OSHPD
Office of Statewide Health Planning and Development

Senate Bill 17
Cost Transparency Rx (CTRx)

California Office of Statewide Health Planning and Development

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.

Purchasers

- State purchaser in California
- Licensed health care service plan
- Health insurer holding a certificate of authority from the Insurance Commissioner
- Pharmacy Benefit Manager

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 notice/ 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

Data Elements

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.

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

Implementation

- Regulations
  - Held a Data User Workshop and a Data Submitter Workshop
  - Drafted regulations
    - Public comment period closed October 2nd
    - Rulemaking package under review - implementation date January 1, 2019
- System development
  - Leveraged existing data reporting system
  - Utilizing Medi-Span data for WAC pricing

Challenges

- Dealing with a brand new set of data providers
  - Working with industry groups to establish relationships
- Legal challenges
  - PhRMA filed lawsuit, judge dismissed finding the trade group lacked standing, but allowed 30 days to refile
  - PhRMA refiled an amended complaint on 9/28