

Prescription Drug Price Transparency

ONLINE REPORTING USER GUIDE

Updated February 23, 2022

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Purpose

The purpose of this document is to guide reporting entities on registering and reporting data to the Minnesota Department of Health (MDH) as required by the Minnesota Prescription Drug Price Transparency Act (the Act).

Questions

Reporting entities are encouraged to review the reporting guidance and support MDH has made available through a Form & Manner document or a collection of Frequently Asked Questions:

- Form & Manner guidance document (https://www.health.state.mn.us/data/rxtransparency/docs/rxformmanner022322.pdf)
- Frequently Asked Questions for Reporting Entities
 (https://www.health.state.mn.us/data/rxtransparency/docs/faq022322.pdf)

Reporting entities may consult that Act's home page for additional information and updates (www.health.state.mn.us/data/rxtransparency/), which is also accessible from the registration portal by using the "Help" button. Reporting entities may also direct technical and content questions to MDH via email: health.Rx@state.mn.us.

Technical Requirements

The <u>RxPT Registration and Reporting Portal (https://rxpt.health.mn.gov)</u> functions on the following browsers: Google Chrome, Microsoft Edge, and Mozilla Firefox.

Register

Prior to filing a report, a reporting entity must register a primary contact on the MDH website using the RxPT Registration and Reporting Portal (https://rxpt.health.mn.gov). Manufacturers and third-party administrators may register a primary contact. Once a request to register has been submitted, MDH reviews and approves requests. Approved registrants will receive an email through which they can activate their account and set their passwords. Successful activation of an account completes the registration process for a primary contact.

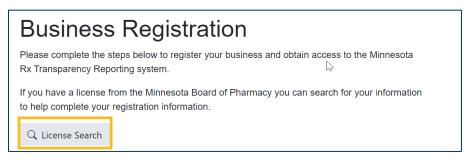
Submit a Registration Request

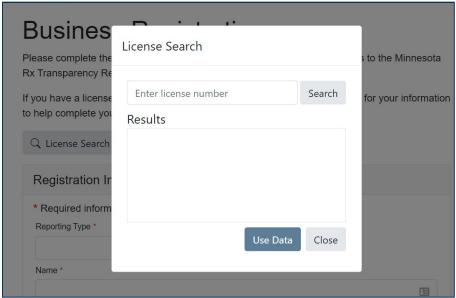
By following the steps below, a reporting entity (a manufacturer or third-party administrator) may register a primary contact.

- 1. Access the RxPT Registration and Reporting Portal online at: https://rxpt.health.mn.gov.
- 2. Click the "Register" button (outlined in yellow).

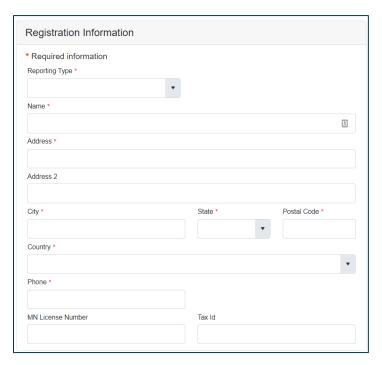


3. (Optional for Manufacturers) Use the "License Search" button to auto-fill contact information by clicking on the "License Search" button and entering the manufacturer's Minnesota license number in the available field.

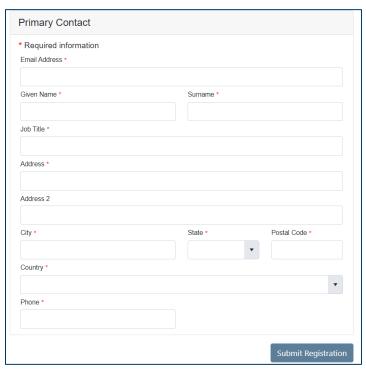




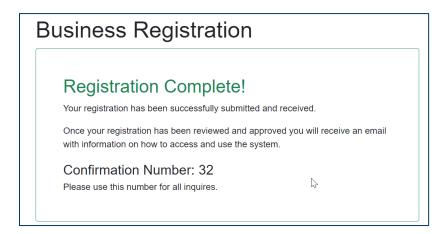
4. Enter business information or review pre-filled information and update if necessary.



5. Enter primary contact information and then click the "Submit Registration" button to submit the registration request.



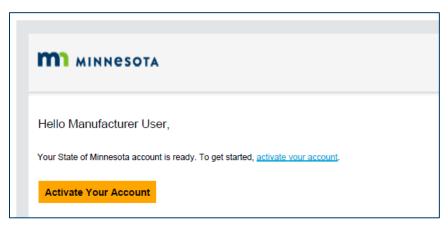
6. A Confirmation Number will be provided after registration has been submitted. Please keep record of it for use in any inquiries regarding the status of a registration request.



