HCAi Department of Health Care Access and Information
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NOTICE OF PROPOSED RULEMAKING

CALIFORNIA CODE OF REGULATIONS
TITLE 22, DIVISION 7, CHAPTER 9.5: PRESCRIPTION DRUG PRICING FOR PURCHASERS

The Department of Health Care Access and Information (the Department) proposes revisions to Chapter 9.5. Prescription Drug Pricing for Purchasers of Title 22 of the California Code of Regulations, which implemented Chapter 9. Prescription Drug Pricing for Purchasers (Health and Safety Code section 127675 et seq.) added by Senate Bill (SB) 17 (Chapter 603, Statutes of 2017). The Department proposes to adopt the revisions described below after considering all comments, objections, and recommendations regarding the proposed action.

Senate Bill (SB) 17 (Chapter 603, Statutes of 2017) made a number of changes to California law to increase transparency in prescription drug pricing. The bill authorized the Department to adopt regulations and issue guidance for the implementation of Chapter 9. Prescription Drug Pricing for Purchasers in Part 2 of Division 107 of the Health and Safety Code (section 127675 et seq.). The Department subsequently adopted the regulations in Chapter 9.5 of Division 7 of Title 22, Sections 96060 - 96087.

The proposed revisions are needed to effectuate the intent of the law by improving the quality, clarity, and completeness of reported prescription drug pricing data, and will increase compliance with data submission requirements as well as overall program efficiency.

In addition, the proposed revisions would update web and email addresses due to the 2021 reorganization of the Office of Statewide Health Planning and Development (OSHPD) into the Department.

I. PUBLIC HEARING

The Department has not scheduled a public hearing on this proposed action. However, the Department will hold a hearing if it receives a written request for a public hearing from any interested person, or his or her authorized representative, no later than 15 days before the close of the written comment period.

II. WRITTEN PUBLIC COMMENT PERIOD AND CONTACT PERSON

Any interested person, or his or her authorized representative, may submit written comments relevant to the proposed regulatory action. All comments must be received by the Department by 5:00 PM Pacific Daylight Time on May 2, 2023. Inquiries and written comments regarding the proposed action should be addressed to the primary contact person named below. Comments delivered by email are suggested. Comments may also be faxed, hand delivered, or mailed.

Jacob Rivera, Staff Services Manager I
Information Services Division
Department of Health Care Access and Information
Tel: (916) 326-3837
Email: jacob.rivera@HCAI.ca.gov
Mailing address: 2020 West El Camino Avenue, Suite 1100
Sacramento, CA 95833-1880

Inquiries and comments may also be directed to the backup contact person at the same mailing address:

Dionne Evans-Dean, Staff Services Manager II
Information Services Division
Department of Health Care Access and Information
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III. AUTHORITY AND REFERENCE

Health and Safety Code section 127685 authorizes the Department to adopt these proposed regulations. These proposed regulations implement, interpret, and make specific sections 127675, 127677, 127679, and 127681 of the Health and Safety Code.

IV. INFORMATIVE DIGEST/POLICY STATEMENT OVERVIEW

a. Summary of Existing Laws and Effect of the Proposed Regulations

The existing regulations in Chapter 9.5 of Division 7 of Title 22, Sections 96060 – 96087 were adopted to implement Chapter 9. Prescription Drug Pricing for Purchasers in Part 2 of Division 107 of the Health and Safety Code (section 127675 et seq.). The primary purpose of these proposed regulatory changes is to clarify reporting thresholds and requirements for prescription drug manufacturers when they introduce certain new prescription drugs and when they execute certain price increases on prescription drugs.

