D Specialty Drug Threshold	An established dollar-per-month threshold above which drugs with sponsor-negotiated prices are eligible for specialty tier placement. The current threshold is set at $670.	• No comments provided

Phrase	Definition	Public Question/Comment
	SOURCE: Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (PL 108-173, December 8, 2003, 117 Stat 2066); Code of Federal Regulations, Title 42, Section 423.578(a)(7)	

General Comments for Definitions

The following comments were made by workshop participants after the review of definitions was complete:

- Legislation did not intend to limit definition scope, definition of prescription drugs, or data collection to be only for outpatient pharmacies.
- Law must cover clinical, inpatient, specialty drugs; specialty medications are some of the largest price increases.
- Medicare Part D Specialty Drug Threshold is a marker used specifically for a threshold; nothing is covered under SB 17 other than WAC cost with regard to legal obligations.
- With respect to innovator, noninnovator, etc., those are things to be reported on, not criteria on drugs to be reported; i.e. if they are applicable.
- Most important definition would be “prescription drug” and that it cannot be limited to outpatient drugs or drugs prescribed by a doctor.

Data Elements

OSHPD solicited questions and comments from panel guests regarding the data elements that were introduced. A summary of each data element and corresponding participant questions or comments is provided in the table below:

Category	Data Element	Public Question/Comment
WAC Cost Increases - Summary	For WAC cost increases, manufacturers will be required to provide OSHPD with a comprehensive summary of the item and include: • NDC Number • WAC Effective Date • WAC Amount • Item Description • Cost Change Reason Description • US Sales Volume (Units) - Previous Calendar Year	• If drug identifier is by NDC, what about NDC switches for formulation change or package change? • OSHPD will be tracking NDC changes with the Medi-Span data.
WAC Cost Increases – History	For WAC cost increases, manufacturers will be required to provide OSHPD with a five-year history of the item and include: • NDC Number • WAC Effective Date • WAC Amount	• No comments provided
WAC Cost Increases – Drug Acquisition	For WAC cost increases for drugs acquired by another manufacturer, the current manufacturers will be required to provide OSHPD with drug acquisition information and include: • NDC Number • Acquisition Date • Company From Which Acquired	• No comments provided

Category	Data Element	Public Question/Comment
	• Acquisition Price • WAC at Acquisition • WAC Calendar Year Prior to Acquisition • Year of Market Introduction • WAC at Market Introduction	
New Specialty Drug – Initial Notice	For new specialty drugs introduced to market with a WAC exceeding the specialty drug threshold, manufacturers will be required to provide initial three-day notice to purchasers and include: • NDC Number • Product Launch Date • WAC Amount	• What is qualified as a "new drug"? New molecule? New item would need to exceed the threshold to be considered. • Is "Specialty" in terms of generic drugs as well, or only specialty drugs? • Dollar threshold does not tie it to Medicaid threshold? • Does the $670 threshold specialty drug tie to course of therapy / treatment overall or for a 30-day supply? • "New Specialty Drug" is not necessarily limited to specialty because any drug that fits within the Medicare threshold will need to be reported on. • If a manufacturer was launching multiple NDCs for one molecule, will they need to report on each of those values? • Will a new dose of an existing drug count as a new drug?
New Specialty Drug – Item Summary	For new specialty drugs introduced to market with a WAC that exceeds the specialty drug threshold, manufacturers will be required to provide a follow-up 30-day summary to specified purchasers and include: • NDC Number • Marketing/Pricing Plan Description • Estimated Patient Volume Units • Breakthrough Therapy Indicator • Priority Review Indicator	• This is specific to the launch of a new item. Each manufacturer would be required to submit information if the new item exceeds the current $670 threshold; introduction of a new drug below the threshold would not trigger the need for reporting. • Is it possible that we hear from a manufacturer during the initial launch and then never again until the cost increases past 16 percent?
Document Management	In addition to the structured data requirements of the law, manufacturers will have the ability to attach supporting documentation for WAC cost changes. Documents collected will be associated with NDC numbers or WAC increase records that have been provided.	• No comments provided

General Comments for Data Elements

The following comments were made by workshop participants after the review of the data elements was complete:

- There is a wealth of information, but it is helpful when dealing with questions regarding formularies to have the information grouped by condition (e.g. Multiple Sclerosis (MS) groups would like to look at information in the MS categories of drugs, same with cancer treatment medication, etc.). Next steps/nice to have search by invested groups, present data in a way that's easy to use.
- We often receive information from manufacturers in the form of PDFs and it is difficult to gather data and do analytics based off these types of document files. What is OSHPD's plan for regulations for data submitted via Excel, PDF, etc.?
- OSHPD should have Excel requirements be part of the file and format specifications in regulation.
- Hospital pharmacy charges are tied to a Chargemaster charge code.

User Story Examples

As part of the objective to understand and incorporate commentary into a data collection and reporting tool, OSHPD presented workshop attendees with User Story cards (Appendix A) that prompted specific scenarios about how a certain type of user would want and/or expect to use data.

