PRESCRIPTION DRUG COSTS TRANSPARENCY FILINGS TO THE OFFICE OF HEALTH STRATEGY

A Manual and Guide for Submissions Required
Pursuant to Connecticut General Statutes § 19a-754b

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Revised 2023
****Please note update to Subsection (d) of section 19a-754b of Conn. General Statutes, page 4**

*The email address is for the Prescription Drug Cost Transparency process only. Please use OHS main email: OHS@ct.gov for other matters.

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Introduction

The Office of Health Strategy ("OHS" or "the Office") was established in 2018. The mission of the Office of Health Strategy is 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. Under Connecticut General Statutes (Conn. Gen. Stat.") § 19a-754a (and other sections of the statutes), the Office is charged with, among other duties: (1) Developing and implementing a comprehensive and cohesive health care vision for the state, including, but not limited to, a coordinated state health care cost containment strategy; (2) Promoting effective health planning and the provision of quality health care in the state in a manner that ensures access for all state residents to cost-effective health care services, avoids the duplication of such services and improves the availability and financial stability of such services throughout the state; (3) Directing and overseeing the State Innovation Model Initiative and related successor initiatives; (4) (A) Coordinating the state's health information technology initiatives, (B) seeking funding for and overseeing the planning, implementation and development of policies and procedures for the administration of the all-payer claims database program established under Conn. Gen. Stat. § 19a-775a, (C) establishing and maintaining a consumer health information Internet web site under Conn. Gen. Stat. § 19a-755b, and (D) designating an unclassified individual from the office to perform the duties of a health information technology officer as set forth in Conn. Gen. Stat. §§ 17b-59f and 17b-59g; and (5) Directing and overseeing the Health Systems Planning Unit established under Conn. Gen. Stat. § 19a-612 and all of its duties and responsibilities as set forth in chapter 368z. The OHS develops health policy that improves health outcomes and limits health care cost growth across all sectors, whether private or public, including hospitals, physicians and clinical services and prescription drugs. Creation of this office brings together critical data sets and health information exchange efforts and allows for collaboration with many stakeholders, including state agency partners. Working with comprehensive data and experts from inside and outside government, OHS will develop and support state-led multi-payer healthcare payment and service delivery reforms.

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 at https://www.cga.ct.gov/2018/ACT/pa/pdf/2018PA-00041-R00HB-05384-PA.pdf. The Public Act has eleven sections; this manual addresses Section 10, which involves filings to the Office of Health Strategy, and which was codified into state statute as Conn. Gen. Stat. §19a-754b, C.G.S. The remaining nine sections of the Public Act are codified into Chapter 38a of the statutes.

OHS has worked in collaboration and partnership with the Office of the State Comptroller in the implementation of Conn. Gen. Stat. §19a-754b.

Statutory Authority

The Prescription Drug Cost data and information filings discussed within this Manual are mandated by Conn. Gen. Stat. § 19a-754b of the Connecticut General Statutes, effective January 1, 2020, as follows:

Sec. 19a-754b (Section 10 of Public Act 18-41, effective January 1, 2020)

(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.

Statute regarding Pipeline Drug Reporting

(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.

Statute Regarding Reporting of Top 10 Drugs with Substantial State Cost

****Sec. 8. Subsection (d) of section 19a-754b of the general statutes is repealed and the following is substituted in lieu thereof (Effective October 1, 2023):**
(d) (1) On or before March 1, 2020, and annually thereafter, the executive director of the Office of Health Strategy, in consultation with the Comptroller, Commissioner of Social Services and Commissioner of Public Health, shall prepare a list of not more than ten outpatient prescription drugs that the executive director, in the executive director's discretion, determines are (A) provided at substantial cost to the state, considering the net cost of such drugs, or (B) critical to public health. The list shall include outpatient prescription drugs from different therapeutic classes of outpatient prescription drugs and not less than one generic outpatient prescription drug.

(2) Prior to publishing the annual list pursuant to subdivision (1) of this subsection, the executive director shall prepare a preliminary list that includes outpatient prescription drugs that the executive director plans to include on such annual list. The executive director shall make such preliminary list available for public comment for not less than thirty days. During the public comment period, any manufacturer of an outpatient prescription drug included on the preliminary list may produce documentation, as permitted by federal law, to the executive director to establish that the wholesale acquisition cost of such drug, less all rebates paid to the state for such outpatient prescription drug during the immediately preceding calendar year, does not exceed the limits established in subdivision (3) of this subsection. If such documentation establishes, to the satisfaction of the executive director, that the wholesale acquisition cost of the drug, less all rebates paid to the state for such drug during the immediately preceding calendar year, does not exceed the limits established in subdivision (3) of this subsection, the executive director shall, not later than fifteen days after the closing of the public comment period, remove such drug from the preliminary list before publishing the annual list pursuant to subdivision (1) of this subsection.

