

Manufacturer Report Form for Top Outpatient Prescription Drug List

Section [19a-754b\(d\)\(4\)](#) of the Connecticut General Statutes (“C.G.S.”) requires the CT Office of Health Strategy (OHS) to establish a standardized form for the collection of prescription drug information for those drugs that appear on the State of Connecticut Top Outpatient Prescription Drug list.¹

Please submit your form for each drug included on the Final Top Outpatient Prescription Drug list. Use the attached spreadsheet file and submit via email to Patricia Blodgett (patricia.blodgett@ct.gov) by Monday, August 18, 2025.

Thank you.

BACKGROUND

The statute referenced above also requires OHS to develop a list of not more than ten outpatient prescription drugs that OHS determines are provided at substantial cost to the state or critical to public health. The list must comport with the specifications outlined in the statute, which are:

- The list must include no less than one generic drug.
- The list must include drugs from different therapeutic classes.
- The list must *not* include any drug whose wholesale acquisition cost (WAC) increased by not less than sixteen per cent cumulatively during the immediately preceding two calendar years and was not less than forty dollars for a course of treatment.

Furthermore, any manufacturer of an outpatient prescription drug included on the list must provide OHS with the following:

- A written, narrative description, suitable for public release, of all factors that caused the increase in the wholesale acquisition cost of the listed outpatient prescription drug.
- Aggregate, company-level research and development costs and such other capital expenditures that the commissioner, in the commissioner’s discretion, deems relevant for the most recent year for which final audited data are available.

¹ As required by [C.G.S. § 19a-754b\(d\)\(4\)](#), this form includes feedback from pharmaceutical manufacturers and was finalized after consulting with them. It was designed to minimize the administrative burden and cost of reporting on OHS and pharmaceutical manufacturers.

Note that the quality and types of information and data that a pharmaceutical manufacturer submits to OHS must be consistent with the quality and types of information and data that the pharmaceutical manufacturer includes in:

- Such pharmaceutical manufacturer's annual consolidated report on Securities and Exchange Commission Form 10-K; or
- Any other public disclosure

OHS may impose a penalty for each violation of the requirements identified above.

PROCESS and INSTRUCTIONS

For each prescription drug (there may be multiple national drug codes [NDCs]) on the list, complete one form. If there are multiple NDCs and they all have the same WAC Price, then only list it once; if there are separate WAC prices, then list each one separately by NDC. Use the definitions found below to assist in completing the form.

I. Drug Identification and Written Narrative

National Drug Code(s) (11-digit NDC)	Prefilled
Proprietary Drug Name	Prefilled
Non-Proprietary Drug Name	Prefilled
Number of Wholesale Acquisition Cost Units Manufactured in 2023	
Wholesale Acquisition Cost Price Per Unit – on 12/31/2023	Prefilled
Wholesale Acquisition Cost Price Per Unit – on 1/1/2022	Prefilled
Wholesale Acquisition Cost Price Per Unit at the Date of Market Introduction or Acquisition	
Date (MM/DD/YYYY) of Market Introduction or Acquisition	
Brand or Generic	Prefilled
If Brand drug, Year (YYYY) of U.S. Patent Expiration	
Manufacturer Tax Identification Number	
Manufacturer Name	Prefilled
Submission Date (MM/DD/YYYY)	

Provide a written narrative description, suitable for public release, of all factors that caused the increase in the wholesale acquisition cost of the listed outpatient prescription drug for the time period of the report: price increase from 1/1/2022 to 12/31/2023.

II. Required: Aggregate, company-level research and development costs and such other capital expenditures that the commissioner, in the commissioner’s discretion, deems relevant for the most recent year for which final audited data are available. <First Column>

Optional: Include data for only the identified drug or allocated to the drug. <Second Column>

If data provided has been allocated to the drug, describe the allocation process here.

