INITIAL STATEMENT OF REASONS

CALIFORNIA CODE OF REGULATIONS

TITLE 22, DIVISION 7, CHAPTER 9.5: PRESCRIPTION DRUG PRICING FOR PURCHASERS

I. BACKGROUND INFORMATION

Senate Bill (SB) 17 (Chapter 603, Statutes of 2017) made a number of changes to California law in an effort to increase transparency in prescription drug pricing. The bill authorized the Department of Health Care Access and Information (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.).

To implement SB 17, the Department adopted the regulations in Chapter 9.5 of Division 7 of Title 22, Sections 96060 - 96087.

There are two primary components of the program. First, prescription drug manufacturers, as defined, must notify the Department within three days of introducing a new prescription drug at a Wholesale Acquisition Cost (WAC) that exceeds the specified threshold and within 30 days of this notification, manufacturers must report additional information to the Department. Second, prescription drug manufacturers, as defined, are required to notify specific drug purchasers and report to the Department certain information when executing a WAC increase that exceeds the specified thresholds.

II. THE PROBLEM TO BE ADDRESSED

Some sections of the regulations adopted to implement SB 17 were written in a way that allowed for conflicting interpretations of reporting requirements, and consequently led to the reporting of inaccurate or incomplete data.

To provide prescription drug manufacturers with greater clarity regarding reporting requirements, certain provisions of existing regulations must be refined and made more specific.

In addition, as the program continues to evolve, program efficiency and efficacy can be improved by adding new and/or revised language in several sections.

III. BENEFITS OF THIS REGULATORY ACTION

The proposed changes will further the intent of the law by improving the clarity and completeness of reported prescription drug pricing data and will increase the quality of data submitted to the Department.

IV. THE PURPOSE AND NECESSITY OF EACH PROPOSED REVISION

These regulations are necessary to interpret and provide clarity and specificity regarding the various components of Chapter 9. Prescription Drug Pricing for Purchasers (Health and Safety Code section 127675, et seq.).

In addition, in 2021, the Office of Statewide Health Planning and Development (OSHPD) underwent an expansion and recast which included a name change to the Department of Health Care Access and Information. The proposed regulations include several updates to program web addresses and email addresses which reflect this change from an Office to a Department; however, because these changes have no regulatory impact, they were not listed below.

22 CCR § 96062. Manufacturer Registration

Health and Safety Code sections 127679 and 127681 require manufacturers to report information to the Department, as specified in those sections. Section 96062 of Chapter 9.5 of Title 22 of the California Code of Regulations identifies the specific information that drug manufacturers must submit when registering their company in the Department's online portal for purposes of reporting information to the Department under Health and Safety Code sections 127679 and 127681.

Section 96062, subdivision (b)(2), currently specifies that the individual that registers the manufacturer account must be an individual authorized by the manufacturer to receive communications from the Department regarding compliance with these reporting requirements.

In some cases, drug manufacturers have retained consulting firms to manage their government reporting programs, and employees of these consulting firms are sometimes the individuals who register the drug manufacturer in the Department's system for purposes of receiving communications from the Department. However, this is not ideal, as communications from the Department are often time sensitive and should be sent directly to the drug manufacturer who is subject to reporting under Health and Safety Code sections 127679 and 127681.

The proposed change to section 96062, subdivision (b)(2), would resolve this issue by clarifying that the individual who is registered by a manufacturer in the Department's system must be an employee of the drug manufacturer in addition to being authorized to receive communications from the Department regarding compliance. This change is necessary to ensure that prescription drug

manufacturers timely submit information required under the statute and to mitigate manufacturer penalties for late reporting by ensuring that communications from the Department are received directly by manufacturers in a timely manner.

22 CCR § 96065. Wholesale Acquisition Cost Increase Notification

Health and Safety Code section 127677, subdivision (a), requires a manufacturer of a prescription drug with a wholesale acquisition cost (WAC) of more than forty dollars ($40) for a course of therapy to notify each purchaser described in section 127675 if the increase in the WAC of a prescription drug is more than 16 percent, including the proposed increase and the cumulative increases that occurred within the previous two calendar years prior to the current year. Section 96065 of Chapter 9.5 of Title 22 of the California Code of Regulations currently clarifies the thresholds at which drug manufacturers must provide notice of a WAC increase. Proposed changes provide additional necessary clarification regarding the thresholds identified in section 96065, subdivisions (b) and (c), as outlined below.