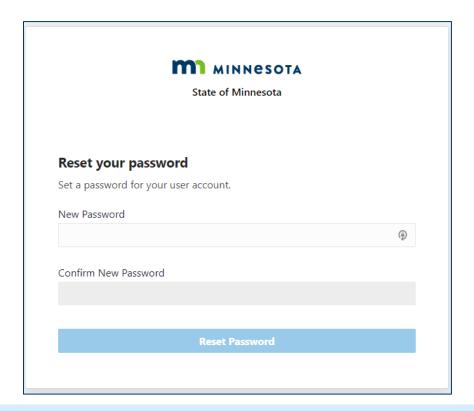
Activate Account

By following the steps below, a manufacturer or third-party administrator may activate the account of their primary contact.

- 1. After MDH approval, the email provided for the primary contact will receive an email for account activation.
- 2. Open the email and click the "Activate Your Account" button.

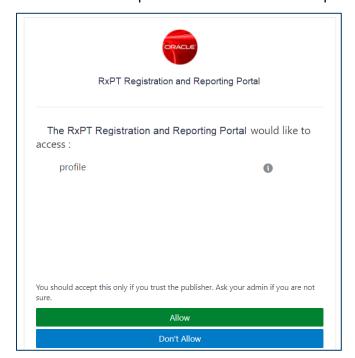


3. Clicking the "Activate Your Account" button will open a browser window that will require users to enter a new password that meets MDH password design requirements. After entering and confirming the new password, click "Reset Password." Re-access the website to log in.



Note: The username (or user login) is the email that is used for registration.

4. Click the green "Allow" button to complete the account activation process.



Log In and Password Recovery

By following the steps below, a reporting entity (a manufacturer or third-party administrator) may log in:

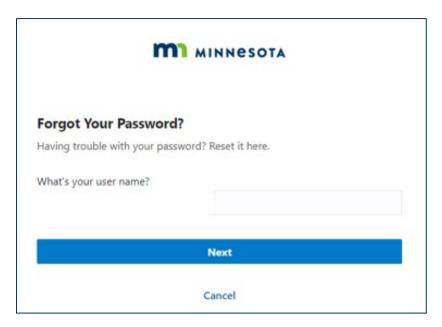
- 1. Access the RxPT Registration and Reporting Portal online at: https://rxpt.health.mn.gov.
- 2. Click the "Login" button (outlined in yellow).



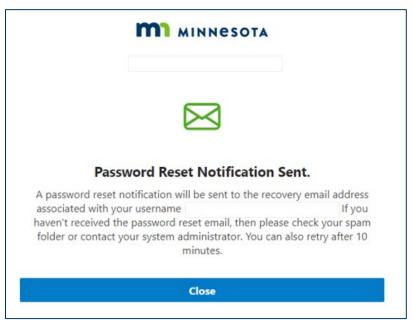
3. Type in the username (email used to register the account) and password, and then click the "Sign In" button.



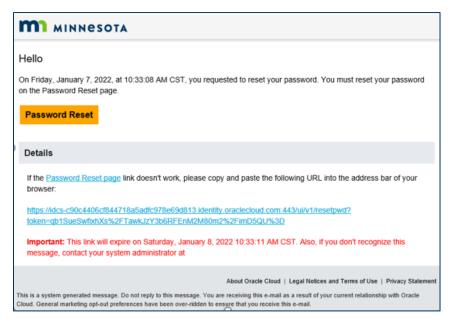
- 4. If you have registered and have trouble signing in, click the link below for password recovery support.
- 5. Enter your user name (email used to register the account) and click the "Next" button.



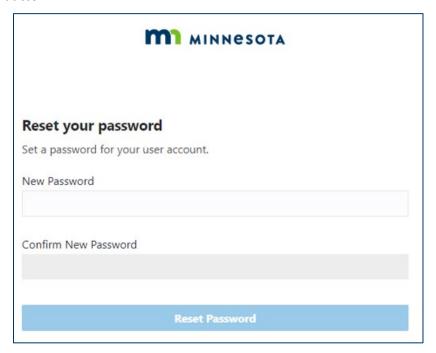
6. Upon successfully requesting support to recover your password, you will receive notification that a password recovery email was sent.



7. Open the password recovery email and click the "Password Reset" button.



8. In the window that opens, enter and confirm the new password and click the "Reset Password" button.



9. A new page will confirm that the password has been set. Click the "Continue to Sign In" button to log in.



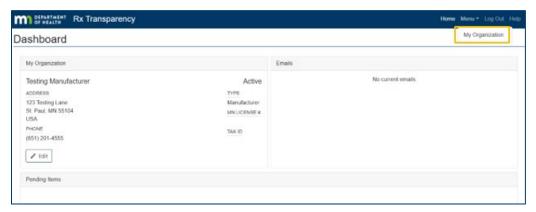
Add and Manage Affiliates (Manufacturers Only - Optional)

Once registered, a manufacturer has the option to add affiliated organizations directly and may establish an affiliation with registered third-party administrators using a lookup feature, as desired.