In addition to updating web, email, and physical addresses due to the organizational change from OSHPD to the Department, the regulations proposed in this rulemaking action would effectuate the following changes:

- Under Health and Safety Code sections 127679 and 127681, a prescription drug manufacturer must report information regarding drugs to the Department, as specified. Section 96062 of Chapter 9.5. of Title 22 of the California Code of Regulations currently requires prescription drug manufacturers to register on the Department's website for the purpose of reporting such information prior to submitting reports. The proposed change to section 96062, subdivision (b)(2), would provide clarification regarding who should register a prescription drug manufacturer account in the Department system, which would help to ensure that important communications are received in a timely manner.
- Under Health and Safety Code section 129679(a), a prescription drug manufacturer must report information, as specified, to the Department for each drug for which an increase in wholesale acquisition cost (WAC) is described in Health and Safety Code section 127677. Health and Safety Code section 127677 identifies the particular threshold at which a prescription drug manufacturer must report the information required by section 127679. Section 96065 of Chapter 9.5 of Title 22 of the California Code of Regulations currently provides clarification regarding the threshold identified in Health and Safety Code section 127677.
    - The proposed change to section 96065, subdivision (b), would add clarifying language regarding the baseline date for calculating cumulative WAC increases when determining whether a WAC increase report is required.
- Under Health and Safety Code section 129679, a prescription drug manufacturer must report information, as specified, to the Department for each drug for which an increase in wholesale acquisition cost (WAC) is described in Health and Safety Code section 127677. Section 96070 of Chapter 9.5 of Title 22 of the California Code of Regulations currently specifies the information prescription drug manufacturers must report to the Department as required by Health and Safety Code section 127679.
    - The proposed change to section 96070, subdivision (b)(8), would require prescription drug manufacturers to submit, in a WAC increase report, the total volume of sales in United States dollars instead of total number of units of a drug product sold, which would resolve issues of conflicting interpretation regarding unit sales.
- Under Health and Safety Code section 127681 subdivision (b)(3), for a new prescription drug introduced to market at a specified threshold specified in subdivision (a), a prescription drug manufacturer must report to the Department the estimated volume of patients that may be prescribed the drug. Section 96076 of Chapter 9.5 of Title 22 of the California Code of Regulations currently identifies the specific information that a prescription drug manufacturer must report to the Department under Health and Safety Code 127681.
    - The proposed change to section 96076, subdivision (b)(2), would provide prescription drug manufacturers additional guidance and clarification regarding the required reporting of the estimated number of patients with a condition for which a new prescription drug may be prescribed.

- Under Health and Safety Code sections 127679 and 127681, a prescription drug manufacturer must provide notice and report information regarding drugs to the Department, as specified. Section 96078 currently specifies the two methods that prescription drug manufacturers can use to submit notices and reports pursuant to Sections 96070, 96075, and 96076. The proposed change to section 96078 would update the format and file specifications for submitting a report via electronic file to account for the proposed change to section 96070, subdivision (b), described above.
- Under Health and Safety Code sections 127679 subdivision (f) and 127681 subdivision (g), assessment of a civil penalty for late reporting of information may, at the request of a prescription drug manufacturer, be reviewed on appeal, and the penalty may be reduced or waived for good cause. Section 96082 currently provides the steps that a prescription drug manufacturer must take to appeal a penalty assessment. The proposed change to section 96082, subdivision (c), would add a requirement that prescription drug manufacturers send a copy of a penalty appeal request directly to program staff in addition to filing the request with the Department Hearing Officer. This proposed change will help to ensure timely communications between parties.
- Under Health and Safety Code sections 127679 subdivision (f) and 127681 subdivision (g), a penalty assessed against a prescription drug manufacturer for late reporting may be reduced or waived for good cause. The proposed addition of section 96082.5 would interpret section 127679 subdivision (f) and 127681 (g) by providing a standard for good cause.
- Under Health and Safety Code sections 127679 subdivision (f) and 127681 subdivision (g), assessment of a civil penalty for late reporting of information may, at the request of a prescription drug manufacturer, be reviewed on appeal. Section 96083 of Chapter 9.5 of Title 22 of the California Code of Regulations provides contact information for the submission of penalty appeal hearing requests and related communications. The proposed revision to section 96083 would provide prescription drug manufacturers with updated contact information for submitting hearing-related communications, including contact information for situations in which the Office of Administrative Hearings (OAH) is designated to hear a penalty appeal.
- Under Health and Safety Code sections 127679 subdivision (f) and 127681 subdivision (g), assessment of a civil penalty for late reporting of information may, at the request of a prescription drug manufacturer, be reviewed on appeal. Section 96084 provides specific instructions to prescription drug manufacturers for requesting a change to the hearing setting from in-person to remote, as provided by Health and Safety Code sections 127679 and 127681. The proposed revision to section 96084 would remove the specification that in-person hearings take place in Sacramento. This would allow for necessary flexibility and efficiency in scheduling and conducting penalty appeal hearings.
- Under Health and Safety Code sections 127679 subdivision (f) and 127681 subdivision (g), assessment of a civil penalty for late reporting of information may, at the request of a prescription drug manufacturer, be reviewed on appeal. Section 96085 provides specific details regarding the conduct of a penalty appeal