Section 96065, subdivisions (b) and (c), further clarify the reporting threshold set by Health and Safety Code section 127677. Health and Safety Code section 127677 sets the reporting threshold of a total WAC increase at more than 16%, with total WAC increase being defined as the current proposed WAC increase plus the WAC increases that occurred in the current calendar year to date and the two previous calendar years.

Several drug manufacturers have indicated that the language in these sections is insufficiently distinct. Manufacturers have indicated that if a WAC increase is made to a drug on January 1 of any given year, the drug was never available at its previous WAC at any point in that same year, so that WAC increase amount should not be included when determining whether the threshold identified in section 96065, subdivisions (b) and (c), has been exceeded.

Proposed changes to section 96065, subdivision (b), would add necessary language clarifying that the baseline date for this calculation is December 31 of the calendar year three years prior to the current calendar year. This change is necessary to ensure consistent reporting on the part of manufacturers as required under Health and Safety Code section 127679.

22 CCR § 96070. Wholesale Acquisition Cost Increase Report

Health and Safety Code section 127679 establishes the information manufacturers are required to report to the Department for each drug for which an increase in WAC is described in section 127677. Health and Safety Code section 127679, subdivision (a)(7), provides that a manufacturer is required to report the total volume of sales of the manufacturer’s drug in the United States for the previous year.

Section 96070 identifies the required components of the WAC increase reports that drug manufacturers must submit to the Department under Health and Safety Code section 127679. However, certain regulatory changes to section 96070 are necessary, as discussed below.

Section 96070, subdivision (b)(8), currently specifies that a prescription drug manufactures is required to report the number of units of the drug product sold in the United States during the one-year period prior to the effective date of the cost increase.

This language has been subject to conflicting interpretations. Specifically, the exact meaning of a unit of a drug product is sometimes unclear due to the variable nature of prescription drug dosage, package size, and delivery format.

The proposed change to this section would specify that drug manufacturers report total volume of sales in United States dollars, instead of number of units of a drug product sold, during the one-year period prior to the effective date of the WAC increase.

Total volume of sales in United States dollars is a less ambiguous and more universally relatable number than number of units of a drug product sold. This change is necessary to further clarify and give effect to Health and Safety Code section 127679, subdivision (a).

22 CCR § 96076. New Drug Report

Health and Safety Code section 127681, subdivision (b), provides that a manufacturer must report certain information to the Department no later than 30 days after notification that that manufacturer is introducing a new prescription drug to market at a wholesale acquisition cost that exceeds the threshold set for a specialty drug under the Medicare Part D program.

Section 96076 details the specific information that a manufacturer is required to report to the Department under Health and Safety Code section 127681, subdivision (b).

Section 96076, subdivision (b)(2), currently requires that a prescription drug manufacturer provide the estimated number of patients in the United States with a condition for which the new prescription drug may be prescribed.

This language has been subject to conflicting interpretations. Some manufacturers have understood this language to refer to the number of prescriptions they anticipate for a given new drug and/or other non-public, proprietary information that manufacturers believe does not have to be reported.

The proposed change to section 96076, subdivision (b)(2), would provide clarification regarding the estimated number of patients by specifying that this requested estimate is not limited to or based on the quantity of the new

prescription drug introduced to market, anticipated to be introduced to market, or anticipated to be prescribed.

This clarification is necessary to effectuate the plain meaning and intent of the statutory language at hand. Specifically, it is conceivable that the number of patients with a certain condition for which that prescription drug *may* be prescribed can, in any given instance, be greater than the quantity of that prescription drug a manufacturer anticipates producing, even if, in the final analysis, not every patient with that condition is in fact prescribed that drug. Additionally, a manufacturer may opt to produce a greater-than-initially-anticipated quantity of a particular prescription drug because, among other reasons, it later anticipates there being more patients with a certain condition for whom that drug may be prescribed. From this, it follows that the estimated number of patients in the United States for which the new prescription drug may be prescribed cannot be limited by or intrinsically linked to the quantity of that drug a manufacturer anticipates producing at the time of reporting.

This additional guidance and clarification will help drug manufacturers comply with this reporting requirement, will increase data accuracy, and will lead to increased program efficiency.

