State of California
Office of Administrative Law

In re:
Department of Health Care Access and Information

Regulatory Action:

Title 22, California Code of Regulations

Adopt section: **96082.5**
Amend sections: **96060, 96061, 96062, 96065, 96070, 96075, 96076, 96077, 96078, 96081, 96082, 96083, 96084, 96085, 96086, and 96087**

NOTICE OF APPROVAL OF REGULATORY ACTION

Government Code Section 11349.3

OAL Matter Number: 2023-1113-01

OAL Matter Type: Regular (S)

In this regular rulemaking, the Department of Health Care Access and Information is adopting and amending regulations regarding reporting prescription drug pricing data.

OAL approves this regulatory action pursuant to section 11349.3 of the Government Code. This regulatory action becomes effective on 4/1/2024.

Date: December 21, 2023

Steven J. Escobar
Senior Attorney

Original: Elizabeth Landsberg, Director
Copy: Jacob Rivera

For: Kenneth J. Pogue
Director

STATE OF CALIFORNIA--OFFICE OF ADMINISTRATIVE LAW

NOTICE PUBLICATION/REGULATION SUBMISSION

REGULAR

STD. 400 (REV. 10/2019)

For use by Secretary of State only

OAL FILE NUMBERS	NOTICE FILE NUMBER	REGULATORY ACTION NUMBER	EMERGENCY NUMBER
	Z-2023-0301-01	2023-1113-01 S	

For use by Office of Administrative Law (OAL) only

OFFICE OF ADMINISTRATIVE LAW

Electronic Submission

RECEIVED DATE	PUBLICATION DATE
3/01/2022	March 17, 2023

NOTICE

OFFICE OF ADMIN. LAW
2023 NOV 13 PM 12:03

REGULATIONS

ENDORSED - FILED
in the office of the Secretary of State
of the State of California

DEC 21 2023

1:36 PM

AGENCY WITH RULEMAKING AUTHORITY
Department of Health Care Access and Information (HCAI)

AGENCY FILE NUMBER (If any)

A. PUBLICATION OF NOTICE (Complete for publication in Notice Register)

1. SUBJECT OF NOTICE	TITLE(S)	FIRST SECTION AFFECTED	2. REQUESTED PUBLICATION DATE
Prescription Drug Cost Transparency	22	96060	03/17/2023

3. NOTICE TYPE	4. AGENCY CONTACT PERSON	TELEPHONE NUMBER	FAX NUMBER (Optional)
[X] Notice re Proposed Regulatory Action [ ] Other	Jacob Rivera	916-326-3837	

OAL USE ONLY	ACTION ON PROPOSED NOTICE	NOTICE REGISTER NUMBER	PUBLICATION DATE
	[ ] Approved as Submitted [ ] Approved as Modified [ ] Disapproved/ Withdrawn	2023, 11-Z	3/17/2023

B. SUBMISSION OF REGULATIONS (Complete when submitting regulations)

1a. SUBJECT OF REGULATION(S)
Prescription Drug Cost Transparency

1b. ALL PREVIOUS RELATED OAL REGULATORY ACTION NUMBER(S)

2. SPECIFY CALIFORNIA CODE OF REGULATIONS TITLE(S) AND SECTION(S) (Including title 26, if toxics related)

SECTION(S) AFFECTED (List all section number(s) individually. Attach additional sheet if needed.)	
TITLE(S) 22	ADOPT 96082.5
	AMEND 96060, 96061, 96062, 96065, 96070, 96075, 96076, 96077, 96078, 96081, 96082, 96083, 96084, 96085, 96086, 96087
	REPEAL

3. TYPE OF FILING

- [X] Regular Rulemaking (Gov. Code §11346)
- [ ] Certificate of Compliance: The agency officer named below certifies that this agency complied with the provisions of Gov. Code §§11346.2-11347.3 either before the emergency regulation was adopted or within the time period required by statute.
- [ ] Emergency Readopt (Gov. Code, §11346.1(h))
- [ ] Changes Without Regulatory Effect (Cal. Code Regs., title 1, §100)
- [ ] Resubmittal of disapproved or withdrawn nonemergency filing (Gov. Code §§11349.3, 11349.4)
- [ ] File & Print
- [ ] Print Only
- [ ] Emergency (Gov. Code, §11346.1(b))
- [ ] Resubmittal of disapproved or withdrawn emergency filing (Gov. Code, §11346.1)
- [ ] Other (Specify)

