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PROPOSED REGULATIONS

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Title 22, Division 7, Chapter 9.5 (New Chapter 9.5 is added)

Chapter 9.5 Prescription Drug Pricing for Purchasers

Article 1. General

§ 96060. Definitions.

For the purposes of this chapter, the following definitions apply:

(a) "Office" means the Office of Statewide Health Planning and Development.

(b) "Drug product" means the finished dosage form of a prescription drug that contains a drug substance, generally, but not necessarily, in association with other active or inactive ingredients, and that has a unique NDC.

(c) "Introduced to market" means made available for purchase in California.

(d) "Manufacturer" means an entity that

(1) holds the NDC for a prescription drug; and

(2) Is described in Health and Safety Code Section 127675.

(e) "National Drug Code (NDC)" refers to a three-segment code maintained by the federal Food and Drug Administration that includes a labeler code, a product code, and a package code for a drug product and that has been converted to an 11-digit format consisting of five digits in the first segment, four digits in the second segment, and two digits in the third segment. A three-segment code shall be considered converted to an 11-digit format when, as necessary, at least one "0" has been added to the front of each segment containing less than the specified amount of digits such that each segment contains the specified amount of digits.

(f) "New prescription drug" means a drug receiving initial approval under an original new drug application under Section 355(b) of Title 21 of the United States Code, under an abbreviated new drug application under Section 355(j) of Title 21 of the United States Code, or under a biologics license application under Section 262 of Title 42 of the United States Code. Each product listed on the application shall be considered a new prescription drug.

(g) "Prescription drug" means a drug, as defined in Section 321(g) of Title 21 of the United States Code, or a biological product as defined in Section 262(i)(1) of Title 42 of the United States Code, that

(1) is intended for human use;

(2) is not a device within the meaning of Section 321(h) of Title 21 of the United States Code;

(3) by federal or state law, can be lawfully dispensed only on prescription by a licensed healthcare professional; and

(4) is purchased or reimbursed by an entity described in subdivision (a) of Health and Safety Code Section 127675.

(h) "Registered purchaser" means an organization described in subdivision (a) of Health and Safety Code Section 127675 and that has registered with the Office pursuant to Section 96061.

(i) "Wholesale Acquisition Cost" means a manufacturer's published list price for a prescription drug product with a unique NDC.

(j) "Date" means calendar date; month, day and year shall be reported in numeric format separated by "/". For example, 3/12/2009.

(k) "Cost" or "price" means a monetary amount in United States currency, which shall be reported in dollars to the cent level.

Note: Authority cited: Section 127685, Health and Safety Code. Reference: Sections 127675, 127677, 127679, and 127681, Health and Safety Code.

§ 96061. Purchaser Registration.

(a) A purchaser or reimbursor identified in subdivision (a) of Health and Safety Code Section 127675 may register with the Office for the purpose of receiving advance notice of cost increases under Health and Safety Code Section 127677.

(b) A purchaser or reimbursor choosing to register must register on the Office's website using the registration portal at <https://oshpd.ca.gov/data-and-reports/cost-transparency/rx/>. A purchaser or reimbursor must provide the following information:

(1) The legal name of the organization.

(2) The organization type as described in subdivision (a) of Health and Safety Code Section 127675.

(3) The name of a contact person designated to receive notices.

(4) The business title of the designated contact person.

(5) A business address.

(6) A business email address.

Note: Authority cited: Section 127685, Health and Safety Code. Reference: Section 127677, Health and Safety Code.

§ 96062. Manufacturer Registration.

(a) Prior to filing a report or notice as required under Sections 96070, 96075, and 96076, a manufacturer must register on the Office's website using the report submission portal at <https://oshpd.ca.gov/data-and-reports/cost-transparency/rx/>. Registration must occur five business days prior to the date the manufacturer's first submission is due.

(b) In order to register, a manufacturer must provide the following information:

(1) Manufacturer name and the following information for the manufacturer:

(A) Business address.

(B) Business phone number.

(2) The name and title of an individual authorized by the manufacturer to receive communications from the Office regarding compliance with this Chapter, and the following information for the authorized individual:

(A) Business mailing address.

(B) Business email address.

(C) Business phone number.

(c) A manufacturer must update the manufacturer's registration each time there is a change to any information provided pursuant to subdivision (b) above. Any required update must be made prior to filing a report or notice as required under Sections 96070, 96075, and 96076.

Note: Authority cited: Section 127685, Health and Safety Code. Reference: Sections 127679 and 127681, Health and Safety Code.

