



# CONNECTICUT Health Strategy

## PRESCRIPTION DRUG REPORTING SYSTEM

### DATA SUBMISSION GUIDE

Pursuant to [Conn. Gen. Statute §19a – 754b](#)

Version 2

Updated: December 5, 2025

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## Contacts

### Connecticut Office of Health Strategy

Address:

450 Capitol Avenue,

MS#51OHS

Hartford, CT 06134

Phone: 860-418-7001

Prescription Drug Cost Transparency Website: <https://portal.ct.gov/ohs/programs-and-initiatives/prescription-drug-cost-transparency>

Email: [HSP@CT.GOV](mailto:HSP@CT.GOV)

This email address is for the Prescription Drug Cost Transparency process only.

Please use the OHS main email: [OHS@ct.gov](mailto:OHS@ct.gov) for any other matters.

## Acronyms

PDRS – Prescription Drug Reporting System

PDUFA – Prescription Drug User Fee Act

NDC – National Drug Code

NDA – National Drug Application

OHS – The Connecticut Office of Health Strategy

WAC – Wholesale Acquisition Cost

## Introduction

The Office of Health Strategy (OHS) was established in 2018 with the mission to implement comprehensive, data driven strategies that promote equal access to high quality health care, control costs and ensure better health for the people of Connecticut.

On May 31, 2018, Public Act 18-41, *AN ACT CONCERNING PRESCRIPTION DRUG COSTS*, was signed into law. The full Public Act can be accessed here: <https://www.cga.ct.gov/2018/ACT/pa/pdf/2018PA-00041-R00HB-05384-PA.pdf>. The Public Act has eleven sections; this manual addresses specific parts of Section 10, which involves filings to the Office of Health Strategy, and which was codified into state statute as [Conn. Gen. Stat. §19a-754b \(a\) \(b\)](#). The remaining nine sections of the Public Act are codified into Chapter 38a of the statutes. OHS worked in collaboration and partnership with the Office of the State Comptroller in the implementation of Conn. Gen. Stat. §19a-754b.

The Prescription Drug Cost data and information filings discussed within this Manual are effective January 1, 2020 and the sections concerning Pipeline Drug Reporting which is accomplished via the Prescription Drug Reporting System (PDRS) are as follows:

(a) For the purposes of this section:

- (1) "Accelerated approval" has the same meaning as provided in 21 USC 356, as amended from time to time;
- (2) "Biologics license application" means an application filed pursuant to Section 601.2 of Title 21 of the Code of Federal Regulations, as amended from time to time;
- (3) "Breakthrough therapy" has the same meaning as provided in 21 USC 356, as amended from time to time;
- (4) "Drug" has the same meaning as provided in section 21a-92;
- (5) "Fast track product" has the same meaning as provided in 21 USC 356, as amended from time to time;
- (6) "New drug application" has the same meaning as provided in Section 314.3 of Title 21 of the Code of Federal Regulations, as amended from time to time;
- (7) "New molecular entity" has the same meaning as such term is used in 21 USC 355-1, as amended from time to time;
- (8) "Orphan drug" has the same meaning as provided in Section 316.3 of Title 21 of the Code of Federal Regulations, as amended from time to time;
- (9) "Pipeline drug" means a drug containing a new molecular entity for which a sponsor has filed a new drug application or biologics license application with, and received an action date from, the federal Food and Drug Administration;

(10) "Prescription drug" means a drug prescribed by a health care provider to an individual in this state;

(11) "Priority review" has the same meaning as such term is used in 21 USC 356, as amended from time to time;

(12) "Rebate" has the same meaning as provided in section 38a-479ooo;

(13) "Research and development cost" means 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;

(14) "Sponsor" has the same meaning as provided in Section 316.3 of Title 21 of the Code of Federal Regulations, as amended from time to time; and

(15) "Wholesale acquisition cost" has the same meaning as provided in 42 USC 1395w-3a, as amended from time to time.

**(b) Beginning on January 1, 2020, each sponsor shall submit to the Office of Health Strategy, established in section 19a-754a, in a form and manner specified by the office, written notice informing the office that such sponsor has filed with the federal Food and Drug Administration:**

**(1) A new drug application or biologics license application for a pipeline drug, not later than sixty days after such sponsor receives an action date from the federal Food and Drug Administration regarding such application; or**

**(2) A biologics license application for a biosimilar drug, not later than sixty days after such sponsor's receipt of an action date from the federal Food and Drug Administration regarding such application.**

(c) (1) Beginning on January 1, 2020, the executive director of the Office of Health Strategy may conduct a study, with the assistance of the Comptroller and not more frequently than once annually, of each pharmaceutical manufacturer of a pipeline drug that, in the opinion of the executive director in consultation with the Comptroller and the Commissioner of Social Services, may have a significant impact on state expenditures for outpatient prescription drugs. The office may work with the Comptroller to utilize existing state resources and contracts, or contract with a third party, including, but not limited to, an accounting firm, to conduct such study.

(2) Each pharmaceutical manufacturer that is the subject of a study conducted pursuant to subdivision (1) of this subsection shall submit to the office, or any contractor engaged by the office or the Comptroller to perform such study, the following information for the pipeline drug that is the subject of such study:

- (A) The primary disease, condition or therapeutic area studied in connection with such drug, and whether such drug is therapeutically indicated for such disease, condition or therapeutic area;
- (B) Each route of administration studied for such drug;
- (C) Clinical trial comparators, if applicable, for such drug;
- (D) The estimated year of market entry for such drug;
- (E) Whether the federal Food and Drug Administration has designated such drug as an orphan drug, a fast-track product or a breakthrough therapy; and
- (F) Whether the federal Food and Drug Administration has designated such drug for accelerated approval and, if such drug contains a new molecular entity, for priority review.

The sections regarding the Top Outpatient Prescription Drugs do not require submission to the Prescription Drug Reporting System at this time.

# Filing Instructions

## General Overview

All Sponsor required submissions are due within sixty (60) days of receipt of Food and Drug Administration (FDA) approval to market the pharmaceutical product. **This filing requirement was effective on January 1, 2020, for FDA Action Dates starting on November 2, 2019.**

The process of data submission consists of two parts, the Sponsor data submission and the Manufacturer data submission. Manufacturer data submissions are only to be completed by the Manufacturers if and when OHS contacts them because it was determined that the drug will have an impact on state's expenditures for outpatient prescription drugs.

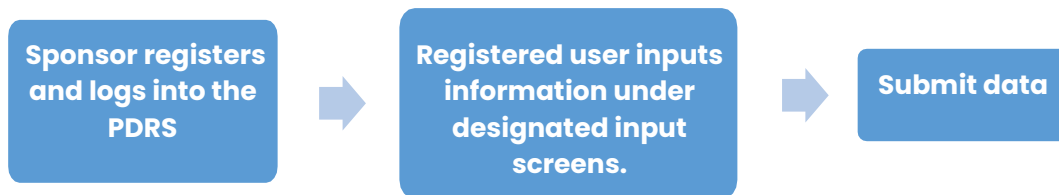
Pursuant to Conn. Gen. Stat. § 19a-754 (e), OHS may impose a penalty of not more than seven thousand five hundred dollars (\$7,500) on a Pharmaceutical Manufacturer or Sponsor for each violation of this section by the Pharmaceutical Manufacturer or Sponsor.

All questions regarding any aspect of the Sponsor's or Manufacturer's Filings should be emailed to [HSP@ct.gov](mailto:HSP@ct.gov).

