Senate Bill 17

Cost Transparency Rx (CTRx)

CALIFORNIA'S DRUG COST TRANSPARENCY LAW

OSHPD Background

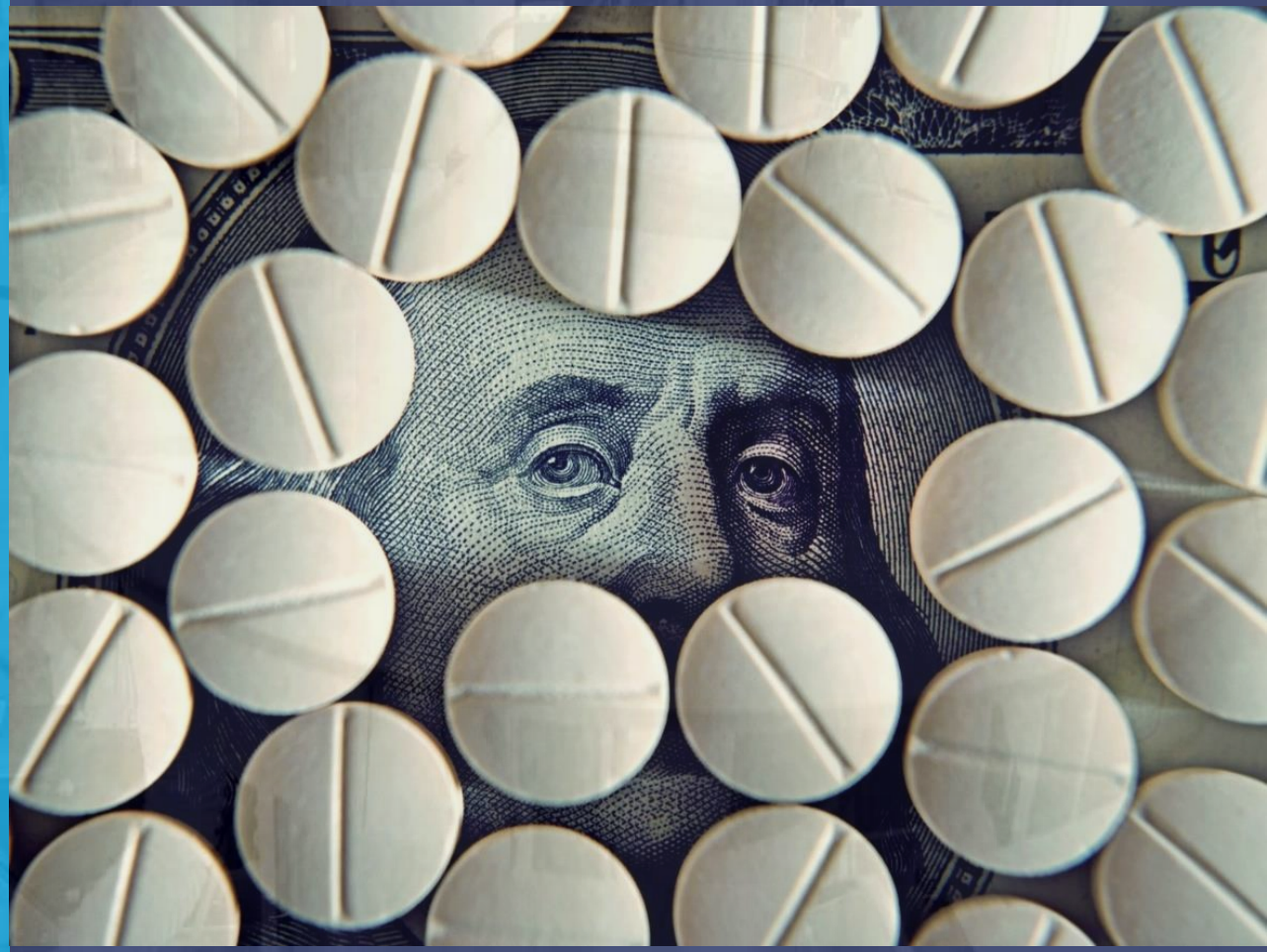
- Collection of Hospital and Skilled Nursing Annual Financial Data since 1975
- Annual Utilization Reports for Hospitals, Clinics, LTC, Home Health, and Hospice since 1978
- Added Hospital Quarterly Financial and Patient Level Discharge Data in 1980
- Nonprofit Hospital Community Benefit Reporting begun 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

What is Senate Bill 17?