Article 2. Prescription Drug Cost Increase Notification and Report Requirements

§ 96065. Wholesale Acquisition Cost Increase Notification.

(a) This section shall apply to each manufacturer of a drug product with a wholesale acquisition cost of more than forty dollars (\$40) for a course of therapy as defined in subdivision (a) Health and Safety Code Section 127677.

(b) When a manufacturer proposes a wholesale acquisition cost increase that will result in a total wholesale acquisition cost increase of more than 16%, the manufacturer shall provide each registered purchaser with advance notice as required by subdivisions (b) and (c) of Health and Safety Code Section 127677.

(c) Total wholesale acquisition cost increase includes the current proposed wholesale acquisition cost increase and the sum of the wholesale acquisition cost increases that occurred in the current calendar year and the two previous calendar years.

Note: Authority cited: Section 127685, Health and Safety Code. Reference: Section 127677, Health and Safety Code.

§ 96070. Wholesale Acquisition Cost Increase Report.

(a) For each drug product wholesale acquisition cost increase for which a notice was required pursuant to Section 96065, a manufacturer shall file a report with the Office.

(b) The report shall include the following information:

(1) The NDC. The NDC shall be reported in numeric form.

(2) A description of the drug product to include the following:

(A) The drug product name.

(B) The drug product strength.

(C) The drug product dosage form.

(D) The drug product package size.

(3) Effective date of wholesale acquisition cost increase.

(4) Amount of wholesale acquisition cost increase.

(5) The wholesale acquisition cost resulting from the reported cost increase.

(6) If the drug is under patent, the patent expiration date. For a drug under multiple patents, the patent expiration date shall be the date on which all of the patents will have expired.

(7) Indicate whether the drug product is one of the following as defined in subparagraph (A) of paragraph (7) of subdivision (k) of Section 1396r-8 of Title 42 of the United States Code:

(A) An innovator multiple source drug;

(B) A noninnovator multiple source drug; or

(C) A single source drug.

(8) 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.

(9) A narrative description of the specific financial and nonfinancial factors used to make the decision to increase the wholesale acquisition cost of the drug product and to decide on the amount of the increase. The description shall include, but shall not be limited to, an explanation of how these factors explain the increase in the wholesale acquisition cost of the drug product.

(10) A narrative description of the change or improvement in the drug product, if any, that necessitates the price increase.

(11) A schedule of wholesale acquisition cost increases for the drug product for any period during the previous five year period in which the drug product was manufactured by the reporting manufacturer. The schedule shall list the date of each wholesale acquisition cost increase, the amount of each wholesale acquisition cost increase, and the wholesale acquisition cost resulting from each wholesale acquisition cost increase.

(12) If the drug product was acquired by the manufacturer within the previous five year period, all of the following information:

(A) The name of the company from which the drug product was acquired.

(B) The date acquired.

(C) The purchase price.

(D) The wholesale acquisition cost of the drug product at the time of acquisition.

(E) The wholesale acquisition cost of the drug product one year prior to the date of acquisition.

(F) The year the drug product was introduced to market.

(G) The wholesale acquisition cost of the drug product at the time it was introduced to market.

(c) A manufacturer may limit the information reported pursuant to subdivision (b) to that which is otherwise in the public domain or publicly available.

(d) A manufacturer may append comments to any information described in subdivision (b).

Note: Authority cited: Section 127685, Health and Safety Code. Reference: Section and 127679, Health and Safety Code.

§ 96071. Wholesale Acquisition Cost Increase Report Periods and Due Dates.

(a) The reports described in Section 96070 are due as follows:

(1) Each report related to a cost increase with an effective date between January 1 and March 31, inclusive, shall be due by April 30 of the same year.

(2) Each report related to a cost increase with an effective date between April 1 and June 30, inclusive, shall be due by July 31 of the same year.

(3) Each report related to a cost increase with an effective date between July 1 and September 30, inclusive, shall be due by on October 31 of the same year.

(4) Each report related to a cost increase with an effective date between October 1 and December 31, inclusive, shall be due by January 31 of the following year.

(b) A report shall be filed by 11:59 p.m., Pacific Time on the due date.

Note: Authority cited: Section 127685, Health and Safety Code. Reference: Section 127679, Health and Safety Code.

Article 3. New Prescription Drug Notice and Report Requirements**§ 96075. New Drug Notice.**

(a) When a manufacturer introduces 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 (Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (Public Law 108-173)), the manufacturer shall file a notice with the Office.