User story cards start with "As a" to indicate user role, followed by "I want" to detail what sort of process or functionality is requested, and end with "so that" to identify the desired end result. Additionally, users were prompted to include acceptance criteria against which requirements can be tested/validated, and to provide any additional comments to go along with the request.

The following user story examples were provided:

Example 1:

As a data analyst at a health plan, **I want** to access statistics related to price increase frequency and average percent increases by drug manufacturers and in aggregate **so that** I can forecast when price increases might happen and by what amount.

Acceptance Criteria: I can define a time period, after which I can access information related to the number, frequency, and average percent increase by manufacturer and in aggregate.

Additional Comments: It would be ideal to be able to print or export this information to Excel.

Example 2:

As a member of the Medical Review Committee, **I want** to view a list of all new specialty drugs introduced during the last x months that were provided breakthrough therapy designation or priority review by the FDA **so that** I can actively search for alternative treatments for patients with chronic conditions and evaluate overall fiscal impact of such therapies.

Acceptance Criteria: After specifying the number of months to look back, I can view a list of specialty items that have been introduced to market that were marked as breakthrough or priority and gain access to related marketing and pricing materials for items relevant to me.

Additional Comments: It would also be nice to compare the number of specialty items introduced to market by manufacturers.

Participant User Stories

User stories provided by workshop participants are provided in the table below. User stories provide a method to document and communicate desired needs and requirements. The user stories will help inform program implementation and system development by providing OSHPD with input to consider from stakeholders.

Category	User Story	Acceptance Criteria	Additional Comment
Consumer Advocate	As a consumer advocate, I want laypeople to have access to important and instructive information (i.e. a plain language description) so that they can better understand why their healthcare costs are so high, and what to expect at the pharmacy counter, and why.	A site visitor without expertise can go to the drug transparency site and read a summary of findings about drugs they care about.	Site usability is important, as is attention to literacy levels for content, such as overviews and summaries, which a visitor may read.
Researcher / Consumer Advocate	As a researcher and consumer advocate, I want to be able to call up discrete data sets (e.g. Hepatitis C drugs) between x date and y date, in a machine-readable format (Excel), and be able to download that information and be able to analyze and manipulate it on my computer (i.e. electronic non-locked CSV files) so that I can present actionable information to consumers and so I can research trends in prescription drug costs and take “snapshots” of costs across time.	I can define a time period and/or condition and/or treatment and get details on number of prescribed, dosage, duration, baseline price, and price change over time.	Must be able to export the file to my own computer or device immediately (not have to put in a request, wait for email, etc.).
Policy Researcher	As a policy researcher, I want the ability to quantify the following for prescription drugs meeting the SB 17 threshold for reporting: “Marketing budgets”, “pricing plans”, “therapeutic uses and conditions” (e.g. HIV, diabetes, hypertension), “estimated volume of patients prescribed the drug” (items in “quotes” are taken directly from the SB 17 statutory language) so that we can produce reports and analyses for our staff and leaders.	None provided.	Machine-readability, specifically Excel-friendly data tables organized by rows that enable pivot table functionality is a key necessity.

Category	User Story	Acceptance Criteria	Additional Comment
Health Consumer Advocate	As a health consumer advocate, I want to access statistics related to price increase frequency and average percent increase by drug manufacturers, grouped by health condition or therapeutic category so that consumers with ongoing or chronic health conditions can evaluate price increases by amount for their entire cost to treat condition.	I can define and access information price increase for each drug prescribed for the treatment of my chronic or ongoing condition and compare it to the previous costs to determine overall cost increases to treat my condition.	It would be ideal to also have this information in Excel and charted in summary.
Consumer Advocate	As a consumer advocate, I want to access all information reported to OSHPD, as required by SB 17, in a readable, digestible format. OSHPD can accomplish this by providing a summary of trends or summaries of the data from the department so that we can accurately communicate to consumers price increases, or average price increase, for example.	I can read a summary of each statutory required provision of the data.	None provided.
Regulatory Consultant	As a recipient of manufacturer price increase notices, I want a means to validate I am receiving all notices. Two of us at our organization are signed up to receive notices and there have been several instances where one of us will receive a notice and the other will not. It may be as simple as having manufacturers submit directly to OSHPD and have OSHPD broadcast the message in turn.	None provided.	None provided.
Senior Health Policy Fellow	As a Senior Health Policy Fellow, I want to be able to set up and alert function for users, alert based on WAC, increase percent, class of drugs for instance so that researchers or payers can follow up quickly with a manufacturer to request other data not included in SB 17.	None provided.	Also, searchability.
Pharmacy Director	As a Pharmacy Director I want detailed drug cost information to do class reviews of medications as well as predict cost increases in	If data from the pharmaceutical companies could be grouped by GPI number it would make putting drugs into	Good for you, posting these drug dollar deltas in a public forum.