	Aggregate Level	Drug Level
Most recent year for which the data is provided		
Number of WAC Units Manufactured		
Manufacturing Costs		
Research and Development Costs		
Describe research and development costs		
Other capital expenditures		
Describe other capital expenditures		
Marketing and advertising expense		
Other administrative expenditures		
Describe other administrative expenditures		

FORM DEFINITIONS

Data element	Definition
National drug code (NDC)	The numerical code maintained by the U.S. Food and Drug Administration (FDA) that includes the labeler code, product code, and package code. A drug's NDC number is typically expressed using 11 digits in a 5-4-2 format (xxxxx-yyyy-zz). The first five digits identify the manufacturer, the second four digits identify the product and strength, and the last two digits identify the package size and type. Reference: Code of Federal Regulations, Title 42, 447.502.
Proprietary Drug Name	The brand or trademark name of the drug reported to the FDA.
Non-Proprietary Drug Name	The generic name assigned by the United States Adopted Names (USAN) Council.
Wholesale Acquisition Cost (WAC) Units Manufactured	The lowest identifiable quantity of the drug or biological that is dispensed, exclusive of any diluent without reference to volume measures pertaining to liquids. If reporting by drug group, it is the total number of WAC units in the drug group. It is also known as the National Council for Prescription Drug Programs (NCPDP) billing units. Reference: 42 U.S. Code § 1395w-3a.
Wholesale Acquisition Cost (WAC) Price Per Unit	The manufacturer's list price to wholesalers or direct purchasers in the United States on January 1 and December 31 of the reference years, as reported in wholesale price guides or other publications of drug or biological pricing data; it does not include prompt pay or other discounts, rebates or reductions in price. The current or proposed WAC is the amount that prompts reporting under this Act. If reported by drug group, it is the average WAC weighted by the relevant number of WAC units. Reference: 42 U.S.C. § 1395w-3a.
Date of Market Introduction or Acquisition	The date in which the manufacturer acquired or first marketed the drug for sale in the U.S.
Brand or Generic	A brand name drug is a drug marketed under a proprietary, trademark-protected name. Therapeutic biological products are included within this definition. A generic drug is a medication created to be the same as an existing approved brand-name drug in dosage form, safety, strength, route of administration, quality, and performance characteristics. An authorized generic drug is considered a generic drug.
Tax Identification Number	The 9-digit tax Taxpayer Identification Number (TIN) used by the Internal Revenue Service (IRS).

Data element	Definition
Manufacturer Name	Any entity that holds the NDC for a prescription drug and is either engaged in the production, preparation, propagation, compounding, conversion, or processing of drug products; or is engaged in the packaging, repackaging, labeling, relabeling, or distribution of drug products and is not a wholesale distributor of drugs or a retail pharmacy licensed under State law. Reference: Code of Federal Regulations, Title 42, 447.502.
Filing Date	The date that the manufacturer completed and submitted this form.
Justification for current year WAC price increase	The reason or reasons that the manufacturer increased the WAC price of the drug between the two reported years.
Wholesale Acquisition Cost (WAC) Units Manufactured	The lowest identifiable quantity of the drug or biological that is dispensed, exclusive of any diluent without reference to volume measures pertaining to liquids. If reporting by drug group, it is the total number of WAC units in the drug group. It is also known as the National Council for Prescription Drug Programs (NCPDP) billing units. Reference: 42 U.S. Code § 1395w-3a.
Manufacturing Cost	Total costs directly related or allocated to the reported drug specifically for sales in the United States or the State as indicated. Such costs include the cost of goods sold and allocated operating expenses, consistent with GAAP.
Research and Development Cost	A cost that a pharmaceutical manufacturer incurs in researching and developing a new product, process or service, including, but not limited to, a cost that a pharmaceutical manufacturer incurs in researching and developing a product, process or service that the pharmaceutical manufacturer has acquired from another person by license.
Other Capital Expenditures	Funds used by a company to acquire, upgrade, and maintain physical assets such as property, plants, buildings, technology, or equipment.
Marketing and Advertising Expense	Expenses incurred to promote a company's products or services.
Other Administrative Expenditures	General and administrative expenses that are not directly related to product sales and/or production.

Form Revision Date: July 17, 2025