

## **CTRx System User's Guide**

### **FAQs – New Drug Reports**

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**Do I need to provide CTRx HCAI with required information relating to all new prescription drugs my company has developed or acquired?**

No. The statute only applies to a new prescription drug that has a wholesale acquisition cost at the time of market introduction that “exceeds the threshold set for a specialty drug under the Medicare Part D program...”

**What is the difference between the notice and the report of a new prescription drug to CTRx HCAI?**

The statute requires a drug manufacturer to notify CTRx HCAI of a new prescription drug within “three days after release of the drug in the commercial market.” A drug manufacturer can comply with this requirement by providing to CTRx HCAI the prescription drug's 11-digit NDC, date of market introduction, and WAC at market introduction. Although not required, we recommend also providing a product description for the drug including its name, dosage, form, and package size.

The statute also requires a drug manufacturer to provide additional information related to the new prescription drug within 30 days after notification to CTRx HCAI of the new prescription drug. California Health & Safety Code Division 107 Chapter 9 Section.

127681(b) 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=](http://leginfo.legislature.ca.gov/faces/codes_displayText.xhtml?lawCode=HSC&division=107.&title=&part=2.&chapter=9.&article=)

### **Why am I only able to enter data on the first four columns of the New Drug report?**

The first four columns of the new drug report are considered the new drug notice. When you first add a new drug report submission in SIERA, you must complete and 'post' the new drug notice to enable the rest of the report elements. After a new drug notice is posted, you will receive a confirmation email. Drug manufacturers will have 30 days from the date the new drug notice is posted, to complete the additional columns of the report.

### **When is the due date for notifying CTRx HCAI of a relevant new prescription drug?**

The statute requires a drug manufacturer to notify CTRx HCAI of a new prescription drug within "three days after release of the drug in the commercial market." A drug manufacturer can comply with this requirement by providing to CTRx HCAI the prescription drug's 11-digit NDC, date of market introduction, and WAC at market introduction.

However, the statute also requires a drug manufacturer to provide to CTRx HCAI additional information related to the new prescription drug. This additional information must be provided to CTRx HCAI no later than 30 days from the initial notification to CTRx HCAI of the new prescription drug.

### **Does it matter under the statute that my company's new prescription drug has several dosages and product package sizes?**

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

**How will I know if I have completely satisfied the requirements for reporting new prescription drug information to CTRx HCAI?**

You will receive an acknowledgement email from CTRx HCAI that confirms the successful notification of the new prescription drug to CTRx HCAI. However, you will still need to provide the statutorily required additional information within 30 days from the date of the initial notification. Once you have submitted all the required additional information to CTRx HCAI, you will receive an email from CTRx HCAI confirming the complete submission of all required information.

However, CTRx HCAI confirmation of complete submission does not absolve you of any liabilities of civil penalties if the complete submission is made after the statutory deadline.

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

Your company can be assessed civil penalties of \$1,000 per day of non-compliance past the due date.

**What is CTRx HCAI's publishing schedule for new prescription drugs?**

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 new prescription drugs. HCAI data on the ODP can be found at:

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