Category	User Story	Acceptance Criteria	Additional Comment
	the future for future forecasting. Also, this information could be sued to check the price increases from our PBM.	therapeutic groups very easy and if there was a month and year associated to each, having a history of each drug would be easy to track.	
Health Plan Strategist	As a health plan strategist, I want to be able to evaluate the price increases in aggregate and by manufacturer [and new high-cost drugs] so that we can monitor/forecast prescription trends and use this in leveraging conversations with manufacturers as appropriate to understand their strategies.	None provided.	Exportable information via Excel or Access to deep dive with the data.
Administrative Manager	As an administrative manager, I want (1) to be able to monitor price increases of prescription drugs and (2) I would also like to be in a position to correlate actual drug ingredient costs to published price increases so that (1) we can implement changes to our formulary by removing high(er) cost drugs for which there are comparably price and effective alternatives and (2) same rationale as in 1.	None provided.	I welcome the opportunity to monitor and quantify manufacturer pricing behavior.
Consumer Advocate	As a consumer advocate organization, I want other information provided voluntarily by drug manufacturers so that additional information can illuminate reasons for price increases.	None provided.	None provided.
Consumer Advocate	As a consumer advocate group, I want the ability to search by disease/condition, and the ability to search by dollar amount.	None provided.	Ability to export to Excel or other sortable formats.

General Comments for User Stories

The following comments were captured from workshop participants after completion of individual user stories:

- Must reiterate the importance of exporting to Excel, data analysts can put together nice pivot tables; could make one regarding drugs acquired with in the last 12 months and then rank by standard deviation around average price increase and then converse with those companies; if conversations go negatively, may influence future transactions.
- We want to be able to look at drugs by therapeutic category, also by percentage increase and absolute price; base price matters in addition to percentage increase (e.g. two-percent increase on $100k drug versus 18-percent increase on $100 drug); also suggested plain language description of the data that will be provided to end users, could take more time to develop but follow up with DMHC; might consider allowing for additional information to be provided by the manufacturers as needed that goes beyond what is stated in the law.
- It would be nice to have an alert function when there are changes in the database that is different than the parameters for reporting (i.e. interested in MS or AIDS drugs, when there's a change or drugs cost more than $15k, some alert function is given) additional to query function. Standardized, don't want to have to register for this functionality.
- This is helpful to keep track of cost increases and monitor activity/behavior of PBMs, and if no record is present then a conversation must be had with PBM. It would be helpful to also track GPI in addition to NDC to help with sorting.
- We need to have the ability to slice and dice the data into usable pieces, use standardized data formats would help with the ability to customize the data in multiple ways.
- This will help if we want to be able to remove overly high cost items from our formulary; if there are other medications in the same class that have not increased, work with the PBMs.
- Searchability would be important, especially since there is qualitative data, so keyword searches would be very useful. Additionally, flexibility so that as things change within the market (biologics, etc.) there is flexibility for those things to be included as well (additional information that may not fit neatly into certain categories) but can be tracked and handled.

Public Comment

At the end of the presentations, OSHPD opened the floor for public comment and allowed workshop participants to share additional remarks. The following comments and questions were captured during the public comment period:

- Kaiser Foundation Health Plan: How will the enforcement be done on the 60-Day notification process? (Mr. Christman relayed that OSHPD is not charged with enforcement of the 60-Day notification process.)
- Kaiser Foundation Health Plan: Also, do 503B compounding pharmacies that are manufacturers have to comply with SB 17? (Mr. Jones indicated that compounding entities are included under the umbrella definition of manufacturer).

- Consumers Union: I am a strong supporter of SB 17 and wanted to thank OSHPD for taking such care and consideration on figuring out how to start the process. I hope data will be machine-readable and dynamic; I hope to have a consumer-friendly user interface with plain language descriptions. Today's meeting was excellent, thanks for allowing public to participate.
- Unite Here: We are exceedingly grateful with seriousness of OSHPD in pursuing implementing SB 17 and feel very gratified. I wanted to place high emphasis on machine readability and Excel access is critical; it is absolutely necessary to have data tables organized by rows that allow for pivot tables. DMHC has familiarity with this via SB 546; minority of those happen in PDF format and is problematic for data analysis.

Closing

In closing the meeting, OSHPD reviewed next steps for the CTRx project team, which included reviewing user stories submitted by workshop participants and other feedback provided during the open comment period. A similar workshop will be held on April 11, 2018, to allow data submitters to provide input related to the data collection process.

Additionally, OSHPD will continue drafting regulations and will provide formal notice for proposed rulemaking in July 2018. There will be a public comment period during Summer 2018.

Appendix A

User Story Card Front:

NAME: **ORGANIZATION:**
EMAIL:

As a:
(What is your role?)

I want:
(Process, functionality, etc.)

So that:
(What is the end result?)

User Story Card Back:

Acceptance Criteria:
(Criteria against which the request is tested/validated)

Comments:
(What else do you want to tell us?)