(3) The executive director shall not list any outpatient prescription drugs under subdivision (1) or (2) of this subsection unless the wholesale acquisition cost of such outpatient prescription drug (A) increased by not less than sixteen per cent cumulatively during the immediately preceding two calendar years, and (B) was not less than forty dollars for a course of treatment.

(4)(A) The pharmaceutical manufacturer of an outpatient prescription drug included on a list prepared by the executive director pursuant to subdivision (1) of this subsection shall provide to the office, in a form and manner specified by the executive director, (i) 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, and (ii) aggregate, company-level research and development costs and such other capital expenditures that the executive director, in the executive director's discretion, deems relevant for the most recent year for which final audited data are available.

(B) The quality and types of information and data that a pharmaceutical manufacturer submits to the office under this subdivision shall be consistent with the quality and types of information and data that the pharmaceutical manufacturer includes in (i) such pharmaceutical manufacturer's annual consolidated report on Securities and Exchange Commission Form 10-K, or (ii) any other public disclosure.

(5) The office shall establish a standardized form for reporting information and data pursuant to this subsection after consulting with pharmaceutical manufacturers. The form shall be designed to minimize the administrative burden and cost of reporting on the office and pharmaceutical manufacturers.

e) The office may impose a penalty of not more than seven thousand five hundred dollars on a pharmaceutical manufacturer or sponsor for each violation of this section by the pharmaceutical manufacturer or sponsor.

(f) The office may adopt regulations, in accordance with the provisions of chapter 54, to carry out the purposes of this section.

Frequently Asks Questions

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. ***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 no later than this date)
November 2, 2019	November 3, 2019	**January 1, 2020**
November 8, 2019	November 9, 2019	**January 7,2020**
November 15, 2019	November 16, 2019	**January 14, 2020**
December 1, 2019	December 2, 2019	**January 30, 2020**
December 10, 2019	December 11, 2019	**February 8, 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**

7. ***Conn. Gen. Stat. §19a-754b provides some but not all related definitions. Where can I find definitions for the required filings?***
   Appendix II of this manual provides a list of Key Definitions.

8. ***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.

9. ***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.

10. ***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 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.

11. ***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.

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

13. ***Are the prescription drug filings include veterinarian medicine?***
    No

14. ***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.

15. ***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.

16. ***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.

17. ***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.

18. ***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.

19. ***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, there will either be a separate manual for the requirements of Conn. Gen. Stat. §19a-754b (d)(3)(A), or this manual will be revised to provide instructions for that specific filing.

20. ***Is there a registration requirement for prescription drug price reporting***?
    For the reporting of additional information related to the Top Ten list, as pursuant to Conn. Gen. Stat §19a-754b(d)(1)(3)(A), registration is not required at this moment. Only for those drugs included on the list, manufacturers of each of those drugs shall provide info about why the drugs price increased and aggregate R&D and capitol expense costs. OHS will notified them on how to file the additional information.

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. ***If registration is required, is there a deadline for registration and are they 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 takes place prior to the end of the 60 days 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.

23. ***Are they any other associated program fees for system registration or assessment of manufacturer drug reports?***
    No

Filing Instructions with Flow Charts

General Instructions

In order to facilitate the reporting of notices and collection of prescription drugs data by the Sponsors and Manufacturers, OHS has developed a new web-based application, the Prescription Drug Reporting System (PDRS) that will allow Sponsors and Manufacturers to file their information. Specific instructions to complete the filing requirements using the PDRS, can be found on **Appendix I** of this manual and on the PDRS. All Sponsor required filings are due within sixty (60) days of receipt of Food and Drug Administration (FDA) approval to market the pharmaceutical product. This filing requirement is effective on January 1, 2020.

The process of data submission consists of two parts, the Sponsor notices data submission, starting January 1st, and the Manufacturer data submission. Manufacturer data submission needs to only 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.

