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SB-852 Health care: prescription drugs. (2019-2020)

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Senate Bill No. 852

CHAPTER 207

An act to add Chapter 10 (commencing with Section 127690) to Part 2 of Division 107 of, and to repeal Sections 127694 and 127695 of, the Health and Safety Code, relating to health care.

[Approved by Governor September 28, 2020. Filed with Secretary of State September 28, 2020.]

LEGISLATIVE COUNSEL'S DIGEST

SB 852, Pan. Health care: prescription drugs.

Existing law authorizes the Department of General Services to enter into exclusive or nonexclusive contracts on a bid or negotiated basis with manufacturers and suppliers of single-source or multisource drugs. Existing law authorizes the department to obtain from those manufacturers and suppliers discounts, rebates, or refunds based on quantities purchased, as permissible under federal law. Existing law authorizes those contracts to include price discounts, rebates, refunds, or other strategies aimed at managing escalating prescription drug prices. Existing law requires certain state agencies to participate in that prescription drug bulk purchasing program, including the State Department of State Hospitals and the State Department of Developmental Services. Existing law establishes the California Health and Human Services Agency, which includes departments charged with the administration of health, social, and other human services.

This bill would require the California Health and Human Services Agency (CHHSA) to enter into partnerships, in consultation with other state departments as necessary to, among other things, increase patient access to affordable drugs. The bill would require CHHSA to enter into partnerships to produce or distribute generic prescription drugs and at least one form of insulin, provided that a viable pathway for manufacturing a more affordable form of insulin exists at a price that results in savings. The bill would, subject to appropriation by the Legislature, require CHHSA to submit a report to the Legislature on or before July 1, 2023, that, among other things, assesses the feasibility and advantages of directly manufacturing generic prescription drugs and selling generic prescription drugs at a fair price. The bill would require CHHSA to report to the Legislature on or before July 1, 2022, a description of the status of the drugs targeted for manufacture and an analysis of how CHHSA's activities have impacted competition, access, and costs for those drugs. The bill would exempt all nonpublic information and documents relating to this program from disclosure under the California Public Records Act in order to protect proprietary, confidential information regarding manufacturer or distribution costs and drug pricing, utilization, and rebates. The bill would state that its provisions are severable.

Existing constitutional provisions require that a statute that limits the right of access to the meetings of public bodies or the writings of public officials and agencies be adopted with findings demonstrating the interest protected by the limitation and the need for protecting that interest.

This bill would make legislative findings to that effect.

Vote: majority Appropriation: no Fiscal Committee: yes Local Program: no

THE PEOPLE OF THE STATE OF CALIFORNIA DO ENACT AS FOLLOWS:

SECTION 1. Chapter 10 (commencing with Section 127690) is added to Part 2 of Division 107 of the Health and Safety Code, to read:

CHAPTER 10. California Affordable Drug Manufacturing Act of 2020

127690. This chapter may be cited as the California Affordable Drug Manufacturing Act of 2020.

127691. For purposes of this chapter, the following definitions shall apply:

(a) "Generic drug" means a drug that is approved pursuant to subdivision (j) of Section 355 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. Sec. 301 et seq.), or a biosimilar, as defined under the federal Public Health Service Act (42 U.S.C. Sec. 262).

(b) "Partnerships" include, but are not limited to, agreements for the procurement of generic prescription drugs by way of contracts or purchasing by a payer, state governmental agency, group purchasing organization, nonprofit organization, or other entity.

127692. (a) The California Health and Human Services Agency (CHHSA) shall enter into partnerships, consistent with subdivision (b) of Section 127693, in consultation with other state departments as necessary, to increase competition, lower prices, and address shortages in the market for generic prescription drugs, to reduce the cost of prescription drugs for public and private purchasers, taxpayers, and consumers, and to increase patient access to affordable drugs.

(b) CHHSA shall have the ability to hire staff to oversee and project-manage the partnerships for manufacturing or distribution of generic prescription drugs, contingent upon an appropriation by the Legislature for this purpose.

127693. (a) CHHSA shall enter into partnerships resulting in the production or distribution of generic prescription drugs, with the intent that these drugs be made widely available to public and private purchasers, providers and suppliers as defined in subdivision (b) of Section 1367.50, and pharmacies as defined in Section 4037 of the Business and Professions Code, as appropriate. The generic prescription drugs shall be produced or distributed by a drug company or generic drug manufacturer that is registered with the United States Food and Drug Administration.

(b) (1) CHHSA shall only enter into partnerships pursuant to subdivision (a) to produce a generic prescription drug at a price that results in savings, targets failures in the market for generic drugs, and improves patient access to affordable medications.