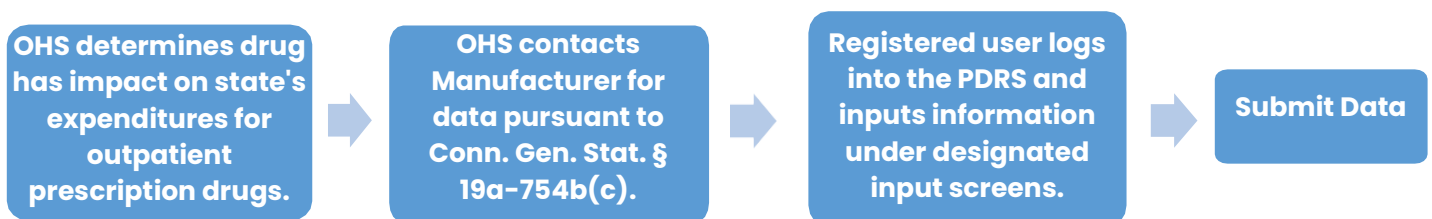
OHS will be relying on the Sponsor's and Manufacturer's accurate filing of the information and it is intended that the non-proprietary information will be used in OHS publications.

## Process Steps

### Part A- Sponsor Data Submission



### Part B-Manufacturer Data Submission



# Prescription Drug Reporting System

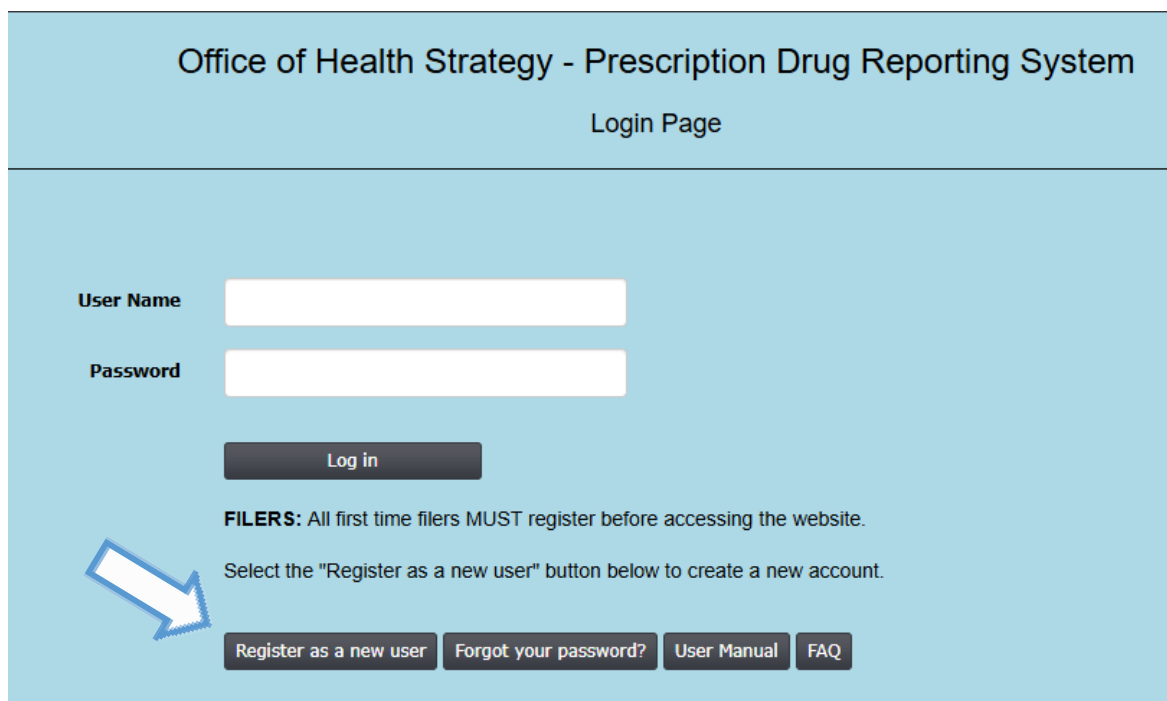
The Prescription Drug Reporting System (PDRS) is a web-based application (the portal) that has been developed to assist Sponsors and Manufacturers of prescription drugs in their reporting of data elements in an efficient and effective manner. This manual provides detailed instructions on how to navigate through the portal. It is intended to walk users through registering as a new user, accessing the input screens and entering data. Instructions can also be found on the PDRS input screens by clicking on the "Instructions" button to the right of the screen.

The PDRS portal can be accessed with different browsers. It is recommended one use the latest version of browsers such as Internet Explorer, Mozilla Firefox or Google Chrome for the system to run properly on their computer. The web-based application can be used from any desktop, laptop or web-based device.

When navigating on an input screen remember to use the TAB key or Mouse pointer to move from one cell to the next. Do not use your web browser's back arrow to navigate through the input form.

## Register as a New User

Enter the website address: <https://ohs-pdrsportal.ct.gov> in your web browser. If you are accessing the web portal for the first time, click the **Register as a new user** button from the login page as shown below.



The following Registration Page appears. Enter all the required fields (\*) on the registration page and click the **Register** button at the bottom of the page. A Manufacturer, who is also a Sponsor, must choose **Sponsor** as **User Type** to fill out the required Sponsor Form.

**OHS Prescription Drug Reporting System**

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Registration Page

**First Name**  \*

**MI**

**Last Name**  \*

**Phone Number**  \*

**Email**  \*

**User Name**  \*  
Choose a username that is 2-50 characters long.


**Password**  \*  
Passwords must have at least one digit('0'-'9'), special char(!, \*, @) and one uppercase('A'-'Z').

**Confirm password**  \*

**User Type** Select User Type \*  
To submit new or biosimilar data a Manufacturer should register as a "Sponsor" to complete the required "Sponsor Form".  
Manufacturers need to only be registered as "Manufacturer" if and when OHS contacts them back for the filing of further require information.

**Company Name**  \*

**User Name 2**



A Registration Confirmation message will appear indicating that the registration request has been received. Upon approval, an automated email notification will be sent verifying the account has been approved and it is then ready to log in to the web portal.

**User Name 2** entry line was created for the primary User to share information with another person at the User's discretion. If User 2 has been assigned the task of entering information, then User 2 must also register. Both individuals must reference each other on the **User Name 2** line in order to view each other's entries.

## Log In

After registering and creating an account in the web portal, go to the home page, enter a Username and Password and click the **Log In** button. If an incorrect User Name or password is entered 5 times, the account holder will be temporarily locked out of the system and will have to try again after 20 minutes.

## Reset Password

If there is a need to reset a password, go to the Login Page, and click the **Forgot your password?**

The following Forgot Password Page screen appears. Next, enter the **User Name** and click the **Submit** button.



Office of Health Strategy - Prescription Drug Reporting System

Forgot Password Page

User Name  \*

[Submit](#) [Back to Login Page](#)

An automated email notification will be sent to the account holder's email, which will contain the Reset Password link.

## User Manual

From time to time, OHS will post updates of the PDRS manual to the web portal. Clicking on the **User Manual** button will download the newest version of the manual.



Office of Health Strategy - Prescription Drug Reporting System

Login Page

User Name

Password

[Log in](#)

**FILERS:** All first time filers MUST register before accessing the web portal.  
Select the "Register as a new user" button below to create a new account.

[Register as a new user](#) [Forgot your password?](#) [User Manual](#) [FAQ](#)

# Input Instructions

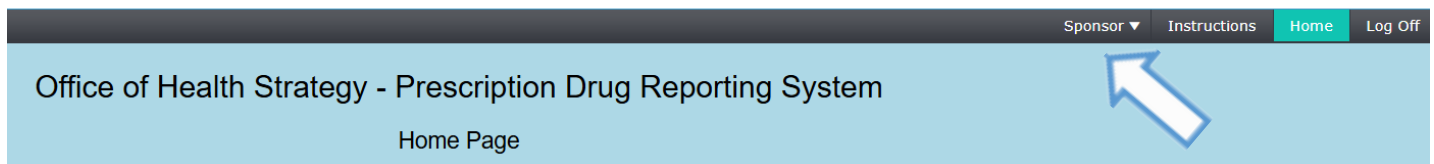
## Sponsor and Manufacturer Data Entry

Prior to completing drug data entry, Sponsor and Manufacturer information must be entered into the web portal. The information for these entities will be carried forward each year so in subsequent years, only new entities need to be entered.