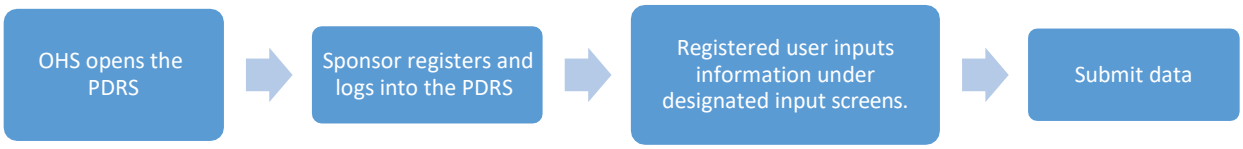
Pursuant to Conn. Gen. Stat. § 19a-754e, OHS may impose a penalty of not more than seven thousand five hundred dollars ($7,500) on a Pharmaceutical Manufacturer or Sponsor for each violation of this section by the Pharmaceutical Manufacturer or Sponsor.

All questions regarding any aspect of the Sponsor's or Manufacturer's Filings should be emailed to HSP@ct.gov.

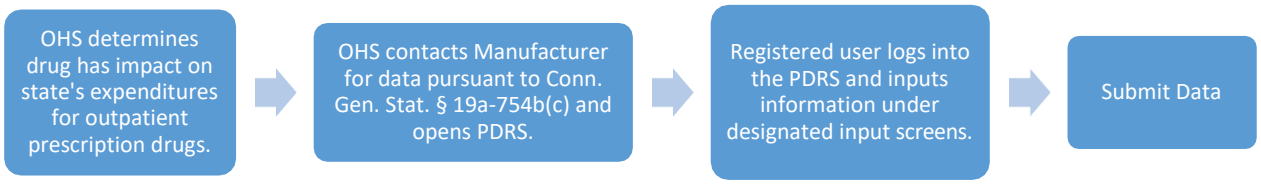
OHS will be relying on the Sponsor's and Manufacturer's accurate filing of the information and it is intended that the non-proprietary information will be used in OHS publications.

Process Steps Summary

Part A- Sponsor Notices Submission (starts January 1, 2020)



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. **Appendix I** 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. There are screen shots taken from the portal along with specific details for each form. Instructions could also be found on the PDRS input screens by clicking on the "Instructions" button to the right of the screen.

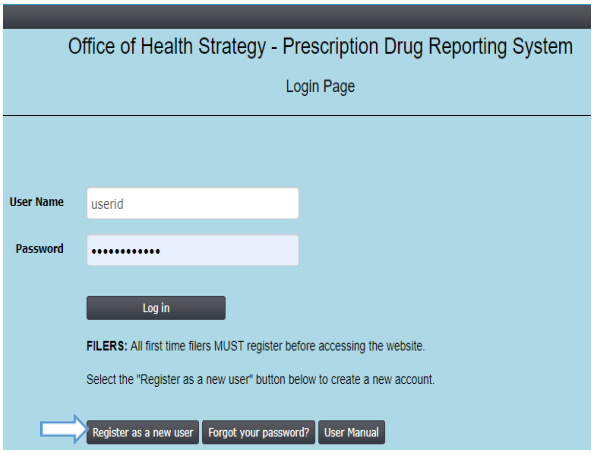
The PDRS portal can be accessed with different browsers. It is recommended you use the latest version of browsers such as Internet Explorer, Mozilla Firefox or Google Chrome for the system to run properly on your computer. The web-based application can be used from any desktop, laptop or web-based device.

Reports will be generated utilizing Microsoft Excel. 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.

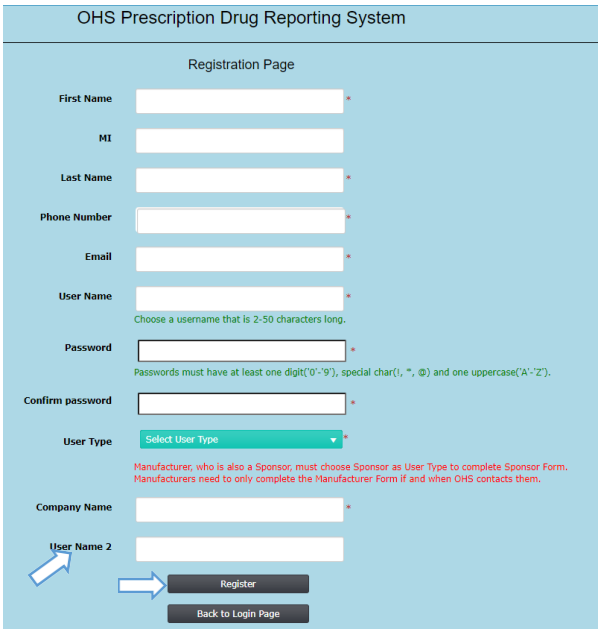
Appendix I
Instructions to Upload to Web-Based Filing Portal (User Manual)

Register as a New User

Enter the website address: **https://ohs-pdrsportal.ct.gov** in your web browser. If 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 required Sponsor Form.