hearing, as provided by Health and Safety Code sections 127679 and 127681. The proposed revision to section 96085 would allow for an administrative law judge from OAH to serve as hearing officer over a penalty appeal hearing, which will allow for greater flexibility and efficiency in the penalty appeals process.

- Under Health and Safety Code sections 127679 subdivision (f) and 127681 subdivision (g), assessment of a civil penalty for late reporting of information may, at the request of a prescription drug manufacturer, be reviewed on appeal, and the penalty may be reduced or waived for good cause. Section 96087 currently provides that a final penalty appeal decision of the Director shall be made within 90 calendar days after the conclusion of the hearing. The proposed revision to section 96087, subdivision (c), would remove the requirement that a final decision be made within 90 calendar days after the conclusion of the hearing. This change would provide administrative flexibility in the penalty appeals process necessary to properly effectuate Health and Safety Code sections 127679 and 127681.

b. Objectives and Anticipated Benefits of the Proposed Regulations

The overall objective of the proposed regulations is to clarify the thresholds and reporting requirements in these regulations to ensure that prescription drug manufacturers have the information they need to submit accurate, complete, and timely data to the Department.

The anticipated benefits of the proposed regulations would be the collection of accurate, complete, and timely data, the availability and provision of more complete and accurate prescription drug pricing information to the public, and improved program efficiency.

c. Determination of Inconsistency/Incompatibility with Existing State Regulations

As required by Government Code section 11346.5(a)(3)(D), the Department evaluated the language contained in the proposed regulations. The Department has determined that these proposed regulations are not inconsistent with or incompatible with existing state regulations. These regulations are necessary to enhance the clarity and efficacy of a statutorily mandated program.

d. Documents Incorporated by Reference

Format and File Specifications for Submission of Prescription Drug Reports Version 2.0 dated May 19, 2022.

V. DISCLOSURES REGARDING THE PROPOSED ACTION

The Department has made the following initial determinations:

a. Mandate on local agencies and school districts: None.

b. Cost or savings to any state agency: None.

c. Cost to any local agency or school district which must be reimbursed in accordance with Government Code sections 17500 through 17630: None.

d. Other nondiscretionary cost or savings imposed on local agencies: None.

e. Cost or savings in federal funding to the state: None.

f. Cost impact on a representative person or business: Revisions to Title 22 Chapter 9.5 are required to increase data accuracy and program efficiency/efficacy. Approximately 1,000 prescription drug manufacturers may incur one-time costs for staff time to evaluate and modify existing business practices related to the reporting requirements of SB 17. For each individual business, this cost is estimated to be no more than 4 hours of staff time at approximately $50 per hour for an estimated statewide one-time cost of $200,000.

g. Statewide adverse economic impact directly affecting businesses and individuals: The Department has made an initial determination that the regulations will not have a significant, statewide adverse economic impact directly affecting business, including the ability of California businesses to compete with businesses in other states.

h. Significant effect on housing costs: None.

i. Cost impact on small business: This proposed action does not affect small business because no entities regulated under the proposed action are small businesses. The Department is not aware of any manufacturer of a prescription drug that qualifies as a small business.