When navigating on an input screen remember to use the TAB key or Mouse pointer to move from one cell to the next. Do not use your web browser's back arrow to navigate through the input form.

The portal does not allow for saving data mid-way. However, time limits were not set, which always keeps the portal open. This allows users to step away from the portal mid-way of entering data and come back later to complete the task.

After logging in, click on the **Sponsor Form** option at the top of the Home Page. Once the option is made, the following screen appears showing the new Sponsor entry page. This will only need to be completed once time per Sponsor.



A Manufacturer, who is also considered a Sponsor, will need to click on the Sponsor button to fill out required **Sponsor Form**. Manufacturers will only need to complete the **Manufacturer Form** if and when the Office of Health Strategy contacts them because it is determined that the drug will have an impact on state's prescription drugs expenditures.

## To Add a New Sponsor

Click on the **Add New Sponsor** button, enter the required data and then click **Save Entry**. Data on greyed out entry lines is system generated; therefore, user input is not required. After clicking on **Save Entry**, the input screen disappears which indicates that the entry was saved.

## To Add Drug Details under a Sponsor

After saving the new Sponsor data, click on the arrow next to the Sponsor's name, to the left of the screen. This will open the drug details input screen. Then, click on the

**Add New Drug** button, enter data and click **Save Entry**. Once again, the input screen will disappear, an indication that the entry was saved.

Office of Health Strategy - Prescription Drug Reporting System

Sponsors

Sponsors Details

+ Add New Sponsor

Sponsor Name	SP City	SP State or Prov	SP Zip Code	SP Country	Agent Name	Agent Email	Agent Phone Num	Agent City	Agent State	Agent Zip Code	Entry Date	User ID
Sponsor 1, LLC				USA	Agent Sponsor 1.	a@a.com	(999) 999-9999 x12345_	Hartford	CT	00000	11-13-2019	mikeb

Drug Details

+ Add New Drug

Prop_Name	Filling_Date Date	Date	App Type

For OHS purposes, an **Agent** is the authorized U.S.A representative of the sponsor submitting the application to the FDA. It is the person that filed, signed and processed the FDA paperwork for the applicant as its representative in the U.S.A.

**Sponsor’s required data elements are marked with an asterisk.** Elements not marked with an asterisk are voluntary and can be considered proprietary by the submitter. Use the **Optional text box** on the PDRS to identify proprietary submitted information and to list additional NDC codes associated with the same drug.

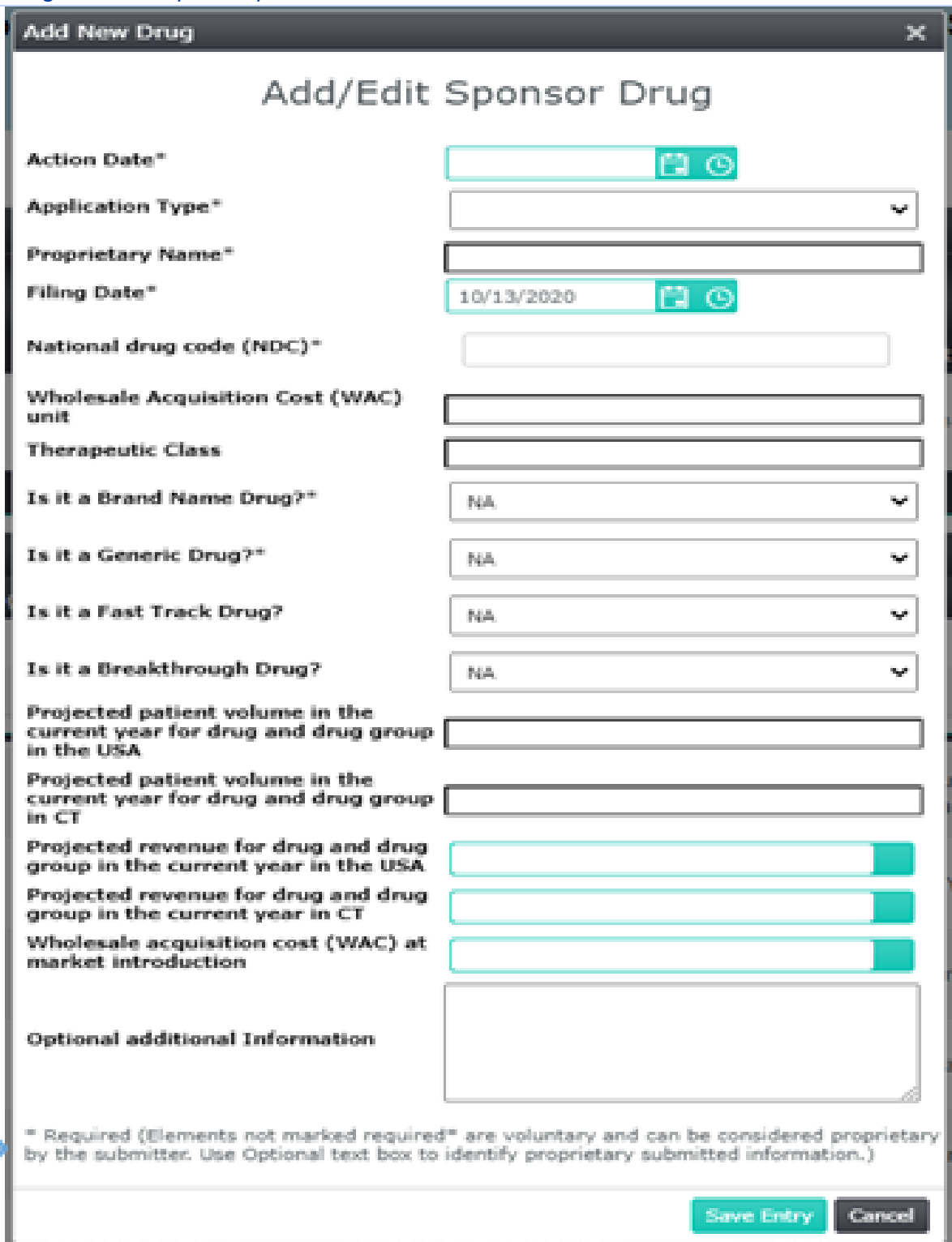
### Add New Sponsor

## Add/Edit Sponsor

<b>Sponsor Name*</b>	<input type="text"/>
<b>Sponsor City</b>	<input type="text"/>
<b>Sponsor State/Province/Region</b>	<input type="text"/>
<b>Zip/Postal Code</b>	<input type="text"/>
<b>Country* (If USA than provide City, State and Zip Code)</b>	<input type="text"/>
<b>Agent Name*</b>	<input type="text"/>
<b>Agent City*</b>	<input type="text"/>
<b>Agent State*</b>	<input type="text"/>
<b>Agent Zip Code*</b>	<input type="text"/>
<b>Agent Email*</b>	<input type="text"/>
<b>Agent Phone Number (include extension if applicable)*</b>	<input type="text"/>
<b>Contact Name for OHS to follow-up*</b>	<input type="text"/>
<b>Contact Email for OHS to follow-up*</b>	<input type="text"/>
<b>Contact Phone Number for OHS to follow-up (include extension when applicable)*</b>	<input type="text"/>
<b>Entry Date</b>	Wed Dec 18 2019 15:21:43 GMT-0500 (Eastern
<b>Entered By</b>	<input type="text"/>

\*Required (Elements not marked required\* are voluntary and can be considered proprietary by the submitter. Use Optional text box to identify proprietary submitted information.)