(b) The notice shall include the following information:

(1) The NDC. The NDC shall be reported in numeric form.

(2) The date the new prescription drug was, or will be, introduced to market.

(3) The wholesale acquisition cost of the new prescription drug as of the introduction to market date.

(c) The notice shall be filed with the Office within three days after the day the drug was introduced to market. If the drug is expected to be introduced to market within three days of approval by the federal Food and Drug Administration, a notice may be filed pending that approval.

Note: Authority cited: Section 127685, Health and Safety Code. Reference: Section 127681, Health and Safety Code.

§ 96076. New Drug Report.

(a) For each new prescription drug for which a notice was filed with the Office under Section 96075, a manufacturer shall file a report with the Office.

(b) The report shall include the following information:

(1) A narrative description of the marketing and pricing plans used in the launch of the new prescription drug in the United States and internationally.

(2) The estimated number of patients in the United States with a condition for which the new prescription drug may be prescribed.

(3) Indicate whether the drug was granted breakthrough therapy designation or priority review by the federal Food and Drug Administration prior to approval.

(4) If the drug was not developed by the manufacturer:

(A) The date the manufacturer acquired the drug; and

(B) The price of acquisition.

(c) A manufacturer may limit the information reported pursuant to subdivision (b) to that which is otherwise in the public domain or publicly available.

(d) A manufacturer may append comments to any information described in subdivision (b).

Note: Authority cited: Section 127685, Health and Safety Code. Reference: Section 127681, Health and Safety Code.

§ 96077. New Drug Report Due Date.

(a) Each report required under Section 96076 shall be filed within 30 days after the notice required under Section 96075 was filed with the Office.

(b) A report shall be filed by 11:59 P.M. Pacific Time of the due date.

Note: Authority cited: Section 127685, Health and Safety Code. Reference: Section 127681, Health and Safety Code.

Article 4. Submission of Notice and Reports

§ 96078. Method of Submission.

(a) A report required under Section 96070, a notice required under Section 96075, or a report required under Section 96076 shall be submitted to the Office through the Office's website using the report submission portal at <https://oshpd.ca.gov/data-and-reports/cost-transparency/rx/>

(b) Reports and notices must be submitted using one of the following methods:

(1) Uploading comma separated value (.csv) files including all of the required information for one or more notices and/or reports. Such files shall comply with the Office's Format and File Specifications for Submission of Prescription Drug Reports Version 1.0, dated June 30, 2018, and hereby incorporated by reference; or

(2) Entering the required information for individual notices or reports online.

Note: Authority cited: Section 127685, Health and Safety Code. Reference: Sections 127679 and 127681, Health and Safety Code.

Article 5. Penalties and Appeals

§ 96080. Penalties for Late Filing of Reports.

A manufacturer that fails to file a required report by the due date established by either Section 96071 or 96077 is liable for a civil penalty of one thousand dollars (\$1,000) for each day after the due date that the required report is not filed.

Note: Authority cited: Section 127685, Health and Safety Code. Reference: Sections 127679 and 127681, Health and Safety Code.

§ 96081. Penalty Assessment.

(a) When either a report required by Section 96070 is filed after the due date specified in Section 96071, or a report required by Section 96076 is filed after the due date specified in Section 96077, the Office will notify the manufacturer of the accrued penalty. The notice shall be provided by email to the authorized individual identified by the manufacturer under subdivision (b)(2) of Section 96062.

(b) The Office will calculate the accrued penalty pursuant to Section 96080.

Note: Authority cited: Section 127685, Health and Safety Code. Reference: Sections 127679 and 127681, Health and Safety Code.

§ 96082. Filing an Appeal.

(a) A manufacturer that has received notice of an accrued penalty under Section 96081 may appeal the penalty assessment by filing a written request for hearing within 15 business days after the date of the notice. The request shall be filed with the Office's hearing officer.

(b) The request for hearing shall include the following:

(1) The name of the manufacturer.

(2) The name of the authorized representative of the manufacturer and contact information for that representative.

(3) The date of the penalty assessment notice.

(4) A statement of the basis for the appeal.

(5) A copy of the penalty notice.

Note: Authority cited: Section 127685, Health and Safety Code. Reference: Sections 127679 and 127681, Health and Safety Code.

§ 96083. Hearing Officer Contact Information.

Hearing requests and other communications, including requests for consolidation, questions about the hearing schedule or process, and all documents and proposed exhibits, shall be addressed to the hearing officer either by mail or by email as follows:

(a) Mail shall be sent to the hearing officer at the Legal Office of the Office of Statewide Health Planning and Development in Sacramento.