22 CCR § 96078. Method of Submission

Health and Safety Code sections 127679 and 127681 require a manufacturer to report information to the Department, as specified in those sections. In addition, Health and Safety Code section 127681 requires a manufacturer to notify the Department if it is introducing a new drug to market, as specified.

Section 96078 specifies the two methods that a prescription drug manufacturer may use to submit reports and notices pursuant to Sections 96070, 96075, and 96076. Manufacturers have the option either to upload electronic files of the required information or to enter the required information directly into the submission portal on the Department's website. The web address of the submission portal is provided in this section.

The current Format and File Specifications for Submission of Prescription Drug Reports: Version 1.1 specifies technical file requirements for a manufacturer submitting a report by uploading an electronic file in comma separated value (.csv) file format.

Because the proposed change to section 96070, subdivision (b), described previously would necessitate a change to one of the required data fields, the format and file specifications need to be modified to indicate to manufacturers what they are required to report. Specifically, the data field for reporting unit sales volume (data element "Unit Sales Volume in U.S.") would change to reflect total volume of sales in United States dollars. The proposed updated version of the format and file specifications document is

included herein (see Format and File Specifications for Submission of Prescription Drug Reports: Version 2.0, dated May 19, 2022).

This change to Section 96078 is necessary to incorporate by reference the new, updated format and file specifications document.

22 CCR § 96082. Filing an Appeal

Health and Safety Code sections 127679, subdivision (f), and 127681, subdivision (g), provide that a civil penalty assessed against a prescription drug manufacturer may, on request, be reduced or waived for good cause.

> Section 96082 details the steps that a drug manufacturer must take to appeal a penalty assessment, a process which stipulates that drug manufacturers file a written request with the Department's hearing officer. Due to a complex and variable workload, the Department's hearing officer is not always able to immediately process an appeal request, in which case both program staff and accounting remain unaware of the pending appeal. This can occasionally lead to miscommunication and inefficiency when program staff, the Department's accounting staff, the Department's hearing officer, and/or the drug manufacturer are operating on incomplete information with different expectations or requirements.**Section 96082, subdivision (c)**, would add a requirement that drug manufacturers also send a copy of the appeal request directly to program staff no later than five days after filing the request with the Department's hearing officer. This proposed change is needed to ensure that penalty appeals are timely received and appropriately and efficiently assessed by program staff.

22 CCR § 96082.5. Good Cause

Health and Safety Code sections 127679, subdivision (f), and 127681, subdivision (g), provide that a civil penalty assessed against a manufacturer may, on request, be reduced or waived for good cause.

The Department proposes to add **Section 96082.5** to Chapter 9.5 of Title 22 of the California Code of Regulations to implement and make specific the good cause standard contained in Health and Safety Code sections 127679, subdivision (f), and 127681, subdivision (g). In the absence of a standard defined in regulation, the Department's Hearing Office has relied upon case law from contexts unrelated to manufacturer penalty appeals in determining whether an appealing manufacturer has failed to report timely for reasons constituting good cause.

Section 95.22 of Title 45 of the Code of Federal Regulations identifies a standard for good cause for late filing of certain claims on the part of states.

Proposed Section 96082.5, subdivision (b), proposes that good cause shall be lateness due to circumstances beyond the control of the manufacturer, and does not include

neglect or administrative inadequacy on the part of the manufacturer or any of its offices, officers, employees, or agents.

This proposed regulation will provide the Hearing Office, appealing manufacturers, and the Department with a more certain delineation between circumstances that constitute good cause and circumstances that do not constitute good cause by more closely aligning the good cause standard of Health and Safety Code sections 127679 and 127681 with the contextually analogous federal standard in Section 95.22 of Title 45 of the Code of Federal Regulations. This proposed regulation is necessary to provide manufacturers with greater certainty regarding the potential outcome of a penalty appeal and to ensure that proposed and final penalty decisions adhere consistently to a clear and fair standard.

This section would also specify that a penalty may be reduced or waived if the Department finds that good cause exists for the late filing of a required report.

22 CCR § 96083. Hearing Officer Contact Information

Health and Safety Code sections 127679, subdivision (f), and 127681, subdivision (g), provide that a civil penalty assessed against a manufacturer may, on request, be reduced or waived for good cause.

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.