The screenshot shows a web form titled "Add/Edit Sponsor Drug" within a window labeled "Add New Drug". The form contains several input fields and dropdown menus. A blue arrow points to the asterisk on the "Action Date" label. The fields include:

- Action Date\***: A date input field with a calendar icon and a refresh icon, currently showing "10/13/2020".
- Application Type\***: A dropdown menu.
- Proprietary Name\***: A text input field.
- Filing Date\***: A date input field with a calendar icon and a refresh icon, currently showing "10/13/2020".
- National drug code (NDC)\***: A text input field.
- Wholesale Acquisition Cost (WAC) unit**: A text input field.
- Therapeutic Class**: A text input field.
- Is it a Brand Name Drug?\***: A dropdown menu with "NA" selected.
- Is it a Generic Drug?\***: A dropdown menu with "NA" selected.
- Is it a Fast Track Drug?**: A dropdown menu with "NA" selected.
- Is it a Breakthrough Drug?**: A dropdown menu with "NA" selected.
- Projected patient volume in the current year for drug and drug group in the USA**: A text input field.
- Projected patient volume in the current year for drug and drug group in CT**: A text input field.
- Projected revenue for drug and drug group in the current year in the USA**: A progress bar with a teal fill.
- Projected revenue for drug and drug group in the current year in CT**: A progress bar with a teal fill.
- Wholesale acquisition cost (WAC) at market introduction**: A progress bar with a teal fill.
- Optional additional Information**: A large text area for notes.

At the bottom, there is a legend: "\* Required (Elements not marked required\* are voluntary and can be considered proprietary by the submitter. Use Optional text box to identify proprietary submitted information.)". Below the legend are two buttons: "Save Entry" and "Cancel".

After all inputs have been successfully entered, click on the [Home Page](#) button to retrieve the Sponsor's data. Instructions to retrieve the data are introduced on the next section of this document.

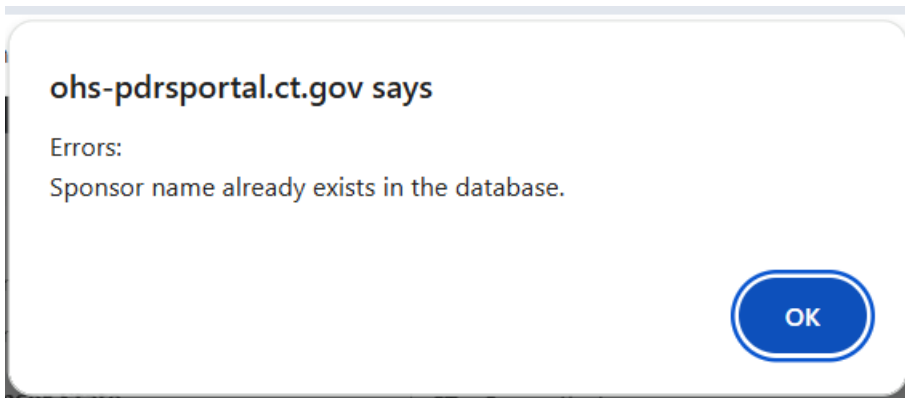
After the data has been saved, Users will have up to a calendar week, from entry date, to **Edit** or **Delete** inaccurate data. The **Edit** and **Delete** feature will not be available after seven days, although the buttons may still be shown.

### To add another drug to the same account

Click on the left arrow next to the Sponsor 's name, which will open up the screen to add the new drug. Next, click on "Add New Drug" to see the form where you can enter the new data. Once it is saved, the new entry will be displayed under the already submitted entry.

If an error message appears, indicating "*Sponsor drug name already exists in the database*" when adding a new drug under the same Sponsor name but different dosage, please ignore it by clicking on the "OK" button. The new data will still be saved.

To enter a new drug under a new Agent and same Sponsor (Entity's name), the Sponsor will need to complete the Sponsor form as "Entity's name 2 or 3 or 4, etc.". Otherwise, the following error message will appear stating that the "*Sponsor name already exists in the database*":



### To add Manufacturer Data (complete only if and when contacted by OHS)

Click on the **Add New Manufacturer** button, enter data and then click **Save Entry**. Data on greyed out entry lines is system generated; therefore, user input is not required. After clicking on **Save Entry**, the input screen disappears which indicates that the entry was saved.

### To add Manufacturer Drug Details

Click on the arrow next to the Manufacturer's name, to the left of the screen. This will open the drug details input screen. Then, click on the **Add New Drug** button, enter data and click **Save Entry**. Once again, input screen will disappear, an indication that the entry was saved.

Office of Health Strategy - Prescription Drug Reporting System

Manufacturers

Manufacturer's Details

+ Add New Manufacturer    Export to Excel

Manufacturer Name	Mfr City	Mfr State or Prov	Mfr Zip Code	Mfr Country	Agent Name	Agent Email	Agent Phone Number (include extension when applicable)*	Agent City	Agent State	Agent Zip Code	Entry Date	User ID	
Manufacturer USA	Anywhere	CT	06060	USA	Test Person	tester@ct.gov	(999) 999-9999 x_____	Hartford	CT	06060	09/25/2025	pblodgett	<a href="#">Edit</a> <a href="#">Delete</a>

Drug Details

+ Add New Drug

Prod Pipeline Name	OHS Filing Date	Dis Cond TherapArea Studied	Ind Dis Cond Therap Area	Clinical Trial Comparators	Est Mkt Entry Date	Act Mkt Entry Date

**Manufacturer's required data elements are marked with an asterisk.** Elements not marked with an asterisk are voluntary and can be considered proprietary by the submitter. Use Optional text box on PDRS to identify proprietary submitted information.

### Add New Manufacturer

## Add/Edit Manufacturer

<b>Manufacturer Name*</b>	<input type="text"/>
<b>Manufacturer Tax ID</b>	<input type="text"/>
<b>Manufacturer City</b>	<input type="text"/>
<b>Manufacturer State/Province/Region</b>	<input type="text"/>
<b>Manufacturer Zip Code</b>	<input type="text"/>
<b>Manufacturer Country*</b>	<input type="text"/>
<b>Agent Name*</b>	<input type="text"/>
<b>Agent City*</b>	<input type="text"/>
<b>Agent State*</b>	<input type="text"/>
<b>Agent Zip Code*</b>	<input type="text"/>
<b>Agent Email*</b>	<input type="text"/>
<b>Agent Phone Number (include extension when applicable)*</b>	<input type="text"/>
<b>Contact Name for OHS to follow-up*</b>	<input type="text"/>
<b>Contact Email for OHS to follow-up*</b>	<input type="text"/>
<b>Contact Phone Number for OHS to follow-up (include extension when applicable)*</b>	<input type="text"/>
<b>Entry Date</b>	Wed Dec 18 2019 15:29:10 GMT-0500 (Eastern
<b>Entered By</b>	<input type="text"/>

\*Required (Elements not marked required\* are voluntary and can be considered proprietary by the submitter. Use Optional text box to identify proprietary submitted information.)