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 care plans and insurers.

Drug manufacturers must now provide 60-day advance notice to specified public and private purchasers before a planned cost increase take effect.



Beginning in 2019, manufacturers must provide information to OSHPD after raising the cost of a prescription drug above a specified level.

OSHPD will publish this data quarterly on its website.

State Publishing of Drug Cost Information

Drug Manufacturer Reporting to Purchasers:
January 1, 2018: Registry of state purchasers, healthcare service plans, health insurers, and pharmacy benefit managers that wish to receive 60-day notices of future increases were made available to drug manufacturers on OSHPD's website.

State Publishing of Information on Prescription Drug Costs:
Beginning Spring 2019: OSHPD to publish information related to new prescription drugs from drug manufacturers quarterly on its website.
By June 2019: OSHPD to publish first quarter 2019 drug cost increase information for existing drugs on OSHPD website.

Manufacturers can limit the information to what is in the public domain or otherwise publicly available.

$1,000 per day civil penalty for failure to report this information.

Other Provisions

Impacts to:

- Health care plans
- Insurers

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

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OSHPD CTRx Data User Workshop

Agenda for Workshop

- Review definitions specific to SB 17
- Review data elements
- Walkthrough User Story scenarios
- Breakout session for participants to develop their own User Stories
- Public comment
- Discuss next steps

Facilitation

- Housekeeping
- Workshop ground rules

SB 17 Definitions

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

SB 17 Definitions

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.

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 covered outpatient 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 – 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: 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 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: 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.

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); https://www.cms.gov/Medicare/Health-Plans/MedicareAdvtgSpecRateStats/Downloads/Announcement2017.pdf

Questions / Comments

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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 Medicate 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 Cost Increases

WAC Increase Item Summary Elements

- NDC Number
- WAC Effective Date
- WAC Amount
- Item Description
- Cost Change Reason Description
- US Sales Volume (Units) - Previous Calendar Year

WAC Cost Increases

5 Year WAC History Elements

- NDC Number
- WAC Effective Date
- WAC Amount

WAC Cost Increases

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 Specialty Drugs

For each item introduced to market with a WAC that exceeds the specialty drug threshold, manufacturers must provide:

- Initial 3 Day Notice
- 30 Day Item Summary

New Specialty Drugs

Initial 3 Day Notice Elements

- NDC Number
- Product Launch Date
- WAC Amount

New Specialty Drugs

30 Day Item Summary Elements

- NDC Number
- Marketing/Pricing Plan Description
- Estimated Patient Volume Units
- Breakthrough Therapy Indicator
- Priority Review Indicator