Proposed changes to Section 96083 would provide drug manufacturers with updated contact information for hearing-related communications, including in situations in which an administrative law judge from the Office of Administrative Hearings (OAH) is designated to serve as hearing officer under proposed changes to section 96085. These proposed changes would further specify that hearing requests must be sent to the Department's hearing officer as opposed to an employee of OAH appointed to serve as hearing officer. This change is necessary to conform section 96083 to proposed changes to section 96085 and to maintain the functionality of the penalty appeal process by ensuring that manufacturers are provided with appropriate contact information.

22 CCR § 96084. Prehearing Provisions

Health and Safety Code sections 127679, subdivision (f), and 127681, subdivision (g), provide that a civil penalty assessed against a manufacturer may, on request, be reduced or waived for good cause.

Section 96084, subdivision (d), of Chapter 9.5 of Title 22 of the California Code of Regulations provides specific instructions to manufacturers for requesting a change to the hearing setting from in-person to remote. The current language indicates that in-person hearings must be held in Sacramento.

The proposed change to Section 96084, subdivision (d), would remove the specification that in-person hearings take place in Sacramento and would allow the hearing officer to determine the location. The proposed change to section 96084, subdivision (d), is necessary to allow for an administrative law judge employed by OAH who does not work in Sacramento to serve as hearing officer under an Interagency Agreement, in alignment with proposed changes to section 96085. This change is needed to allow for greater flexibility in scheduling appeal hearings and to increase the overall efficiency of the appeals process.

22 CCR § 96085. Conduct of Hearing

Health and Safety Code sections 127679, subdivision (f), and 127681, subdivision (g), provide that a civil penalty assessed against a manufacturer may, on request, be reduced or waived for good cause. Section 96085 of Chapter 9.5 of Title 22 of the California Code of Regulations provides necessary specificity regarding the conduct of a hearing held pursuant to a manufacturer appeal for good cause.

The Department's hearing officer has a complex and variable workload, and the penalty appeal process can sometimes take a considerable amount of time, which can decrease the effectiveness of the process in some cases. To mitigate this issue, the Department has been exploring the possibility of outsourcing some hearings to OAH by way of an Interagency Agreement. This would allow for greater flexibility in scheduling appeal hearings and would increase the overall efficiency of the appeals process.

Proposed changes to section 96085 would allow for an administrative law judge employed by OAH to be designated by the Director of the Department to serve as hearing officer under an Interagency Agreement. Further, proposed changes to this section would allow for an administrative law judge employed by OAH who does not work in Sacramento to serve as hearing officer under an Interagency Agreement by removing the requirement that hearings be conducted in Sacramento. These changes are needed to allow for greater flexibility in scheduling appeal hearings and increase the overall efficiency of the appeals process.

22 CCR § 96087. Decision

Health and Safety Code sections 127679, subdivision (f), and 127681, subdivision (g), provide that a civil penalty assessed against a manufacturer may, on request, be reduced or waived for good cause. Section 96087 provides information regarding department hearing decisions for appeals for good cause.

> **Section 96087, subdivision (c)**, currently states that the Director of the Department shall make a decision within 90 days after the conclusion of an appeal hearing.
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> The proposed change to section 96087, subdivision (c), would remove the 90-day timeframe. The removal of the 90-day time frame provides necessary

administrative flexibility to allow the hearing office to draft proposed decisions and to the Director to issue final decisions.

V. TECHNICAL, THEORETICAL, OR EMPIRICAL STUDY, REPORTS, OR SIMILAR DOCUMENTS RELIED UPON

None.

VI. ECONOMIC IMPACT ANALYSIS

The proposed changes impose no additional reporting requirements on any businesses, organizations, or individuals.

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 these changes to the health and welfare of California residents, worker safety, and the state's environment are to further achieve the goals of SB 17, as related to Chapter 9. Prescription Drug Pricing for Purchasers (Health and Safety Code sections 127675 et seq.). Health and Safety Code section 127676 includes the following statement(s): "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."

VII. EVIDENCE SUPPORTING FINDING OF NO SIGNIFICANT ADVERSE ECONOMIC IMPACT ON ANY BUSINESS

The Department has determined that adoption of the proposed changes would not have an adverse economic impact on any business in the State of California because the regulations do not add any additional reporting requirements or other burdens to the existing statutorily mandated program, Chapter 9. Prescription Drug Pricing for Purchasers (Health and Safety Code section 127675 et seq.).

VIII. CONSIDERATION OF ALTERNATIVES

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