Add New Drug
X

### Add/Edit Manufacturer Drug

<b>Product Pipeline Name*</b>	<input type="text"/>		
<b>Filling Date*</b>	<input type="text" value="12/18/2019"/>	<b>Given by injection into the space around the spinal cord (intrathecally, IT)*</b>	<input type="text" value="NA"/>
<b>Proposed indication for Use*</b>	<input type="text"/>	<b>Given by injection beneath the skin (subcutaneously, sc)*</b>	<input type="text" value="NA"/>
<b>Primary disease, Condition or Therapeutic Area Studied*</b>	<input type="text"/>	<b>Placed under the tongue (sublingually)*</b>	<input type="text" value="NA"/>
<b>Is it therapeutically indicated for such disease, condition or Therapeutic Area?</b>	<input type="text" value="NA"/>	<b>Placed between the gums and cheek (buccally)*</b>	<input type="text" value="NA"/>
<b>Clinical Trial Comparators (if applicable)*</b>	<input type="text"/>	<b>Inserted in the rectum (rectally)*</b>	<input type="text" value="NA"/>
<b>Estimated date of market entry*</b>	<input type="text"/>	<b>Inserted in the vagina (vaginally)*</b>	<input type="text" value="NA"/>
<b>Actual date of market entry (if applicable)</b>	<input type="text"/>	<b>Placed in the eye (by the ocular route)*</b>	<input type="text" value="NA"/>
<b>Is this an FDA designated Orphan drug?*</b>	<input type="text" value="NA"/>	<b>Placed in the ear (by the otic route)*</b>	<input type="text" value="NA"/>
<b>Is this an FDA Fast track product?*</b>	<input type="text" value="NA"/>	<b>Sprayed into the nose and absorbed through the nasal membranes (nasally)*</b>	<input type="text" value="NA"/>
<b>Is this an FDA designated Breakthrough therapy?*</b>	<input type="text" value="NA"/>	<b>Breathed into the lungs through the mouth (by inhalation)*</b>	<input type="text" value="NA"/>
<b>Was it designated for accelerated approval by FDA?*</b>	<input type="text" value="NA"/>	<b>Applied to the skin (cutaneously) for a local (topical)*</b>	<input type="text" value="NA"/>
<b>Does it contain a new molecular entity for priority review?*</b>	<input type="text" value="NA"/>	<b>Applied to the skin (cutaneously) for a bodywide (systemic) effect*</b>	<input type="text" value="NA"/>
<b>Taken by mouth (orally)*</b>	<input type="text" value="NA"/>	<b>Delivered through the skin by a patch (transdermally) for a systemic effect*</b>	<input type="text" value="NA"/>
<b>Given by injection into a vein (intravenously, IV)*</b>	<input type="text" value="NA"/>	<b>Optional additional Information</b>	<input style="width: 100%; height: 40px;" type="text"/>
<b>Given by injection into a muscle (intramuscularly, IM)*</b>	<input type="text" value="NA"/>		

\*Required (Elements not marked required\* are voluntary and can be considered proprietary by the submitter. Use Optional text box to identify proprietary submitted information.)

Save Entry
Cancel

After all inputs have been successfully entered, click on the **Home Page** button to retrieve the data. Instructions to retrieve the data are introduced on next section of this document.

After the data has been saved, Users will have up to a calendar week, from entry date, to **Edit** or **Delete** inaccurate data. The **Edit** and **Delete** feature will not be available after seven days, although the buttons may still be shown.

## To Quickly Enter Multiple Drugs

**Data may also be submitted using a comma delimited (CSV) template. This option is under development.** If many different drugs need to be reported, choose this option. Simply click the [Download CSV Template](#) button, open the downloaded file, enter data as instructed and save the file. **Do not format the fields in the file.** Do not include commas, hyphens or dollar signs (\$) – these will affect the uploading of the data. Next, click the [Upload](#) button in the lower left-hand corner of the input screen, choose the file just saved and click open. This will populate the input screen. A message will appear that the data uploaded successfully. Then click on the [Back to Home Page](#) button.

## Retrieve Submitted Data

To filter, view and save a report when there is more than one Sponsor or Manufacturer listed, go to the dropdown menus on the [Home Page](#), select [the Sponsor or Manufacturer Facility, Filing Year, Report Type](#), click on [Get Filing Data](#) and then on the [Export to Excel](#) button. To view and save all reports into one document without filtering, skip the dropdown menus selections and directly click on the [Export to Excel](#) button.

When the message at the bottom of the page appears asking [Open, Save or Cancel](#), click on option of choice. Prompt will appear indicating the file is in Protected View, click [Allow](#). An Excel report will then be downloaded. To allow editing, click on the [Enable Editing](#) button at the top of the screen.

For [Report Type](#), Sponsors and Manufacturers who are also Sponsors should choose the [Sponsor Data](#) report type. The [Manufacturer Data](#) report type is only for Manufacturers who had completed the drug details entries per OHS request as mandated under Conn. Gen. Stat. §19a-754c.



## Appendices

### Appendix A – Frequently Asked Questions

#### Definitions

*1. What is a Sponsor?*

Sponsor means the entity that assumes responsibility for a clinical or nonclinical investigation of a drug, including the responsibility for compliance with applicable provisions of the act and regulations. A Sponsor may be an individual, partnership, corporation, or Government agency and may be a manufacturer, scientific institution, or an investigator regularly and lawfully engaged in the investigation of drugs. For purposes of the Orphan Drug Act, FDA considers the real party or parties in interest to be a Sponsor.

*2. What does “Action Date” mean?*

For purposes of the submission of information to OHS, the ‘action date’ means the date of FDA approval for the pharmaceutical product to go to market.

*3. What is an Agent?*

An “Agent” is the authorized U.S.A. representative of the sponsor submitting the application to the FDA. It is the person that filed, signed and processed the FDA paperwork for the applicant, as its representative in the U.S.A.

*4. What is a Pipeline Drug?*

A drug containing a new molecular entity for which a sponsor has filed a new drug application or biologics license application with, and received an action date from, the federal Food and Drug Administration. (Conn. Gen. Stat. §19a-754b)

*5. What is a New Molecular Entity?*

A New Molecular Entity is an active ingredient that contains no active moiety that has been previously approved by the FDA in an application submitted under section 505 of the Federal Food, Drug, and Cosmetic Act or has been previously marketed as a drug in the United States.

*6. I did not see a definition for “Filing Date”. Is this the date that we entered the data into the PDRS or is it the date the NDA was filed with the FDA?*

Filing date is the date the data is submitted to OHS and entered into the PDRS.

## Statute Questions and When to Submit

7. *Could you provide clarity and examples of how the 60 days will be calculated?*

The 60 days are calendar days and Day One of the count starts at the first full day after the FDA approval date. Here are some examples to illustrate:

FDA Approval Date	Day One of Count	Day Sixty of Count (due not later than this date)
November 2, 2019	November 3, 2019	January 1, 2020
November 15, 2019	November 16, 2019	January 14, 2020
December 30, 2019	December 31, 2019	February 28, 2020
January 6, 2020	January 7, 2020	March 6, 2020
January 31, 2020	February 1, 2020	March 31, 2020

8. *Conn. Gen. Stat. §19a-754b provides some but not all related definitions. Where can I find definitions for the required filings?*

Appendix B of this manual provides a list of Key Definitions and Terms.

9. *Are the prescription drug filings for both adult and pediatric prescriptions?*

Yes

10. *Do the prescription drug filings include veterinarian medicine?*

No

11. *Are prescription cosmetic products included in the Sponsor Notice requirements?*

Yes, any product (for human use) that has received approval from the FDA for a new drug application or biologics application for a pipeline drug or a biologics license application for a biosimilar drug must file the Sponsor Notice.

12. *If a prescription drug is not typically reimbursed by 3rd party payers, is a Sponsor Notice still required?*

Yes, the related statute, 19a-754(b)(1)-(2) does not refer to reimbursement or payer status.

13. *Do sponsors of influenza vaccines need to file into the PDRS?*

Influenza vaccine sponsors or manufacturers do not need to report into the PDRS as influenza drugs are not generally ordered or prescribed.