4. ALL BEGINNING AND ENDING DATES OF AVAILABILITY OF MODIFIED REGULATIONS AND/OR MATERIAL ADDED TO THE RULEMAKING FILE (Cal. Code Regs. title 1, §44 and Gov. Code §11347.1)
08/31/2023 to 09/15/2023

5. EFFECTIVE DATE OF CHANGES (Gov. Code, §§ 11343.4, 11346.1(d); Cal. Code Regs., title 1, §100)

- [X] Effective January 1, April 1, July 1, or October 1 (Gov. Code §11343.4(a))
- [ ] Effective on filing with Secretary of State
- [ ] §100 Changes Without Regulatory Effect
- [ ] Effective other (Specify)

6. CHECK IF THESE REGULATIONS REQUIRE NOTICE TO, OR REVIEW, CONSULTATION, APPROVAL OR CONCURRENCE BY, ANOTHER AGENCY OR ENTITY

- [ ] Department of Finance (Form STD. 399) (SAM §6660)
- [ ] Fair Political Practices Commission
- [ ] State Fire Marshal
- [ ] Other (Specify)

7. CONTACT PERSON	TELEPHONE NUMBER	FAX NUMBER (Optional)	E-MAIL ADDRESS (Optional)
Jacob Rivera	(916)326-3837		jacob.rivera@hcai.ca.gov

8. I certify that the attached copy of the regulation(s) is a true and correct copy of the regulation(s) identified on this form, that the information specified on this form is true and correct, and that I am the head of the agency taking this action, or a designee of the head of the agency, and am authorized to make this certification.

SIGNATURE OF AGENCY HEAD OR DESIGNEE	DATE
J Scott Christman (Nov 9, 2023 10:36 PST)	11/09/2023

TYPED NAME AND TITLE OF SIGNATORY
J Scott Christman (Chief Deputy Director) for Elizabeth Landsberg (Director)

For use by Office of Administrative Law (OAL) only

ENDORSED APPROVED

DEC 21 2023

Office of Administrative Law

CALIFORNIA CODE OF REGULATIONS

Title 22, Division 7, Chapter 9.5

Chapter 9.5 Prescription Drug Pricing for Purchasers

Article 1. General

§ 96060. Definitions.

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

(a) "Department"~~"Office"~~ means the Department of Health Care Access and Information~~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 DepartmentOffice 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 reimburser identified in subdivision (a) of Health and Safety Code Section 127675 may register with the DepartmentOffice for the purpose of receiving advance notice of cost increases under Health and Safety Code Section 127677.

(b) A purchaser or reimburser choosing to register must register on the Department'sOffice's website using the registration portal at https://hcai.ca.gov/data-and-reports/cost-transparency/rx/https://oshpd.ca.gov/data-and-reports/cost-transparency/rx/. A purchaser or reimburser 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.

(c) A purchaser or reimburser who has registered with the DepartmentOffice pursuant to subdivision (b) above must notify the DepartmentOffice by email at ctrx@hcai.ca.govctrx@oshpd.ca.gov of any change to their registration information.

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 Department'sOffice's website using the report submission portal at https://hcai.ca.gov/data-and-reports/cost-transparency/rx/https://oshpd.ca.gov/data-and-reports/cost-transparency/rx/. Registration must occur at least 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 who is employed by the manufacturer and who is authorized by the manufacturer to receive communications from the DepartmentOffice 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% above the wholesale acquisition cost of the drug product on December 31 of the calendar year three years prior to the current calendar year, 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 to date 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 Department~~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~~ Total volume of gross sales in United States dollars 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 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 Department~~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 Department~~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 Department~~Office~~ under Section 96075, a manufacturer shall file a report with the Department~~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 annual number of patients in the United States with a condition for which the new prescription drug may be prescribed. This estimated number shall account for the total number of patients with a condition for which the new prescription drug may be prescribed and shall not be limited to or based on the quantity of the particular new prescription drug introduced to market, anticipated to be introduced to market, or anticipated to 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 DepartmentOffice.

(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 DepartmentOffice through the Department'sOffice's website using the report submission portal at https://hcai.ca.gov/data-and-reports/cost-transparency/rx/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 Department's~~Office's~~ Format and File Specifications for Submission of Prescription Drug Reports Version 2.0~~1.0~~, dated May 19, 2022~~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

§ 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 Department~~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 Department~~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, as explained in Section 96083, a written request for hearing no later than 30 days from the date of the notice. The request shall be filed with the Department's~~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.

