

Senate Bill 17
Cost Transparency Rx (CTR_x)

OSHDPD
Data Submitter Workshop

Workshop Overview

Thank you for attending – the purpose of today's workshop is to:

- Share OSHPD's approach to data program administration
- Discuss proposed definitions, data elements and reporting processes
- Review input received to date and how it has been incorporated
- Solicit feedback and listen to all perspectives

OSHPD Data Programs

- Collection of Hospital and Skilled Nursing Annual Financial Data since 1975
- Annual Utilization Reports for Hospitals, Clinics, LTC, Home Health, and Hospice since 1978
- Added Hospital Quarterly Financial and Patient Level Discharge Data in 1980
- Nonprofit Hospital Community Benefit Reporting begun in 1996
- Clinical data for Coronary Artery Bypass Graft surgeries enacted in 2001
- Collection of Patient Level Emergency Department and Ambulatory Surgery Data started 2004
- Submission of Hospital Charge Description Masters added in 2005
- Collection of Hospital Discount Payment Policies, Procedures, and Application Forms in 2008

OSHPD Approach

OSHPD looks to work with all interested parties in program implementation and management by:

- Listening empathetically to stakeholder suggestions and taking action, as appropriate
 - 60-Day notice registration update
 - Stakeholder outreach / workshops
- Minimizing administrative burden
 - Proactive noticing of expected reports
 - Structured data collection / pre-population of existing elements
- Providing transparency to process
 - Collaborative review of key components and proposed approach
 - Receptivity to technical input

Senate Bill 17 Overview

SB 17 (Hernandez, Statutes of 2017) seeks to increase prescription drug cost transparency by:

1. Requiring advance notification to public and private purchasers before a specified cost increase occurs, and making public certain information associated with the increase.
2. Providing information about the impact of cost increases to health plans and insurers.

SB 17 charges OSHPD with the collection and publication of prescription drug cost information, and administration of penalties where compliance issues arise.

Manufacturer Provisions

- 60-day advance notice to specified purchasers of items with a WAC increase of more than 16% including the current increase and all cumulative increases that occurred within the previous two calendar years – January 1, 2018
- 3-day / 30-day report of new prescription drugs with initial WAC of \$670 or more – January 1, 2019
- Quarterly retrospective report of all items with a WAC increase of more than 16% including the current increase and all cumulative increases that occurred within the previous two calendar years— April 1, 2019

Health Plan / Insurer Provisions

Health Plans and Insurers must provide the following information to state health plan and insurer regulators by October 1, 2018 and annually thereafter:

- 25 most frequently prescribed drugs
- 25 most costly drugs by total annual plan spending
- 25 drugs with the highest year-over-year increase in total plan spending
- Other aggregate data on the impact of drug costs to large group health care plans and health insurance policies

DMHC Reporting Requirement

- DMHC will issue report to Legislature with aggregate data beginning January 1, 2019 and annually thereafter
- Prescription drug cost data will be included in DMHC's annual public meeting on aggregate trends in large group market

OSHPD CTRx Timeline

- Draft Regulations: April 2018 - June 2018
- Publish proposed Regulations: July 2018
- Public comment period: July – August 2018
- Public forum: July 2018
- System development: July – November 2018
- Data submitter registration: November – December 2018

Agenda for Workshop

- Review definitions specific to SB 17
- Review data elements for submission
- Outline data submission, review and publication process
- Discuss compliance and penalties
- Discuss next steps
- Hear public comment

Facilitation

- Housekeeping
- Workshop ground rules

Definitions

SB 17 Definitions

Prescription Drug – an FDA-approved drug only available as prescribed by an authorized licensed health care professional, and intended to be used by one person.

SOURCE: adapted from fda.gov

SB 17 Definitions

Breakthrough Therapy Designation – applied by the FDA 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.

SOURCE: fda.gov

SB 17 Definitions

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

SB 17 Definitions

Single Source Drug – a drug that is produced or distributed under an original New Drug Application (NDA) approved by FDA.

SOURCE: gpo.gov (United States Code, Title 42, Section 1396r-8(k)(7)(A); Code of Federal Regulations, Title 42, 447.502)

SB 17 Definitions

Multiple Source Drug – a 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: gpo.gov (United States Code, Title 42, Section 1396r-8(k)(7)(A); Code of Federal Regulations, Title 42, 447.502)

SB 17 Definitions

Innovator Multiple Source Drug – a multiple source drug that was originally marketed under an original new drug application (NDA) approved by FDA.

