

CTRx System User's Guide

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What is SB 17 ('Healthcare: prescription drug costs' - Senator Ed Hernandez; Senate Sessions 2017-2018)?

The statute, referred to as SB 17 prior to becoming law, is now the CA Health and Safety Code Division 107 Chapter 9, which seeks to increase prescription drug cost transparency by:

1. Requiring advance notification to public and private purchasers and reimbursers before a significant prescription drug wholesale acquisition cost increase occurs, and making public certain information associated with the increase.

2. Requiring the provision of information about the impact to health care plans and insurers of cost increases.

Title 22, Division 7, Chapter 9.5 of the California Code of Regulations implements the statute.

What state organization collects the relevant reports related to prescription drugs under the statute?

The Cost Transparency: Prescription Drugs (CTRx) Unit within California's Department of Health Care Access and Information (HCAI) collects your reports. The CTRx unit was created to administer the programmatic functions needed to implement the statute. You can contact CTRx through email: ctrx@hcai.ca.gov.

I am aware that there is an active lawsuit challenging the constitutionality of SB 17. Do I need to comply with the statute while the lawsuit is active?

Yes. Unless a court issues an order preventing HCAI from implementing the statute, you must comply with law. No order is in place.

My company does not manufacture any prescriptions drugs but holds the NDCs of the prescription drugs it sells. Therefore, is it correct that the statute does not apply to my company?

No. California Code of Regulations Title 22 Division 7 Chapter 9.5 Article 1 Section 96060(d) defines a prescription drug manufacturer as "...an entity that

(1) holds the NDC for a prescription drug; and

(2) is described in Health and Safety Code Chapter 9 Division 107 Section 127675."

Note: a pharmacy benefit manager (PBM) is also required to notify its prescription drug purchasers when the PBM receives notification of a WAC increase consistent with Health and Safety Code Chapter 9 Division 107 Section 127677(a).

When do I need to file a report with CTRx HCAI?

The specific due dates can be found in Title 22, Division 7, Chapter 9.5 of the California Code of Regulations. However, you can also find the information in the report-specific FAQs provided in the Resources section on the SIERA homepage.

It is strongly recommended that a report be submitted at least a few business days before the report's due date. When a report is submitted to CTRx HCAI, it is reviewed to ensure compliance with all statutory requirements. If one or more compliance-related issues are identified during CTRx HCAI's review, the report may NOT be considered 'Completed'.

What is the difference between a report and a submission?

A prescription drug manufacturer can have several products with each product having its own unique National Drug Code (NDC). Each required report is associated with a single NDC, or a unique prescription drug product.

The CTRx system allows you to create, save, edit, and submit one or more reports in a single submission. Each submission can only include reports of the same type, either WAC increase or new drug reports. Furthermore, all of the reports in a single submission will share the same due date.

Therefore, civil penalties for a late submission are assessed for each report in the submission, multiplied by the number of days past due. For example, a submission with 3 WAC increase reports that was 3 days late will result in a total of \$9,000 in civil penalties; \$1,000 per late report multiplied by the 3 days past due.

If required information is not publicly available, do I still need to provide the information to CTRx HCAI?

No. Leave the data field blank, and then select the relevant Non-Pub Ind box provided in SIERA that indicates the information is proprietary. If a relevant Non-Pub Ind is not available, use the most relevant comment field to state that the information is not publicly available. If information is found to be publicly available by CTRx HCAI, CTRx HCAI will notify you that the information should be provided to comply with the statute.

What are examples of sources of publicly available information?

The following are examples of online and offline sources of publicly available information: annual and quarterly reports, SEC filings, press releases, shareholder updates, shareholder meeting minutes, subscription services, and company websites. The examples given are not meant to be an exhaustive list of sources of publicly available information.

How can I get help in using SIERA to report information for a given event?

In the Resources box of the Home page are several links for assistance. If you need further assistance, you can email CTRx HCAI at ctrx@hcai.ca.gov.

Who will be able to access the information I provide CTRx HCAI?

The information you provide relating to new prescription drugs and WAC increases are made available to the public. However, the contact information provided in SIERA for primary contacts and other users will be kept confidential.

Do I need to resend another advance notice to purchasers if the proposed WAC increase date on the initial notice has been changed?

Yes. The manufacturer is still required to send a new advance notice to purchasers with the new proposed effective date. The new advance notice still needs to comply with all the requirements stated in the California Health & Safety Code Division 107 Chapter 9 Section 127677, which also include notifying purchasers 60 days in advance to the proposed effective date of the WAC increase.