

CAL RX: CALIFORNIA GENERIC DRUG MANUFACTURING INITIATIVE

PRESENTATION TO MARYLAND PRESCRIPTION DRUG AFFORDABILITY BOARD, MARCH 22, 2021

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CALIFORNIA SENATE BILL 852 (PAN, CHAPTER 207, STATUTES OF 2020)

- *Goal: to increase patient access to affordable drugs*
 - Requires the California Health and Human Services Agency (CHHS) to enter into partnerships to produce or distribute generic prescription drugs, including at least one form of insulin.
 - The intent is that these drugs be made widely available to public and private purchasers, providers, and consumers.

PRIORITIZATION CRITERIA ACCORDING TO SB 852

- *Generic prescription drugs + insulin*
- *CHHSA shall prioritize generic prescription drugs that have the greatest impact on lowering drug costs to patients, increasing competition and addressing shortages in the prescription drug market, improving public health, or reducing the cost of prescription drugs to public and private purchasers.*
- Drugs must be produced at a price that results in *savings for providers, patients, and purchasers.*

PRICING CONSIDERATIONS IN SB 852

- *The price shall consider all of the following:*
 - (A) *United States Food and Drug Administration user fees.*
 - (B) *Abbreviated new drug application acquisition costs amortized over a five-year period*
 - (C) *Mandatory rebates.*
 - (D) *Total contracting and production costs for the drug.*
 - (E) *Research and development costs attributed to the drug over a five-year period.*
 - (F) *Other initial start-up costs amortized over a five-year period.*
- *Drugs shall be made available to providers, patients, and purchasers at a **transparent price and without rebates**, other than federally required rebates.*

IDENTIFYING TOP DRUGS

- CHHS has engaged Johns Hopkins University (JHU) Bloomberg School of Public Health, Drug Access and Affordability Initiative, as a project partner to support implementation through research and analysis.
- **Data Collection:** JHU is analyzing utilization and spending data on generic and branded drugs from:
 - Medi-Cal (California's Medicaid Program);
 - California Public Employees Retirement System (CalPERS); and
 - Covered California (ACA marketplace).

IDENTIFYING TOP DRUGS

- **Evaluation Framework:** JHU developed a target drug evaluation framework and worked with CHHS to developed a strategy for weighting drug selection criteria:
 - **Public health relevance** – criteria that examine the potential of each drug to impact public health.
 - **Economic impact** – criteria that examine the potential of each drug to impact spending.
- **Prioritization Survey:** A survey was sent out to 40+ stakeholders to help weight these criteria so CalRx can better gauge how important criteria are relative to each other.
- **Top Drug List:** JHU applied these weighted criteria to utilization data to identify potential “target drugs.” This list will then be narrowed based on manufacturing feasibility and legal/regulatory barriers.

NEXT STEPS

- If approved in the State Fiscal Year 2021 Budget, CHHS will have resources to support various research and analytical tasks that will proceed along three tracks:
 - **Completing Top Drug Analysis** (what drugs)
 - **Assessing legal, market, policy, and regulatory factors** (the feasibility of which drugs to manufacture)
 - **Strategic and operational issues** (the how of getting these drugs to consumers)
- SB 852 also requires CHHS to complete a legislative report on the feasibility of the state itself directly manufacturing generic drugs. This report will be due July 1, 2023.