

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 1.1~~
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".

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.

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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
<u>Total Volume of Sales</u> Unit Sales Volume in U.S. Dollars	UNIT_SALES_VOLUME_US_DOLLARS	Decimal	12,2
<u>Total Volume of Sales</u> Unit Sales Volume Nonpublic Indicator	UNIT_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