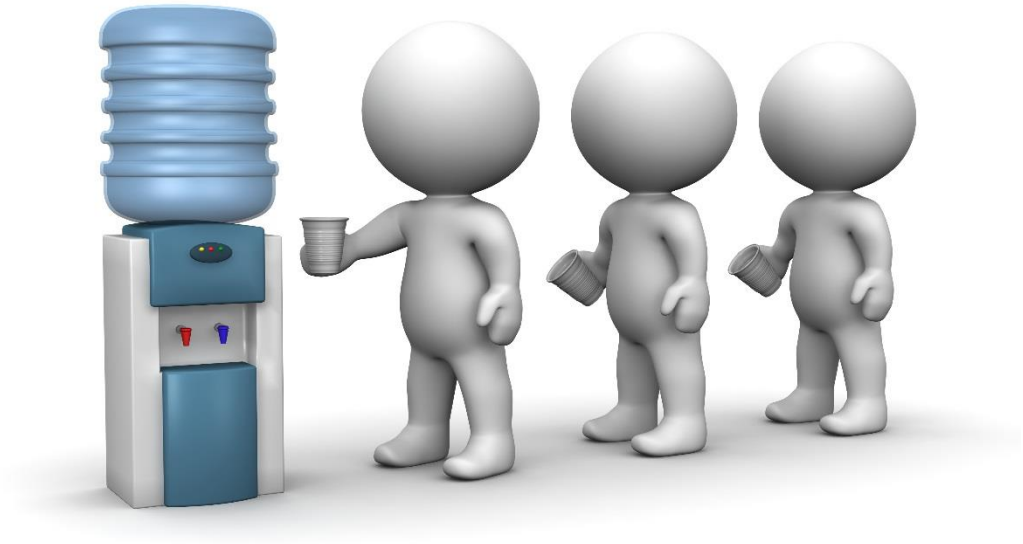
Document Management

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.

Questions / Comments

Quick Break



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User Stories

We Want Your Input!

OSHPD values the input of workshop participants and is soliciting feedback about how you will use the data collected from the drug manufacturers.

As part of this breakout session, we are asking you to create your own User Stories based on how you plan to use this information.

User Stories – Data Analyst

NAME: *John Smith* **ORGANIZATION:** *XYZ Health*
EMAIL: *jsmith@xyzhealth.org*

As a:
(What is your role?)

Data Analyst at a Health Plan

I want:
(Process, functionality, etc.)

To access statistics related to price increase frequency and average percent increase by drug manufacturer and in aggregate

So that:
(What is the end result?)

I can forecast when price increases might happen and by what amount

User Stories – Data Analyst

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

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

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

It would be ideal to be able to print or export this information to Excel

User Stories – Medical Review Committee

NAME : *Ronnie Easltand*
EMAIL : *reastland@mrc.gov*
ORGANIZATION: *Medical Review Committee*

As a:
(What is your role?)
Member of the Medical Review Committee

I want:
(Process, functionality, etc.)
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 FDA

So that:
(What is the end result?)
I can actively search for alternative treatments for patient with chronic conditions and evaluate the overall fiscal impact of such therapies

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User Stories – Medical Review Committee

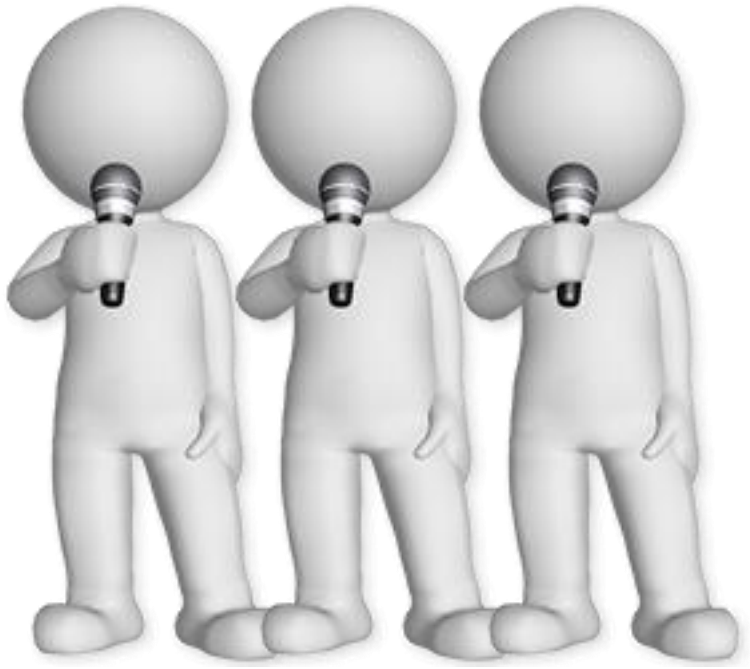
Acceptance Criteria:
(Criteria against which the request is tested/validated)

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.

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

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

User Story Discussion



Next Steps for CTRx

- Review User Stories and feedback
- Meet with data submitters on April 11, 2018
- Continue drafting regulations
- Formal notice in July 2018
- Public comment period Summer 2018

Public Comment

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Thank You for Participating