HEALTH AND SAFETY CODE - HSC

DIVISION 107. HEALTH CARE ACCESS AND INFORMATION [127000 - 130079] *(Heading of Division 107 amended by Stats. 2021, Ch. 143, Sec. 28.)*

PART 2. HEALTH POLICY AND PLANNING [127280 - 127697] *(Part 2 added by Stats. 1995, Ch. 415, Sec. 9.)*

CHAPTER 10. California Affordable Drug Manufacturing Act of 2020 [127690 - 127697] *(Chapter 10 added by Stats. 2020, Ch. 207, Sec. 1.)*

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

(Added by Stats. 2020, Ch. 207, Sec. 1. (SB 852) Effective January 1, 2021.)

127691. For purposes of this chapter, the following definitions 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, grant agreements, or purchasing by a payer, state governmental agency, group purchasing organization, nonprofit organization, or other entity.

(c) “California Health and Human Services Agency” or “CHHSA” means the California Health and Human Services Agency, or any of its departments, including the Department of Health Care Access and Information, selected to implement this chapter.

(Amended by Stats. 2023, Ch. 42, Sec. 50. (AB 118) Effective July 10, 2023.)

127692. (a) The California Health and Human Services Agency (CHHSA) or its departments 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) For purposes of implementing this chapter, CHHSA and its departments, including the Department of Health Care Access and Information, may enter into exclusive or nonexclusive contracts on a bid or negotiated basis. Contracts entered into or amended pursuant to this section are exempt from Chapter 6 (commencing with Section 14825) of Part 5.5 of Division 3 of Title 2 of the Government Code and Part 2 (commencing with Section 10100) of Division 2 of the Public Contract Code, and are exempt from the review or approval of any division of the Department of General Services. When appropriate, CHHSA shall establish initial and ongoing metrics to measure progress and efficiency, and remedies in the case those metrics are not met in any partnership contract entered into pursuant to this section.

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

(d) It is the Legislature’s intent that any manufacturing partnership contract entered into pursuant to subdivision (b) is a partnership intended to create a California-branded label for generic drugs. It is further the Legislature’s intent that any manufacturing that is done under this section is intended to benefit the residents of this state by ensuring adequate supplies and access to generic prescription drugs and lowering health care costs through savings to public health care programs and private health insurance coverage.

(Amended by Stats. 2023, Ch. 42, Sec. 51. (AB 118) Effective July 10, 2023.)

127693. (a) CHHSA shall enter into partnerships resulting in the production, procurement, 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, or 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, procure, 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 a 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, as appropriate, 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 made available at production and dispensing costs, if one does not already exist in the market. Dispensing costs may include related expenses such as transportation, distribution, and market operations. Any partnership shall also consider:

(A) Guaranteeing priority access to insulin supply for the state.

(B) Guaranteeing the manufacture of at least four high-priority drugs for California, as identified pursuant to paragraph (5) of subdivision (b).

(C) Creating a state brand identifying biosimilar insulin and generic prescription drugs sold in California under this section.

(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, as appropriate, to develop a list of generic prescription drugs to be manufactured or distributed through partnerships:

(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.

(e) Before effectuating a partnership pursuant to this section, CHHSA shall consider the volume of each generic prescription drug over a multiyear period to support a market for a lower cost generic prescription drug, if volume is an important factor in driving down the cost of the drug. For partnerships involving procurement, CHHSA shall determine minimum thresholds for procurement of an

entity's expected volume of a targeted drug from the company or manufacturer over a defined target period. In making advance commitments, CHHSA may consult with the Statewide Pharmaceutical Program and the California Pharmaceutical Collaborative.

(f) The listed entities in paragraphs (2) to (4), 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 (4), inclusive, of subdivision (d), so long as purchaser engagement includes a reasonable representation from these groups.

(h) Any partnership entered into pursuant to this section may include representation and involvement with the governance of the contractor entity.

(Amended by Stats. 2023, Ch. 42, Sec. 52. (AB 118) Effective July 10, 2023.)

127694. (a) On or before December 31, 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, 2028, and as of that date is repealed.

(Amended by Stats. 2022, Ch. 47, Sec. 22. (SB 184) Effective June 30, 2022. Repealed as of January 1, 2028, by its own provisions.)

127694.1. Upon appropriation by the Legislature, CHHSA shall develop a California-based manufacturing facility for insulin, with the intent of creating high-skill, high-paying jobs with the state. The facility shall be at a location jointly determined between the state and the partner pursuant to Section 127692.

(Added by Stats. 2022, Ch. 603, Sec. 3. (SB 838) Effective January 1, 2023.)

127695. (a) On or before December 31, 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, 2028, and as of that date is repealed.

(Amended by Stats. 2022, Ch. 47, Sec. 23. (SB 184) Effective June 30, 2022. Repealed as of January 1, 2028, by its own provisions.)

127696. Notwithstanding any other provision of law, all nonpublic information and documents obtained or prepared under this chapter shall not be required to be disclosed pursuant to the California Public Records Act (Division 10 (commencing with Section 7920.000) of Title 1 of the Government Code), or any similar local law requiring the disclosure of public records.

(Amended by Stats. 2023, Ch. 42, Sec. 53. (AB 118) Effective July 10, 2023.)

127697. In addition to partnerships authorized pursuant to Sections 127692 and 127693, the California Health and Human Services Agency may, subject to an appropriation by the Legislature, enter into partnerships to increase competition, lower prices, and address supply shortages under any of the following circumstances:

(a) For over-the-counter naloxone products. Partnerships entered into pursuant to this section may allow the development, manufacturing, or distribution of over-the-counter naloxone products by an entity that is authorized to do so under federal or state law.

(b) For generic or brand name drugs to address emerging health concerns, including in reproductive health care or gender affirming health care.

(c) For the development, production, procurement, or distribution of vaccines, by an entity that is authorized to do so under federal or state law, with the intent that these vaccines be made widely available to public and private purchasers, providers, suppliers, and pharmacies.

(d) For the manufacture, purchase, or distribution of medical supplies or medical devices.

(Repealed and added by Stats. 2025, Ch. 21, Sec. 43. (AB 116) Effective June 30, 2025.)