(c) No later than five days after filing the request for hearing, the manufacturer shall provide a copy of the request to the Department by email at ctrx@hcai.ca.gov.

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

§ 96082.5. Good Cause.

(a) A penalty for which a written request for hearing has been filed under Section 96082 may be reduced or waived if the hearing officer finds that good cause exists for the late filing of the report required by Section 96070 or Section 96076 for which the penalty was issued.

(b) For purposes of this section, good cause for the late filing of a required report shall be lateness due to circumstances beyond the control of the manufacturer. Circumstances beyond the control of the manufacturer does not include neglect or administrative inadequacy on the part of the manufacturer or any of its offices, officers, employees, or agents.

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

§ 96083. Hearing Officer Contact Information.

(a) 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 Department's hearing officer either by mail or by email as follows:

(1)~~(a)~~ Mail shall be sent to the hearing officer at the Legal Office of the Department of Health Care Access and Information~~Office of Statewide Health Planning and Development~~ in Sacramento.

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

(b) Other communications, including requests for consolidation of appeals, questions about the hearing schedule or process, and all documents and proposed exhibits, shall be addressed as follows:

(1) For appeals before an employee of the Department appointed by the Director of the Department to serve as hearing officer under Section 96085, as provided in subdivision (a) of this section.

(2) For appeals before an administrative law judge employed by the California Office of Administrative Hearings serving as hearing officer, as specified in the notice provided under subdivision (a) of section 96084.

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 DepartmentOffice will be notified of the hearing date and time at least 30 days in advance.

(b) The manufacturer and the DepartmentOffice 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 person as specified by the hearing officerSacramento 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 DepartmentOffice consent, the hearing officer may, but is not required to, conduct the hearing by telephone or other electronic means. The manufacturer and the DepartmentOffice 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 DepartmentOffice 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 DepartmentOffice 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 DepartmentOffice. The non-appearance 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 one of the following, as determined by the Department:

(1) Aan employee of the DepartmentOffice appointed by the Director of the DepartmentOffice to serve as hearing officer.

(2) An administrative law judge employed by the California Office of Administrative Hearings serving 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 DepartmentOffice 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 DepartmentOffice; the recommended decision shall be in writing and shall include findings of fact and conclusions of law.

(b) The Director of the DepartmentOffice 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 18090 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.

STATE OF CALIFORNIA
~~OFFICE OF STATEWIDE HEALTH PLANNING & DEVELOPMENT~~
DEPARTMENT OF HEALTH CARE ACCESS AND INFORMATION

FORMAT AND FILE SPECIFICATIONS FOR SUBMISSION OF PRESCRIPTION DRUG REPORTS

~~Version 1.0~~
Version 2.0

FORMAT AND FILE SPECIFICATIONS FOR SUBMISSION OF PRESCRIPTION DRUG REPORTS

GENERAL INFORMATION

This document specifies requirements for electronic files submitted to the ~~Office of Statewide Health Planning and Development (OSHPD)~~ Department of Health Care Access and Information (HCAI) in accordance with California Code of Regulations, Title 22, Section 96078. If a prescription drug manufacturer chooses to submit the reports specified in Section 96070 or 96076 by uploading comma separated value (.csv) files, the files must meet the following technical format and file specifications.

All files must begin with a header record with the data element labels as specified below, in .csv format. All of the data element labels must be included in the file.

Multiple prescription drug product reports may be included in a single file.

While each prescription drug product report is not required to include all of the data elements outlined in the specifications below, if a data element is not included, the file must include a blank column, delimited by commas, in its place.

Dates shall be in a numeric format with month, day, and year (four digit) separated by slashes ("/"). For example, 3/12/2009 (also commonly referred to as "m/d/yyyy" format).

Any currency amounts shall be reported in United States dollars, in numeric format to two decimal points (except for Acquisition Price, which can be reported as a whole dollar amount), with no commas or dollar symbols.

The drug source type shall be reported as one of three values:

"Innovator Multiple Source Drug",
"Non-innovator Multiple Source Drug", or
"Single Source Drug".

Any data element which contains a comma within the value must be placed within quotation marks (" "). Alternatively, all alphanumeric fields may be placed within quotation marks, whether they contain a comma within the value or not.