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*14. Do prescription drugs that receive Supplemental approvals from the FDA need to file or refile information in the PDRS?*

No, only newly approved drugs that have received an FDA action date, as that term has been defined by OHS for purposes of the PDRS filings, need to submit new or further information. We do not need to have entries for each supplemental approval an already approved drug might receive over time from the FDA.

*15. If a manufacturer acquires a drug and starts selling the drug on their own labeler code (so on a brand new NDC), would that trigger the new product launch reporting requirements?*

The reporting of a new product launch to OHS would be triggered by the development of a new drug that has received an action date from the FDA, not the labeler code. For example, if the acquiring manufacturer developed a new drug based on changes to the molecular entity, active ingredient of the acquired drug, then it will need to submit an NDA to the FDA. Which, after the receipt of an action date from the FDA, will have to be reported to OHS.

*16. The instructions in this manual relate only to Conn. Gen. Stat. §19a-754b (b) & (c), the new pipeline or biosimilar drugs by Sponsors and Pharmaceutical Manufacturers. Will there be separate instructions or a separate manual for Conn. Gen. Stat. §19a-754b(d)(3)(A), Pharmaceutical Manufacturer filings related to the ten outpatient prescription drugs that are provided at substantial cost to the state or are critical to public health?*

Yes, instructions for the requirements of Conn. Gen. Stat. §19a-754b (d)(3)(A) are provided separately on the Prescription Drug Cost Transparency website:

<https://portal.ct.gov/ohs/programs-and-initiatives/prescription-drug-cost-transparency>

*17. Is there a registration requirement for prescription drug price reporting?*

For reporting additional information related to the Top Ten list, as pursuant to Conn. Gen. Stat §19a-754b(d)(1)(3)(A), registration is not required. Manufacturers of drugs included on the list, shall provide information about the medication. OHS will notify the manufacturers annually about how to file the additional information.

*18. Are there any reporting requirements to the State of Connecticut for instituting a price increase?*

The State of Connecticut does not currently have any price increase reporting requirements at this time. We do evaluate wholesale acquisition cost (WAC) price increases as part of a report, but do not require the manufacturer to submit information unless we specifically request it.

*19. If registration is required, is there a deadline for registration and are there any penalties for not complying with the registration requirements?*

The Sponsor, or Manufacturer who is also a Sponsor, is required to submit a written notice to OHS within 60 days of receiving an action date. Therefore, we recommend that the registration

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takes place prior to the end of the 60-day period. Pursuant to Conn. Gen. Stat. § 19a-754e, OHS may impose a penalty of not more than seven thousand five hundred dollars (\$7,500) on a Pharmaceutical Manufacturer or Sponsor for each violation of this section by the Pharmaceutical Manufacturer or Sponsor.

*20. Are there any other associated program fees for system registration or assessment of manufacturer drug reports?*

No

*21. Is PDRS system registration required for compliance with HB 5384's regulation if a manufacturer is not submitting any reports that year/quarter?*

Registration to the PDRS system is required for compliance in two instances:

- 1) For the reporting of notices from sponsors of new pipeline drug and biosimilar Drug pursuant to Conn. Gen. Stat. § 19a-754b(b) and
- 2) For the reporting of additional information related to pipeline drugs pursuant to Conn. Gen. Stat §19a-754b(c)(2).

If none of these instances apply, then the Manufacturer does not have to register.

*22. Are we required to notify OHS or report into the PDRS when there is an NDC replacement at the request of the FDA?*

No notification or submission is required for replacement of NDCs that are not for new “pipeline” drugs or for a biologics license application for a biosimilar drug as defined in the law and referenced in our manual.

“Pipeline drug” means a drug containing a new molecular entity for which a sponsor has filed a new drug application or biologics license application with, and received an action date from, the federal Food and Drug Administration.

“Biologics license application” means an application filed pursuant to Section 601.2 of Title 21 of the Code of Federal Regulations, as amended from time to time.

*23. We have received a Prescription Drug User Fee Act (PDUFA) date for a recently filed NDA. What are the CT requirements for registering this information into PDRS system?*

OHS does not require submission of information based on a PDUFA date but on an FDA “Action Date”. For submission, “Action Date” is the date that the FDA approved the drug to be released onto the market, basically the final step in the FDA approval process. It is not the PDUFA date. Any data submitted based on the PDUFA should be deleted from the PDRS if it does not correlate with the Action Date.

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*24. Are there any distinctions between an acquisition of a product vs. licensing a product for the purposes of reporting? Many state transparency reports request additional information on a product that is “acquired”.*

For the purposes of reporting pipeline drugs in the state of Connecticut, we do not distinguish between acquisition or licensing change. Regardless of the reason, any new drug application needs to be entered into our PDRS within 60 days after an action date has been received from the FDA regarding the application.

We appreciate being informed with updated information about acquisitions, however, no official submission is required at that time.

## PDRS Entry Questions

*25. Does the Prescription Drug Reporting System (PDRS) require a specific format for data submission?*

Yes, click on PDRS to be directed to an Excel file that includes documents describing the format and file specifications needed for submission of notices and prescription drugs data through the PDRS. The file also includes a list of Key Definitions related to the statute.

*26. The data filing format has some Data Elements that are required (marked by an \*). Some Data Elements are not marked with an \*. Confirm that those data elements are not required.*

Data Elements that are not marked with an \* are not required and are considered voluntary. That information can be submitted but the filer may consider the information proprietary for public use purposes. There is an Optional Text Box available on both the Sponsor and the Manufacturer filing input screens that can be used for explaining what optional data elements are being submitted but are considered proprietary.

*27. There are two input processes for the filings related to new pipeline or biosimilar drugs, there’s a form called Sponsor Form and one called Manufacturer Form. This is confusing particularly as a “Sponsor” of a new pipeline or biosimilar drug may in fact be a Pharmaceutical Manufacturer. Please clarify.*

Sponsors can include, but are not limited to, entities that are also Pharmaceutical Manufacturers. The Sponsor form or Sponsor filing process is specifically related to the notice information required by Subsection (b)(1) and (2) of Conn. Gen. Stat. §19a-754b, C.G.S, which is to be filed by a Sponsor of a new drug application or biologics license for a pipeline drug or a biologics license for a biosimilar drug. Again, the term Sponsor includes both Pharmaceutical Manufacturers and other entities that meet the definition explained in Question #1 above.

The Manufacturer form or Manufacturer filing process is separate from the above Sponsor notice. That filing process is specific to Subsection (c)(2) of Conn. Gen. Stat. §19a-754b, C.G.S. That filing

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will be required by the Pharmaceutical Manufacturers of an outpatient pipeline drug, that are notified by OHS if and when it has been determined that there is a significant impact on state expenditures. That filing format and process is specifically related to the filing elements listed in Subsection (c)(2)(A) – (F) of the law.

*28. Could a Sponsor who is also a Manufacturer submit the notice and study data at the same time?*

No, Sponsor notices are due first, starting on January 1. Manufacturers need to only complete the Study report if and when OHS contacts them because it has been determined that the drug will have an impact on state's prescription drugs expenditures.

*29. What is the best way to reassign the portal credentials without having to create a new account?*

In order to reassign a current account, first the new person will have to register and create a username. Then, contact OHS with the contact information and username of both the new person and of the current holder of the account in order to conduct the transfer.

*30. A product has been approved with four different strengths/dosages. For three of the dosages, the WAC price will be available to market early in the year and one not until mid-year. How will the WAC price for the one available mid-year be added to the portal once available as the Manual and Guidance Document indicates that the registration cannot be edited after 7 days?*

If the product was approved to market with four different strengths, then they should all be reported within 60 days of the action date (this is the approval to market date by the FDA, basically the final step in the FDA approval process). For reporting purposes, action date is the date the FDA approved the drug to go to market, not when the entity will be available in the market. For the one with the WAC price to be added later, please enter all the information available and then contact OHS with the follow up information if the seven days have passed, and it will be added to the system for you.