(2) For top drugs identified pursuant to the criteria listed in paragraph (5), CHHSA shall determine if viable pathways exist for partnerships to manufacture or distribute generic prescription drugs by examining the relevant legal, market, policy, and regulatory factors.

(3) CHHSA shall consider the following, if applicable, when setting the price of the generic prescription drug:

(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, including a reasonable amount for administrative, operating, and rate-of-return expenses of the drug company or generic drug manufacturer.

(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.

(4) Each drug shall be made available to providers, patients, and purchasers at a transparent price and without rebates, other than federally required rebates.

(5) CHHSA shall prioritize the selection of 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.

(c) (1) In identifying generic prescription drugs to be produced, CHHSA shall consider the report produced by the Department of Managed Health Care pursuant to subdivision (b) of Section 1367.243, the report produced by the Department of Insurance

pursuant to subdivision (b) of Section 10123.205 of the Insurance Code, and pharmacy spending data from Medi-Cal and other entities for which the state pays the cost of generic prescription drugs.

(2) The partnerships entered into pursuant to subdivision (a) shall include the production of at least one form of insulin, provided that a viable pathway for manufacturing a more affordable form of insulin exists.

(3) CHHSA shall prioritize drugs for chronic and high-cost conditions, and shall consider prioritizing those that can be delivered through mail order.

(d) CHHSA shall consult with all of the following public and private purchasers to assist in developing a list of generic prescription drugs to be manufactured or distributed through partnerships and to determine the volume of each generic prescription drug that can be procured over a multiyear period to support a market for a lower cost generic prescription drug:

(1) The Public Employees' Retirement System, the State Department of Health Care Services, the California Health Benefit Exchange (Covered California), the State Department of Public Health, the Department of General Services, and the Department of Corrections and Rehabilitation, or the entities acting on behalf of each of those state purchasers.

(2) Licensed health care service plans.

(3) Health insurers holding a valid outstanding certificate of authority from the Insurance Commissioner.

(4) Hospitals.

(5) Pharmacy benefit managers.

(e) Before effectuating a partnership pursuant to this section, CHHSA shall determine minimum thresholds for procurement of an entity's expected volume of a targeted drug from the company or manufacturer over a multiyear period. In making advance commitments, CHHSA shall consult with the Statewide Pharmaceutical Program and the California Pharmaceutical Collaborative.

(f) The listed entities in paragraphs (2) to (5), inclusive, of subdivision (d) shall not be required to purchase prescription drugs from CHHSA or entities that contract or partner with CHHSA pursuant to this chapter.

(g) CHHSA shall not be required to consult with every entity listed in paragraphs (2) to (5), inclusive, of subdivision (d), so long as purchaser engagement includes a reasonable representation from these groups.

127694. (a) On or before July 1, 2023, CHHSA shall submit a report to the Legislature that assesses the feasibility of directly manufacturing generic prescription drugs and selling generic prescription drugs at a fair price. The report shall include an analysis of governance structure options for manufacturing functions, including chartering a private organization, a public-private partnership, or a public board of directors.

(b) This section shall only go into effect if the Legislature appropriates funds for this purpose in the annual budget.

(c) The report shall be submitted in compliance with Section 9795 of the Government Code.

(d) This section shall remain in effect only until January 1, 2025, and as of that date is repealed.

127695. (a) On or before July 1, 2022, CHHSA shall report to the Legislature on both of the following:

(1) A description of the status of all drugs targeted under this chapter.

(2) An analysis of how the activities of CHHSA may impact competition, access to targeted drugs, the costs of those drugs, and the costs of generic prescription drugs to public and private purchasers.

(b) This section shall remain in effect only until January 1, 2026, and as of that date is repealed.

127696. In order to protect proprietary, confidential information regarding manufacturer or distribution costs and drug pricing, utilization, and rebates, it is necessary that this act limit the public's right of access to that information. Notwithstanding any other provision of law, all nonpublic information and documents obtained under this section shall not be required to be disclosed pursuant to the California Public Records Act, Chapter 3.5 (commencing with Section 6250) of Division 7 of Title 1 of the Government Code, or any similar local law requiring the disclosure of public records.

SEC. 2. The Legislature finds and declares that Section 1 of this act, which adds Section 127696 of the Health and Safety Code, imposes a limitation on the public's right of access to the meetings of public bodies or the writings of public officials and agencies within the meaning of Section 3 of Article I of the California Constitution. Pursuant to that constitutional provision, the Legislature makes the following findings to demonstrate the interest protected by this limitation and the need for protecting that interest:

In order to protect proprietary, confidential information regarding manufacturer or distribution costs and drug pricing, utilization, and rebates, it is necessary for that information to remain confidential.

SEC. 3. The provisions of this act are severable. If any provision of this act or its application is held invalid, that invalidity shall not affect other provisions or applications that can be given effect without the invalid provision or application.