(b) Email shall be sent to the following email address: HearingOfficer@oshpd.ca.gov

Note: Authority cited: Section 127685, Health and Safety Code. Reference: Sections 127679 and 127681, Health and Safety Code.

§ 96084. Prehearing Provisions.

(a) The manufacturer and the Office will be notified of the hearing date and time at least 30 days in advance.

(b) The manufacturer and the Office shall provide copies of all proposed exhibits to the hearing officer and to the other party no later than 10 business days prior to the hearing date.

(c) Request to Change Hearing Date. Either party may request a change of hearing date, if necessary. Requests for rescheduling must be submitted to the hearing officer at least 10 business days before the scheduled hearing. Requests for rescheduling must be based upon good cause, as determined by the hearing officer, and will only be granted if the change would not prejudice the other party.

(d) Request to Change Hearing Method. All hearings will be held in Sacramento at the business location of the Office; however, the hearing officer may schedule a hearing to be conducted by telephone or other electronic means. If so, either party may object; upon receipt of such an objection, the hearing officer will schedule an in-person hearing in Sacramento. If the hearing officer does not initially plan to conduct a hearing by telephone or other electronic means, either party may so request; if the manufacturer and the Office consent, the hearing officer may, but is not required to, conduct the hearing by telephone or other electronic means. The manufacturer and the Office will be notified of the hearing officer's decision.

(e) Request for Consolidation. The hearing officer may, on her or his own determination or upon written request of one of the parties, consolidate for hearing or decision any number of appeals when the facts and circumstances

are similar and no substantial right of any party will be prejudiced. The hearing officer shall notify both the manufacturer and the Office if consolidation is occurring. Either party may request consolidation by filing a request with the hearing officer containing the following information:

(1) Identification of the appeals to be consolidated.

(2) A statement of the basis for consolidation.

(f) Request for Interpreter. If a party or a witness of a party does not speak English proficiently, that party may request language assistance and the Office will provide an interpreter. Such a request must be received by the hearing officer at least 10 business days before the hearing. The cost of providing an interpreter shall be paid by the requesting party unless otherwise directed by the hearing officer.

(g) Request for Court Reporter. Hearings will be recorded electronically; however, either party may provide a court reporter at that party's expense. If a party chooses to provide a court reporter, that party shall notify the hearing officer in advance and make all necessary arrangements. The original of the transcript shall be provided directly to the Office. The nonappearance of a court reporter will not be considered adequate grounds for cancelling or rescheduling a hearing.

Note: Authority cited: Section 127685, Health and Safety Code. Reference: Sections 127679 and 127681, Health and Safety Code.

§ 96085. Conduct of Hearing.

(a) The hearing shall be conducted by an employee of the Office appointed by the Director of the Office to serve as hearing officer.

(b) The hearing shall be conducted in person in Sacramento or by telephone or other electronic means as determined by the hearing officer, as specified in Section 96084.

(c) The hearing shall not be conducted according to technical rules relating to evidence and witnesses. Any relevant evidence shall be admitted if it is the sort of evidence on which responsible persons are accustomed to rely in the conduct of serious affairs.

(d) All testimony at the hearing shall be taken under oath or affirmation.

(e) The hearing shall be recorded by electronic means unless one party has chosen to provide a court reporter at their own expense as specified in Section 96084. A court reporter shall provide the original of the transcript directly to the hearing officer.

(f) The hearing shall be open to the public.

Note: Authority cited: Section 127685, Health and Safety Code. Reference: Sections 127679 and 127681, Health and Safety Code.

§ 96086. Settlement.

If a settlement is reached between the parties prior to the hearing, the Office shall notify the hearing officer and no hearing shall be held.

Note: Authority cited: Section 127685, Health and Safety Code. Reference: Sections 127679 and 127681, Health and Safety Code.

§ 96087. Decision.

(a) The hearing officer shall prepare a recommended decision for the Director of the Office; the recommended decision shall be in writing and shall include findings of fact and conclusions of law.

(b) The Director of the Office may either adopt or reject the proposed decision. If the Director does not adopt the proposed decision as presented, she or he will independently prepare a decision based upon the hearing record;

the Director may adopt factual findings of the hearing officer.

(c) The decision of the Director shall be made within 90 calendar days after the conclusion of the hearing. The decision shall be in writing and shall be final.

Note: Authority cited: Section 127685, Health and Safety Code. Reference: Sections 127679 and 127681, Health and Safety Code.