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 its okay to log in to the web portal.

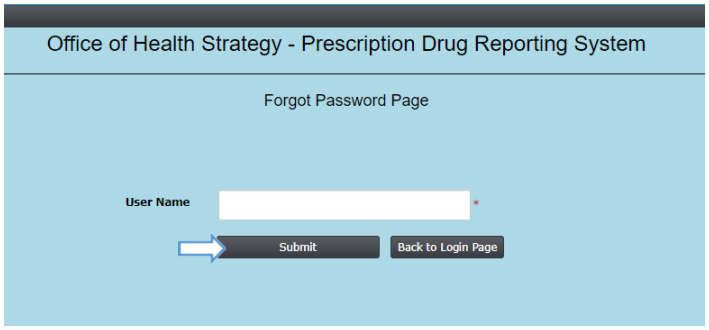
User Name 2 entry line was created for the primary User to share information with another person at the User's discretion. If User 2 has been assigned the task of entering information, then, User 2 must also register. Both individuals must reference each other on the User Name 2 line in order to view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

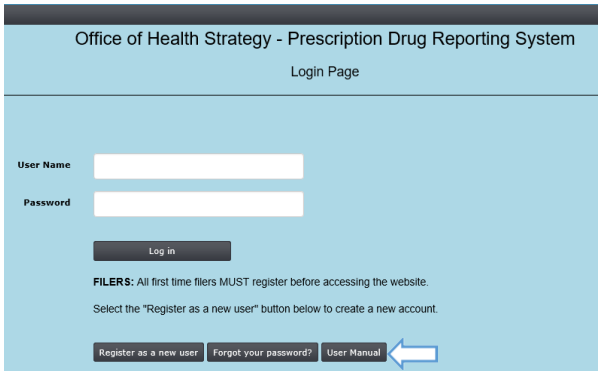
Reset Password

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.



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

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.



Input Instructions

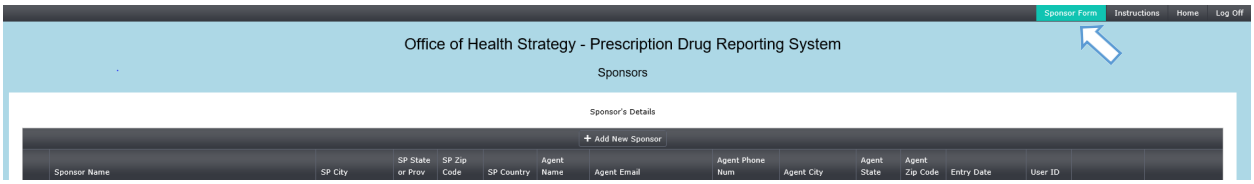
Sponsor and Manufacturer Data Entry

Prior to completing data entry, Sponsors and Manufacturers information must be entered into the web portal first. The information for these entities will carry 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.

At the present time, the portal does not allow for saving data mid-way. However, time out limits were not set which always keeps the portal open. This allow 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.



A Manufacturer, who is also a Sponsor, will need to also click on the Sponsor button to fill out required Sponsor Form. Manufacturers need to **only** 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.

If after logging in the Manufacturer Form appears, as seeing below, contact OHS for assistance to switch your registration to Sponsor User Type.

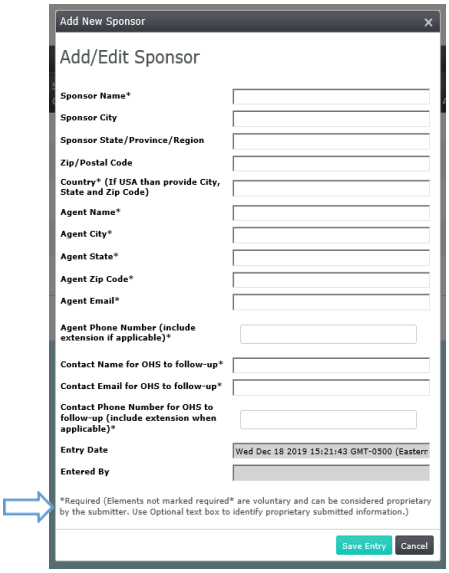
To add Sponsor Data, click on the Add New Sponsor button, enter data and then click Save Entry. Data on greyed out entry lines is system generated; therefore, User input is not required. After clicking on Save Entry, the input screen disappears which indicates that the entries were saved.

