

CTRx System User's Guide

FAQs – Wholesale Acquisition Cost (WAC) Increase Reports

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Do I have to provide to CTRx HCAI information related to every WAC increase to any prescription drugs?

No. The statute requires a drug manufacturer to report to CTRx HCAI information related to an increase in WAC when:

- 1) the WAC of the prescription drug is more than forty dollars (\$40) for a course of therapy, AND
- 2) the increase in WAC of the prescription drug is “more than 16 percent, including the proposed increase and the cumulative increases that occurred within the previous two calendar years prior to the current year.”

If the two criteria stated above are *not* BOTH met, then you do not have to report the WAC increase to CTRx HCAI.

Note: providing CTRx HCAI with the information related to relevant WAC increases of prescription drugs is in addition to the statute’s requirement that prescription drug manufacturers directly provide advance notice to prescription drug purchasers of relevant WAC increases of prescription drugs.

What is considered a “course of therapy”?

The statute defines a course of therapy as EITHER of the following:

- 1) “The recommended daily dosage units of a prescription drug pursuant to its prescribing label as approved by the federal Food and Drug Administration for 30 days”.
- 2) “The recommended daily dosage units of a prescription drug pursuant to its prescribing label as approved by the federal Food and Drug Administration for a normal course of treatment that is less than 30 days”.

There is a unit WAC and package WAC for my prescription drug; which WAC should I use?

Use the package WAC for all your reporting, for consistency’s sake. The unit WAC often does not reflect a “course of therapy” and can be below the \$40 WAC threshold for reporting. Therefore, reporting the unit WAC can cause confusion to the public.

What specific information do I need to provide to CTRx HCAI when reporting a relevant WAC increase of a prescription drug?

California Health & Safety Code Division 107 Chapter 9 Section 127679(a) defines the information required for submission to CTRx HCAI. The link is provided below:

http://leginfo.legislature.ca.gov/faces/codes_displayText.xhtml?lawCode=HSC&division=107.&title=&part=2.&chapter=9.&article=

What do I need to provide to CTRx HCAI if I have multiple WAC increases in one quarter?

Every WAC increase consistent with California Health & Safety Code Division 107 Chapter 9 Section 127677(a) requires the prescription drug manufacturer to provide related information to CTRx HCAI.

Each SIERA submission provides multiple entry lines (with the option to add more entry lines) to allow you to enter multiple WAC increases for one or more NDCs.

For example, if there were three relevant WAC increases for a given NDC in a quarter, three entry lines should be completed – one entry line per WAC increase. You would input the same NDC in each of the three entry lines to reflect the three separate WAC increases for the same NDC. In this situation, you would only need to submit one five-year WAC increase history for all three WAC increases in the quarter.

If there are relevant WAC increases for different NDCs during the same quarter, it is important to enter the proper 11-digit NDC in each entry line.

When is the due date to CTRx HCAI for providing information related to relevant WAC increases?

Required information related to a relevant WAC increase is due no later than the end of the following month after the end of the quarter in which the relevant WAC increase took effect.

For example, if there was a relevant WAC increase in the quarter ending March 31st, then the related information to this WAC increase must be provided to CTRx HCAI no later than April 30 of that year.

The exact time is by end of day, Pacific Time (by 11:59:59 PM, Pacific Time). The CTRx system automatically time and date stamps submissions.

What information do I need to provide to CTRx HCAI of relevant WAC increases for a prescription drug that has several dosages and product packaging sizes?

As each unique combination of dosage and product package size of a prescription drug has its own unique 11-digit NDC, you must report the required information for a relevant WAC increase for each unique 11-digit NDC of a prescription drug. Each SIERA submission provides several entry lines with the option to add more entry lines to report multiple 11-digit NDCs.

How is the five-year period determined for reporting the five-year history of WAC increases?

The five-year period is determined from the effective date of the current WAC increase. For example, if the current WAC increase that is being reported was effective 3/1/2019, then count five years back from 3/1/2019, which ends 3/2/2014. So, the five-year history of WAC increases should include all WAC increases from 3/2/2014 to 3/1/2019.

What will happen if required information is not reported to CTRx HCAI by the statutory due date?

Your company can be assessed civil penalties of \$1,000 per every day of non-compliance past the due date. Even if a report is submitted before the statutory deadline, it can be considered past due if the report is not in full compliance. Therefore, it is strongly recommended to submit reports to CTRx HCAI at least a few business days before the deadline to resolve any potential compliance-related issues with the contents of the reports.

What is CTRx HCAI's publishing schedule for WAC increases?

CTRx HCAI will publish quarterly on the California Health and Human Services Agency Open Data Portal (ODP) the information submitted by drug manufacturers related to relevant WAC increases. HCAI data on the ODP can be found at:

<https://data.chhs.ca.gov/group/healthcare?organization=department-of-health-care-access-and-information>

Is the company still liable for civil penalties due to report delinquency if I am the only registered user (Primary Contact) in SIERA and I have been on extended leave or have left the company, and subsequently a pending report has become delinquent?

Yes. A prescription drug manufacturer must comply with the statute and is liable for civil penalties due to non-compliance.

It is strongly recommended that the company add at least two additional registered users in SIERA. Registered users associated to a manufacturer account receive email reminders and notices from SIERA for pending due dates and delinquencies.

In addition, it is vital to email CTRx as soon as possible when there is a change in the Primary Contact on an account as CTRx HCAI staff are the only individuals who can change this information in SIERA.

Note: unless responding to a question from a registered user other than the Primary Contact, CTRx staff will generally contact the Primary Contact registered in SIERA to clarify or resolve issues with submitted reports and/or SIERA account information.