*31. I have been authorized by the entity to assist in compliance with federal and state regulations. When completing the Sponsor form, do I enter my contact information as the Agent?*

No. The Agent information is of the person authorized to submit sponsor data to the FDA including the filing, signing, and processing of FDA paperwork for the applicant, as its representative in the U.S.A. The person authorized by the sponsor to assist with federal and state regulations compliance is considered the Direct Contact person for OHS.

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## Appendix B – Key Terms

Please note that not all definitions listed below are used in the Sponsor & Manufacturer new pipeline/biosimilar drug filings.

Term / Data Element	Definition	Source
Accelerated Approval	The U.S. Food and Drug Administration (“FDA”) designates a drug for accelerated approval if it is a product for a serious or life- threatening disease or condition, including a fast track product, under 21 U.S.C. § 355(c) or Section 261(a) of Title 42 of the Public Health Service Act upon a determination that the product has an effect on a surrogate endpoint that is reasonably likely to predict clinical benefit, or on a clinical endpoint that can be measured earlier than irreversible morbidity or mortality, that is reasonably likely to predict an effect on irreversible morbidity or mortality or other clinical benefit, taking into account the severity, rarity, or prevalence of the condition and the availability or lack of alternative treatments.	21 U.S.C. §356
Acquisition Date	The month and year that the manufacturer registered with the FDA as the labeler for the drug.	National Academy for State Health Policy <a href="https://nashp.org">https://nashp.org</a>
Action Date	For purposes of the submission to OHS, the 'action date' means the date of FDA approval to market.	FDA Glossary of Terms at <a href="https://www.fda.gov/drugs/drug-approvals-and-databases/drugsfda-glossary-terms">https://www.fda.gov/drugs/drug-approvals-and-databases/drugsfda-glossary-terms</a>
Approval Letter	An official communication from the FDA to a new drug application (NDA) sponsor that allows the commercial marketing of the product.	FDA Glossary of Terms at <a href="https://www.fda.gov/drugs/drug-approvals-and-databases/drugsfda-glossary-terms">https://www.fda.gov/drugs/drug-approvals-and-databases/drugsfda-glossary-terms</a>
Biologic License Application	Applications for biological products are approved for marketing under the provisions of the Public Health Service (PHS) Act. The Act requires a firm who manufactures a biologic for sale in interstate commerce to hold a license for the product. A biologics license application is a submission that contains specific information on the manufacturing processes, chemistry, pharmacology, clinical pharmacology and the medical effects of the biologic product.	FDA Glossary of Terms at <a href="https://www.fda.gov/drugs/drug-approvals-and-databases/drugsfda-glossary-terms">https://www.fda.gov/drugs/drug-approvals-and-databases/drugsfda-glossary-terms</a>

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Term / Data Element	Definition	Source
Biosimilar Drug	A biological product that is highly similar to the reference product notwithstanding minor differences in clinically inactive components; Any differences between the biological product and the reference product with respect to safety, purity, or potency are not clinically meaningful.	<a href="https://www.fda.gov/files/drugs/published/FDA's-Overview-of-the-Regulatory-Guidance-for-the-Development-and-Approval-of-Biosimilar-Products-in-the-US.pdf">https://www.fda.gov/files/drugs/published/FDA's-Overview-of-the-Regulatory-Guidance-for-the-Development-and-Approval-of-Biosimilar-Products-in-the-US.pdf</a>
Breakthrough Therapy	A drug is designated by the FDA as breakthrough therapy if the drug is intended, alone or in combination with 1 or more other drugs, to treat a serious or life-threatening disease or condition and preliminary clinical evidence indicates that the drug may demonstrate substantial improvement over existing therapies on 1 or more clinically significant endpoints, such as substantial treatment effects observed early in clinical development	21 U.S.C. §356
Brand-Name Drug	A brand name drug is a drug marketed under a proprietary, trademark-protected name. Therapeutic biological products are included within this definition.	National Academy for State Health Policy <a href="https://nashp.org">https://nashp.org</a>
Clinical Trial Comparators (Comparator Drug)	A clinical trial is an interventional clinical study involving human volunteers (also called participants) that is intended to add to medical knowledge. A clinical trial comparator is an intervention/treatment that health care providers consider to be effective and is received by a group of participants (or "arm") in a clinical trial.	<a href="https://clinicaltrials.gov/study-basics/glossary">https://clinicaltrials.gov/study-basics/glossary</a>
Comparator Drug	A comparator drug is drug that health care providers consider to be effective and is received by a group of participants (or "arm") in a clinical trial.	<a href="https://pharmaphorum.com/views-and-analysis/strategies-success-comparator-clinical-trials/#_edn2">https://pharmaphorum.com/views-and-analysis/strategies-success-comparator-clinical-trials/#_edn2</a>
Current Calendar Year Projections	The amounts the manufacturer anticipates will occur in the current calendar year; or if so, allowed by the Connecticut Office of Health Strategy, has occurred in the current calendar year to date.	National Academy for State Health Policy <a href="https://nashp.org">https://nashp.org</a>
Drug	A drug means an article that is: (A) recognized in the official United States Pharmacopoeia, official Homeopathic Pharmacopoeia of the United States or official National Formulary, or any supplement to any of them; (B) intended for use in the diagnosis, cure, mitigation, treatment or prevention of disease in humans or other animals; (C) other than food, intended to affect the structure or any function of the body of humans or	C.G.S. § 19a-754b at <a href="https://www.cga.ct.gov/current/pub/chap_368dd.htm#sec_19a-754b">https://www.cga.ct.gov/current/pub/chap_368dd.htm#sec_19a-754b</a>

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Term / Data Element	Definition	Source
	any other animal; and (D) intended for use as a component of any articles specified in this subdivision; but shall not include devices or their components, parts or accessories.	
Fast track product	A fast track product, as designated by the FDA, is a drug that (A) is intended, whether alone or in combination with one or more other drugs, for the treatment of a serious or life-threatening disease or condition, and it demonstrates the potential to address unmet medical needs for such a disease or condition, or (B) is designated by the Secretary as a qualified as a qualified infectious disease product under 21 U.S.C. §355f(d).	21 U.S.C. § 356
Generic Drug	A generic drug is the same as a brand name drug in dosage, safety, strength, how it is taken, quality, performance, and intended use. A generic drug product must contain identical amounts of the same active ingredient(s) as the brand name product. Drug products evaluated as "therapeutically equivalent" can be expected to have equal effect and no difference when substituted for the brand name product.	FDA Glossary of Terms at <a href="https://www.fda.gov/drugs/drug-approvals-and-databases/drugsfda-glossary-terms">https://www.fda.gov/drugs/drug-approvals-and-databases/drugsfda-glossary-terms</a>
Justification for Current-Year Price Increase	The reason or reasons that the manufacturer increased the Whole Sale Acquisition Cost (WAC) of the drug or drug group, compared with last year.	National Academy for State Health Policy <a href="https://nashp.org">https://nashp.org</a>
Manufacturer	Manufacturer means any entity that holds the NDC for a covered outpatient drug or biological product and meets the following criteria: (1) Is engaged in the production, preparation, propagation, compounding, conversion, or processing of covered outpatient drug products, either directly or indirectly by extraction from substances of natural origin, or independently by means of chemical synthesis, or by a combination of extraction and chemical synthesis; or (2) Is engaged in the packaging, repackaging, labeling, relabeling, or distribution of covered outpatient drug products and is not a wholesale distributor of drugs or a retail pharmacy licensed under State law. (3) For authorized generic products, the term "manufacturer" will also include the original holder of the NDA. (4) For drugs subject to private labeling arrangements, the term "manufacturer" will also include the entity under whose own label or trade name the product will be distributed.	42 C.F.R. §447.502