VI. STATEMENT OF THE RESULTS OF THE ECONOMIC IMPACT ANALYSIS (EIA)

The Department originally tailored these regulations in a way that imposes only minor additional reporting or other requirements on any businesses, organizations, or individuals. The proposed revisions do not change the scope or nature of that original burden.

Therefore, the Department concludes that:

(1) this regulatory action will not create jobs within the state;

(2) this regulatory action will not eliminate jobs within the state;

(3) this regulatory action will not create new businesses;

(4) this regulatory action will not eliminate existing businesses;

(5) this regulatory action will not affect the expansion of businesses currently doing business in the state; and

(6) the benefits of the regulations to the health and welfare of California residents are to achieve the goals of SB 17, as related to Chapter 9. Prescription Drug Pricing for Purchasers. Health and Safety Code section 127676 includes the following statements: "The Legislature finds and declares that the State of California has a substantial public interest in the price and cost of prescription drugs. …It is the intent of the Legislature in enacting this chapter to provide notice and disclosure of information relating to the cost and pricing of prescription drugs in order to provide accountability to the state for prescription drug pricing." This regulatory action will have no anticipated benefit to worker safety or the state's environment.

VII. REASONABLE ALTERNATIVES

The Department must determine that no reasonable alternative considered by the Department or that has otherwise been identified and brought to the attention of the Department would be more effective in carrying out the purpose for which the action is proposed, would be as effective and less burdensome to affected private persons than the proposed action, or would be more cost-effective to affected private persons and equally effective in implementing the statutory policy or other provision of law.

The Department invites interested persons to present statements or arguments with respect to alternatives to the proposed rulemaking action during the written comment period.

VIII. AVAILABILITY OF EXPRESS TERMS, INITIAL STATEMENT OF REASONS, AND INFORMATION UPON WHICH PROPOSED RULEMAKING IS BASED

The Department will have the entire rulemaking file available for inspection and copying throughout the rulemaking process at its office at the address given for the contact persons. As of the date this notice is published in the Notice Register, the rulemaking file consists of this notice, the text of the proposed regulations, the Format and File Specifications document incorporated by reference, the initial statement of reasons, an economic impact analysis contained in the initial statement of reasons, and information upon which this proposed rulemaking is based. Copies may be obtained by contacting the listed contact person using the contact information above.

IX. AVAILABILITY OF SUBSTANTIAL CHANGES TO ORIGINAL PROPOSAL

After considering all timely and relevant comments received, the Department may adopt the proposed regulations substantially as described in this notice. If the Department makes modifications which are sufficiently related to the originally proposed text, it will

make the modified text, with the changes clearly indicated, available to the public for at least 15 days before the Department adopts the regulations as revised.

Please send requests for copies of the modified text to the listed contact person. The modified text will also be available on the website at https://hcai.ca.gov/about/laws-regulations/. The Department will accept written comments on the modified regulations for 15 days after the date on which they are made available.

X. AVAILABILITY OF FINAL STATEMENT OF REASONS

The Final Statement of Reasons, including all of the comments and responses, will be available, after its completion, through the Department's website at https://hcai.ca.gov/about/laws-regulations/. The Final Statement of Reasons will also be available for review from the above designated contact person.

XI. AVAILABILITY OF DOCUMENTS ON THE INTERNET

Copies of the Notice of Proposed Action, the Initial Statement of Reasons, the text of the proposed regulations, and the Format and File Specifications for Submission of Prescription Drug Reports Version 2.0 can be accessed through the Department's website at https://hcai.ca.gov/about/laws-regulations/.