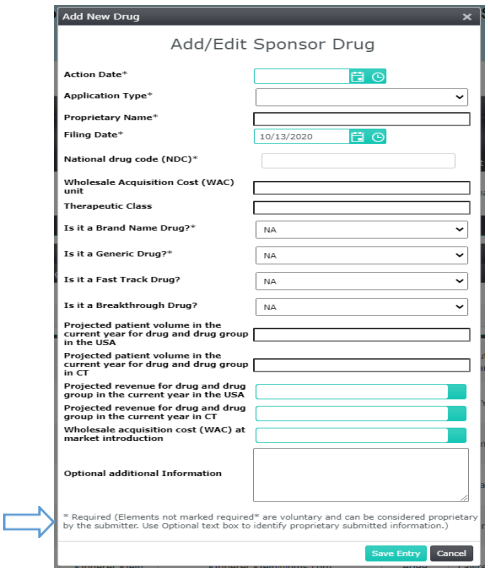
To add Sponsor drugs details, after saving the new Sponsor data, click on the arrow next to the Sponsor's name, to the left of the screen. This will open the drug details input screen. Then, click on the

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

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 required are voluntary and can be considered proprietary by the submitter. Use Optional text box on PDRS to identify proprietary submitted information and to list additional NDC codes associated with the same drug.





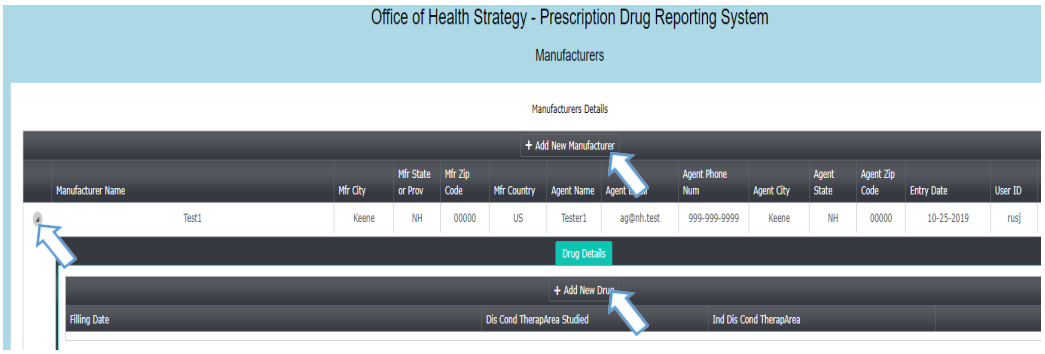
After all inputs have been successfully entered, click on the Home Page button to retrieve the Sponsor's data. Instructions to retrieve the data are introduced on the next section of this document.

After the data has been saved, Users will have up to a 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.

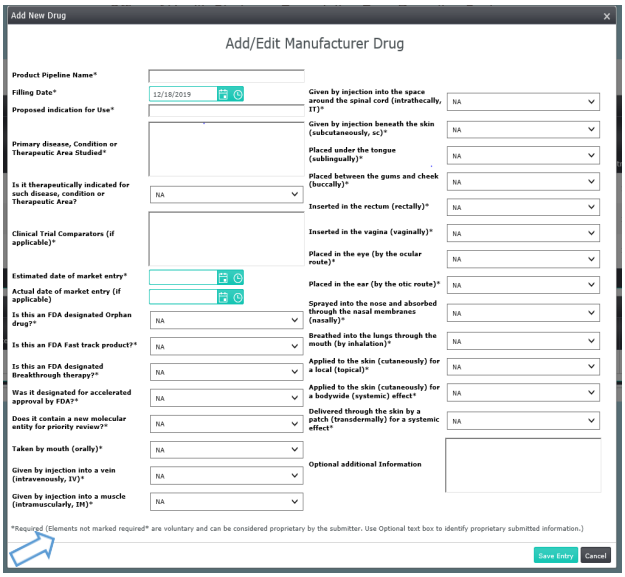
<u>To add another drug to the same account</u>, click on the left arrow next to the Sponsor 's name, which will open up the screen to add the new drug. Next, click on "Add New Drug" to see the form where you can enter the new data. Once it is saved, the new entry will be display under the already submitted entire.

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 entries were saved.

To add Manufacturer drugs 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 entries were saved.