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Term / Data Element	Definition	Source
Manufacturer 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 Generally Accepted Accounting Principles (GAAP).	GAAP
Manufacturer Sales Volume	The number of Wholesale Acquisition Cost (WAC) units of the drug or drug group that the manufacturer has sold or expects to sell in the reference year, to any wholesaler or other direct purchaser in the United States or the State, as indicated.	42 U.S.C. §1395w-3a.
Market Introduction or Market Entry	The month and year in which the manufacturer acquired or first marketed the drug for sale in the U.S.	National Academy for State Health Policy <a href="https://nashp.org">https://nashp.org</a>
National Drug Code (NDC)	The numerical code maintained by the 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 (xxxx-yyy-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.	42 C.F.R. §447.502
New Drug Application (NDA)	New drug application, or NDA is the application described under § 314.50, including all amendments and supplements to the application. An NDA refers to "stand-alone" applications submitted under section 505(b)(1) of the Federal Food, Drug, and Cosmetic Act and to 505(b)(2) applications.	21 C.F.R. §314.3
New Molecular Entity	A new molecular entity (NME) is an active ingredient that contains no active moiety that has been previously approved by the FDA in an application submitted under section 505 of the Federal Food, Drug, and Cosmetic Act or has been previously marketed as a drug in the United States.	FDA Glossary of Terms at <a href="https://www.fda.gov/drugs/drug-approvals-and-databases/drugsfda-glossary-terms">https://www.fda.gov/drugs/drug-approvals-and-databases/drugsfda-glossary-terms</a>
Nonproprietary Name	The generic name assigned by the United States Adopted Names (USAN) Council.	Merck Manual, Consumer Version
Orphan Drug	Means a drug intended for use in a rare disease or condition as defined in Section 526 of the Food, Drug, and Cosmetic Act.	21 C.F.R. § 316.3
Patient Volume	The number of patients expected to be prescribed the drug in the indicated year	CA Senate Bill No. 17 CHAPTER 603
Pharmacy Benefits Manager (PBM)	Any person that administers the prescription drug, prescription device, pharmacist services or prescription drug and device and pharmacist services portion of a health care plan on behalf of an issuer.	<a href="#">C.G.S. § 38a-479ooo</a>

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Term / Data Element	Definition	Source
Pipeline Drug	A drug containing a new molecular entity for which a sponsor has filed a new drug application or biologics license application with, and received an action date from, the federal Food and Drug Administration.	C.G.S. § 19a-754b at <a href="https://www.cga.ct.gov/current/pub/chap_368dd.htm#sec_19a-754b">https://www.cga.ct.gov/current/pub/chap_368dd.htm#sec_19a-754b</a>
Prescription drug	A drug prescribed by a health care provider to an individual in this state.	C.G.S. § 19a-754b at <a href="https://www.cga.ct.gov/current/pub/chap_368dd.htm#sec_19a-754b">https://www.cga.ct.gov/current/pub/chap_368dd.htm#sec_19a-754b</a>
Priority review	A set of review classifications for a drug that appears to represent an advance over available therapy.	21 U.S.C. § 356
Product Cost	The cost of material, direct labor, and overhead. Product cost is defined consistent with GAAP.	GAAP
Proprietary name	The brand or trademark name of the drug reported to the FDA.	<a href="https://www.fda.gov/medial/88496/download">https://www.fda.gov/medial/88496/download</a>
Rebate	A price discount or concession that affects the price of an outpatient prescription drug, and that a pharmaceutical manufacturer directly provides to a (1) health carrier for an outpatient prescription drug manufactured by the pharmaceutical manufacturer, or (2) pharmacy benefits manager after the manager processes a claim from a pharmacy or a pharmacist for an outpatient prescription drug manufactured by the pharmaceutical manufacturer "Rebate" does not mean a bona fide service fee, as such term is defined in 42 C.F.R. § 447.502, as amended from time to time.	C.G.S. §§ 19a-754b and 38a-479ooo at <a href="https://www.cga.ct.gov/current/pub/chap_368dd.htm#sec_19a-754b">https://www.cga.ct.gov/current/pub/chap_368dd.htm#sec_19a-754b</a> and <a href="https://www.cga.ct.gov/2025/pub/chap_700c.htm#sec_38a-479ooo">https://www.cga.ct.gov/2025/pub/chap_700c.htm#sec_38a-479ooo</a>
Reporting Entity	Any manufacturer, issuer, pharmacy benefits manager, wholesale drug distributor, or any other entity required to report to the Connecticut Office of Health Strategy.	N/A
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.	C.G.S. § 19a-754b at <a href="https://www.cga.ct.gov/current/pub/chap_368dd.htm#sec_19a-754b">https://www.cga.ct.gov/current/pub/chap_368dd.htm#sec_19a-754b</a>
Revenue	The total gross revenue associated with the drug or drug group in the United States or the State, as indicated. Revenue is defined consistent with Generally Accepted Accounting Principles (GAAP).	GAAP
Review Classification	A way of describing drug applications upon initial receipt and throughout the review process and prioritizing their	FDA Glossary of Terms at <a href="https://www.fda.gov/drugs/dru">https://www.fda.gov/drugs/dru</a>

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Term / Data Element	Definition	Source
	review. FDA Review Classifications are Priority review drug (i.e., a drug that appears to represent an advance over available therapy), Standard review drug (i.e., a drug that appears to have therapeutic qualities similar to those of an already marketed drug), and Orphan drug (i.e., a product that treats a rare disease affecting fewer than 200,000 Americans).	<a href="https://www.fda.gov/drugs/drug-approvals-and-databases/drugsfda-glossary-terms">g-approvals-and-databases/drugsfda-glossary-terms</a>
Route of Administration	A route of administration is a way of administering a drug to a site in a patient. A comprehensive list of specific routes of administration appears in the CDER Data Standards Manual.	FDA Glossary of Terms at <a href="https://www.fda.gov/drugs/drug-approvals-and-databases/drugsfda-glossary-terms">https://www.fda.gov/drugs/drug-approvals-and-databases/drugsfda-glossary-terms</a>
Sponsor	Sponsor means the entity that assumes responsibility for a clinical or nonclinical investigation of a drug, including the responsibility for compliance with applicable provisions of the act and regulations. A sponsor may be an individual, partnership, corporation, or Government agency and may be a manufacturer, scientific institution, or an investigator regularly and lawfully engaged in the investigation of drugs. For purposes of the Orphan Drug Act, FDA considers the real party or parties in interest to be a sponsor.	C.G.S. § 19a-754b at <a href="https://www.cga.ct.gov/current/pub/chap_368dd.htm#sec_19a-754b">https://www.cga.ct.gov/current/pub/chap_368dd.htm#sec_19a-754b</a>
Tax Identification Number	The 9-digit tax Taxpayer Identification Number (TIN) used by the Internal Revenue Service (IRS).	IRS
Volume	The total number of Wholesale Acquisition Costs (WAC) units of each drug or summed across all drugs in a drug group.	National Academy for State Health Policy <a href="https://nashp.org">https://nashp.org</a>
Wholesale Acquisition Cost (WAC)	The manufacturer’s list price to wholesalers or direct purchasers in the United States on December 31 of the reference year, 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.	42 U.S.C. § 1395w-3a.
Wholesale Acquisition Cost (WAC) Unit	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 as indicated by the Connecticut Office of Health Strategy, it is the total number of WAC units in the drug group.	42 U.S.C. § 1395w-3a.