SOURCE: gpo.gov (United States Code, Title 42, Section 1396r-8(k)(7)(A); Code of Federal Regulations, Title 42, 447.502)

SB 17 Definitions

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;
- (4) Any drug that has not gone through an FDA approval process, but otherwise meets the definition of covered outpatient drug.

SOURCE: SOURCE: gpo.gov (United States Code, Title 42, Section 1396r-8(k)(7)(A); Code of Federal Regulations, Title 42, 447.502)

SB 17 Definitions

Manufacturer – any entity that holds the NDC for a prescription drug and is either 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: adapted from gpo.gov (Code of Federal Regulations, Title 42, 447.502)

SB 17 Definitions

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: gpo.gov (Code of Federal Regulations, Title 42, 447.502)

SB 17 Definitions

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>)

SB 17 Definitions

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**.

Note: The threshold amount is the sole component of this definition relevant to SB 17. That is, a drug need not meet the definition but only exceed the threshold to trigger reporting requirements for a new prescription drug.

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)

Questions / Comments



Data Elements

Overview

SB 17 requires manufacturers to report specific data elements including drug identifiers and costs, and supporting information, such as marketing plans and cost change rationale.

Manufacturer Data

Specifically, manufacturers must submit information for drugs where:

- The WAC for an item increases more than 16% including the increase and all previous increases during the previous two calendar years
- A new drug is introduced in the market at a WAC that is higher than the threshold set for a specialty drug under the Medicare Part D program – currently \$670.

Baseline Data

In addition to manufacturer submitted data, OSHPD has procured 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.

WAC Increase Data

For each item that exceeds the WAC increase threshold of the law, manufacturers must provide:

- WAC Increase Summary
- 5 Year WAC History
- Drug Acquisition Information

WAC Increase Data

WAC Increase Item Summary Elements

- NDC Number
- Item Description
- WAC Effective Date
- WAC Amount
- Description of Specific Financial & Nonfinancial Factors
- Patent Expiration Date – as applicable
- Drug Source Type
- Change / Improvement Description – as applicable
- US Sales Volume (Units) - Previous Calendar Year

WAC Increase Data

5 Year WAC History Elements

- NDC Number
- WAC Effective Date
- WAC Amount

WAC Increase Data

Drug Acquisition Data Elements

- NDC Number
- Acquisition Date
- Company From Which Acquired
- Acquisition Price
- WAC at Acquisition
- WAC Calendar Year Prior to Acquisition
- Year of Market Introduction
- WAC at Market Introduction

New Prescription Drugs

For each item introduced to market with a WAC that exceeds the threshold set for a specialty drug under the Medicare Part D program (currently \$670), manufacturers must provide:

- Initial 3 Day Notice
- 30 Day Item Summary

New Prescription Drugs

Initial 3 Day Notice Elements

- NDC Number
- Product Launch Date
- WAC Amount

New Prescription Drugs

30 Day Item Summary Elements

- NDC Number
- Marketing/Pricing Plan Description
- Estimated Patient Volume Units
- Breakthrough Therapy Indicator
- Priority Review Indicator
- Acquisition Date – as applicable
- Acquisition Price – as applicable

Document Management

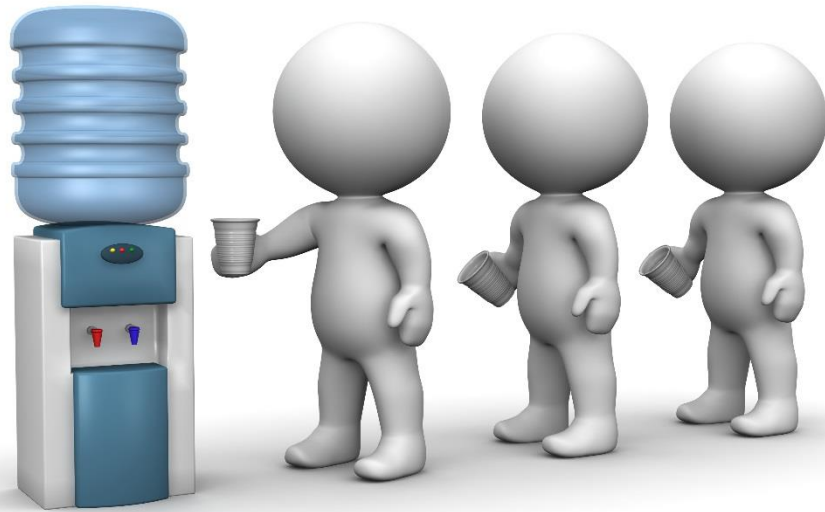
In addition to the structured data requirements of the law, manufacturers will have the ability to attach supporting documentation for WAC cost changes and new prescription drugs.