Certain data elements have a subsequent data element that can be completed to indicate that the item is not provided because it is not in the public domain or publicly available. This shall be reported as Boolean, where "1" represents indicated and blank represents not indicated.

The ~~Office~~Department may reject any report that does not comply with these specifications.

FORMAT AND FILE SPECIFICATIONS
FOR SUBMISSION OF
PRESCRIPTION DRUG REPORTS

STANDARD RECORD FORMAT

Wholesale Acquisition Cost Increase Report:

Data Element	Label	Format	Size
NDC Number	NDC	Alphanumeric	11
Drug Product Description	DRUG_PROD_DESC	Alphanumeric	255
WAC Effective Date	WAC_EFFECTIVE_DATE	Date	10
WAC Increase Amount	WAC_INCREASE_AMOUNT	Decimal	10,2
WAC After Increase	WAC_AFTER_INCREASE	Decimal	10,2
Patent Expiration Date	PATENT_EXPIRATION_DATE	Date	10
Drug Source Type	DRUG_SOURCE_TYPE	Alphanumeric	34
Total Volume of Gross Sales ~~Unit Sales Volume~~ in U.S. Dollars	~~UNIT~~GROSS_SALES_VOLUME_US_DOLLARS	Numeric	10
Total Volume of Gross Sales ~~Unit Sales Volume~~ Nonpublic Indicator	~~UNIT~~GROSS_SALES_VOLUME_NONPUBLIC	Boolean	1
Cost Increase Factors	COST_INCREASE_FACTORS	Alphanumeric	5000
Cost Increase Factors Nonpublic Indicator	COST_INCREASE_FACTORS_NONPUBLIC	Boolean	1
Change/Improvement Description	CHANGE_IMPROVEMENT_DESC	Alphanumeric	5000
Change/Improvement Nonpublic Indicator	CHANGE_IMPROVEMENT_NONPUBLIC	Boolean	1
Acquisition Date	ACQUISITION_DATE	Date	10
Company Acquired From	ACQUIRED_FROM_COMPANY	Alphanumeric	255
Acquisition Price	ACQUISITION_PRICE	Numeric	12
Acquisition Price Nonpublic Indicator	ACQUISITION_PRICE_NONPUBLIC	Boolean	1
Acquisition Price Comment	ACQUISITION_PRICE_COMMENT	Alphanumeric	5000
WAC at Acquisition	WAC_AT_ACQUISITION	Decimal	10,2
WAC One Year Prior to Acquisition	WAC_YEAR_PRIOR_TO_ACQ	Decimal	10,2
Year Acquired Drug Introduced to Market	YEAR_INTRODUCED	Numeric	4
WAC at Introduction to Market	WAC_AT_INTRODUCTION	Decimal	10,2
General Comments	GENERAL_COMMENTS	Alphanumeric	5000

Five Year WAC History (for each increase report):

Data Element	Label	Format	Size
NDC Number	NDC	Alphanumeric	11
WAC Effective Date	WAC_EFFECTIVE_DATE	Date	10
WAC Increase Amount	WAC_INCREASE_AMOUNT	Decimal	10,2
WAC After Increase	WAC_AFTER_INCREASE	Decimal	10,2

New Prescription Drug Report:

Data Element	Label	Format	Size
NDC Number	NDC	Alphanumeric	11
Drug Product Description	DRUG_PROD_DESC	Alphanumeric	255
Introduced to Market Date	INTRODUCED_TO_MARKET_DATE	Date	10
WAC at Introduction	WAC_AT_INTRODUCTION	Decimal	10,2
Marketing/Pricing Plan Description	MARKETING_PRICING_PLAN	Alphanumeric	5000
Marketing/Pricing Plan Nonpublic Indicator	MARKETING_PRICING_NONPUBLIC	Boolean	1
Estimated Number of Patients	ESTIMATED_PATIENTS	Numeric	10
Breakthrough Therapy Indicator	BREAKTHROUGH_THERAPY_INDICATOR	Boolean	1
Priority Review Indicator	PRIORITY_REVIEW_INDICATOR	Boolean	1
Acquisition Date	ACQUISITION_DATE	Date	10
Acquisition Price	ACQUISITION_PRICE	Numeric	12
Acquisition Price Nonpublic Indicator	ACQUISITION_PRICE_NONPUBLIC	Boolean	1
Acquisition Price Comment	ACQUISITION_PRICE_COMMENT	Alphanumeric	5000
General Comments	GENERAL_COMMENTS	Alphanumeric	5000