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



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 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.

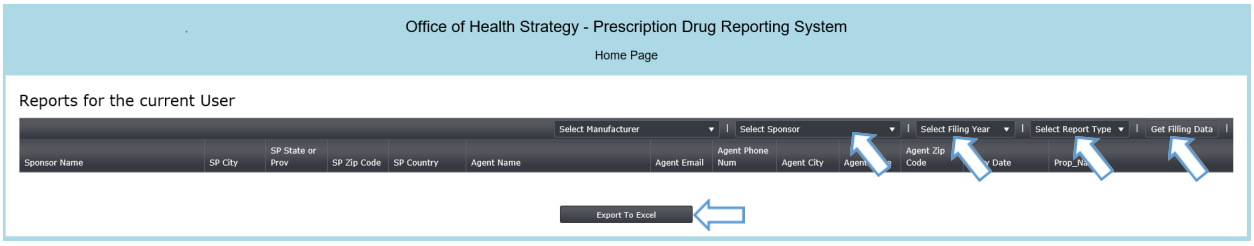
Data may also be submitted using a CSV template (under development, not available). If an abundance of data needs to be reported, choose this option. Simply click the Download CSV Template button, open the downloaded file, enter data and save the file. **Do not format the data in the file.** Including commas, hyphens or dollar signs ($) 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 various 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 to 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 download. To allow for 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 type. Report labeled as Manufacturer Data is only for Manufacturers who had completed the drug details entries per OHS request as mandated under Conn. Gen. Stat. §19a-754c.



Appendix II

GLOSSARY OF TERMS OR KEY DEFINITIONS

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

Term or Data Element	Definition Used	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/Mathematica Policy Research https://nashp.org
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 https://www.fda.gov/drugs/drug-approvals-and-databases/drugsfda-glossary-terms
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 https://www.fda.gov/drugs/drug-approvals-and-databases/drugsfda-glossary-terms
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	FDA Glossary of Terms at https://www.fda.gov/drugs/drug-approvals-and-databases/drugsfda-glossary-terms

	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.	
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.	https://www.fda.gov/files/drugs/published/FDA%E2%80%99s-Overview-of-the-Regulatory-Guidance-for-the-Development-and-Approval-of-Biosimilar-Products-in-the-US.pdf
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/Mathematica Policy Research https://nashp.org
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.	https://clinicaltrials.gov/ct2/about-studies/glossary
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.	https://pharmaphorum.com/views-and-analysis/strategies-success-comparator-clinical-trials/#_edn2
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/Mathematica Policy Research https://nashp.org
Drug	A drug means an article that is: (A) recognized in the official United States Pharmacopoeia, official Homeopathic	C.G.S § 19a-754b https://www.cga.ct.gov/cu

	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 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.	rrent/pub/chap_368dd.htm#sec_19a-754b
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 the 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 https://www.fda.gov/drugs/drug-approvals-and-databases/drugsfda-glossary-terms
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/Mathematica Policy Research https://nashp.org
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	42 C.F.R. § 447.502

	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.	
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/Mathematica Policy Research https://nashp.org
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 (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.	42 C.F.R. § 447.502
New Drug Application	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	21 C.F.R. § 355-1FDA Glossary of Terms at https://www.fda.gov/drugs

	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.	/drug-approvals-and-databases/drugsfda-glossary-terms
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.	C.G.S. § 38a-479ooo
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 https://www.cga.ct.gov/current/pub/chap_368dd.htm#sec_19a-754b
Prescription drug	A drug prescribed by a health care provider to an individual in this state.	C. G. S. § 19a-754b https://www.cga.ct.gov/current/pub/chap_368dd.htm#sec_19a-754b
Priority review	A 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.	https://www.fda.gov/media/88496/download
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 https://www.cga.ct.gov/current/pub/chap_368dd.htm#sec_19a-754b

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 https://www.cga.ct.gov/current/pub/chap_368dd.htm#sec_19a-754b
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 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).	FDA Glossary of Terms at https://www.fda.gov/drugs/drug-approvals-and-databases/drugsfda-glossary-terms and https://www.fda.gov/drugs/drug-approvals-and-databases/drugsfda-frequently-asked-questions#chemtype_reviewclass
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 https://www.fda.gov/drugs/drug-approvals-and-databases/drugsfda-glossary-terms
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 https://www.cga.ct.gov/current/pub/chap_368dd.htm#sec_19a-754b

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/Mathematica Policy Research https://nashp.org
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.

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