Documents collected will be associated with one or more drug items that have been submitted.

Questions / Comments



Quick Break



Data Submission Process

Existing Data Submission Platform

OSHPD currently uses a web portal to collect, validate and collaborate about data required for submission by healthcare systems at a frequency prescribed by statute.

This system will be updated to provide similar functionality for SB 17 data submitters.

Existing Data Submission Platform

Core portal functionality includes:

- 24x7 Access
- User Registration / Profile Administration
- Facility Mapping
- Access to Previously Submitted Reports
- Data Entry / Upload Capabilities
- Collaborative / Iterative Data Validation and Certification
- Security features

Registration

In the Fall of 2018 manufacturers will be invited to register for access to the data portal.

As part of the registration process, organizations and representative system users will be vetted, and login credentials will be provided after OSHPD review.

During Q4 2018, OSHPD will provide access to user guides and make available contact information for user support and technical assistance.

Collection Timeline

Beginning January 1, 2019 and April 1, 2019, for new prescription drugs and WAC increases respectively, manufacturers will be able to access the data portal and provide item information online (one record at a time) or using structured data templates for offline completion and upload.

Collection Timeline

- Notification of new drugs is due within three days of introduction to market.
- New drug information is due within 30 days of notification of introduction to market.
- WAC increase information reported quarterly based on increases during that calendar quarter.
- Due date for WAC increase information will be the end of the month following the calendar quarter.

Data Submission Process

To the extent possible, the data portal will pre-populate existing data elements (item description, source type, etc.) and allow users to confirm accuracy or make applicable modifications.

As information is entered, users will have the ability to upload supporting documents for association with one or more records.

Data Submission Process

Information provided may be limited to what is in the public domain or otherwise publicly available; however, users will be asked to indicate that any data elements not provided are not currently in the public domain.

Data Validation

Once data has been entered and saved, the data portal will perform data validations to check that information is complete and meets formatting requirements. Records that do not pass validation constraints will be flagged for user remediation or explanation.

Data Validation

Validation errors may be corrected or explained on a record-by-record basis, and users have the ability to log on and off intermittently during the correction process.

Once all edits have been satisfied, users may officially submit records, certifying all information to be true and correct to the best of their knowledge.

Submission Review

After records are submitted, they are reviewed by OSHPD staff to ensure that all validation issues have been sufficiently addressed.

Where issues remain, OSHPD staff may apply additional validation notes and notify the submitter that records require additional attention. Submitters may then log into the data portal, provide adjustments or explanations, and resubmit.

Data Publication

Reports that satisfy all validation requirements are marked final and accepted by OSHPD staff, making report data available for publication as prescribed by the Bill.

Users may continue to access reports that have been marked final and accepted but cannot make additional changes.

Data Publication

Data will be available in a structured, machine readable format at the level of data granularity provided.

Unstructured data submitted in the form of documents will also be available for public retrieval.

Additionally, reports that provide summary information or allow users to filter by item attributes may be made available. OSHPD continuously evaluates the value and effectiveness of all its reports and data products.

Questions / Comments



Compliance and Penalties

Compliance and Penalties

A manufacturer of a prescription drug that does not report the information required is liable for a civil penalty of one thousand dollars (\$1,000) per day for every day after the reporting period described that the required information is not reported.

A civil penalty shall be assessed and recovered in a civil action brought by the office in the name of the people of the State of California. Assessment of a civil penalty may, at the request of any manufacturer of a subject prescription drug, be reviewed on appeal, and the penalty may be reduced or waived for good cause.

Citation: H&S Code Sections 127679(e)-(f), 127681(f)-(g)

Questions / Comments



Next Steps for CTRx

- Review workshop feedback
- Provide workshop summary
- Continue drafting regulations
- Formal notice in July 2018
- Public comment period Summer 2018

Public Comment



Thank You for Participating!

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