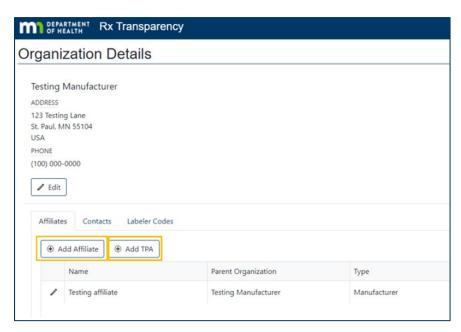
Add Affiliates

By following the steps below, a manufacturer may add an affiliated organization:

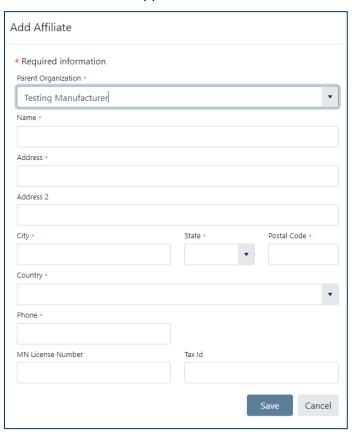
1. From the home page dashboard, click on the drop-down "Menu" located in the upper-right of the window and click "My Organization."



2. Click on the "Affiliates" tab and then the "Add Affiliate" button to manually add an affiliate or the "Add TPA" button to establish an affiliation with a registered third-party administrator.



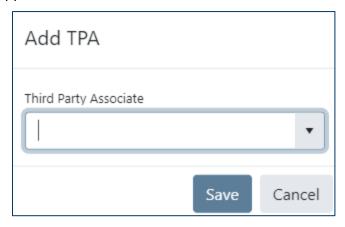
3. If adding an affiliate, enter the business information for the affiliate organization and click the "Save" button in the window that appears.



Note: The "Parent Organization" field allows users to define the level of access an affiliate and its associated contacts have to data and communications within the system. Parent organizations will have access to information submitted by related affiliates; however,

affiliate organizations will not be able to access information submitted by parent organizations.

4. If adding a registered third-party administrator, use the drop-down menu to review the list of registered third-party administrators, make your selection, and click the "Save" button in the window that appears.



5. The newly added affiliate will appear in the "Affiliates" tab.

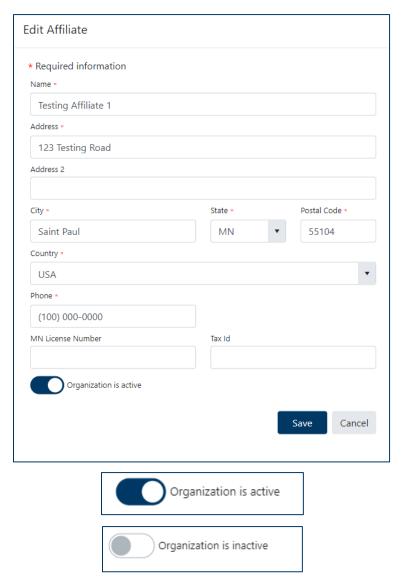
Manage Affiliates

Once affiliates have been established, a manufacturer may edit affiliate information, inactivate affiliates, and reactive inactive affiliates. A manufacturer may remove an affiliation with a third-party administrator but cannot update information related to the third-party administrator.

Edit, Inactivate, or Activate an Affiliate

By following the steps below, a manufacturer may edit the information of, activate, or inactivate an affiliate they added manually.

- 1. On the "My Organization" page, click the "Affiliates" tab, identify the affiliate to modify, and click on the pencil-shaped icon to the left of the affiliate's name.
- 2. In the window that appears, a user may edit the contact information of the affiliate, as well as activate or inactivate the affiliate using the toggle button at the bottom of the window.

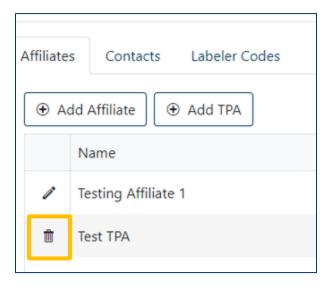


3. Click the "Save" button and the affiliate's contact information will be saved.

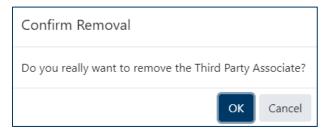
Remove a TPA Affiliate

By following the steps below, a manufacturer may remove an affiliation with a third-party administrator.

1. On the "My Organization" page, click the "Affiliates" tab, identify the third-party administrator to remove, and click on the garbage-can-shaped icon to the left of the affiliate's name.



2. In the window that appears, confirm the affiliate's removal by clicking the "OK" button.



3. The third-party administrator will no longer appear in the list of affiliated organizations on the "Affiliates" tab of the "My Organization" page.

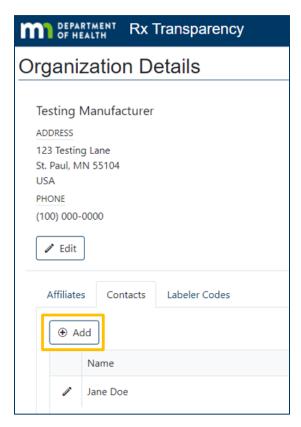
Add and Manage Contacts (Optional)

Once registered, a reporting entity (a manufacturer or a third-party administrator) has the option to add additional contacts.

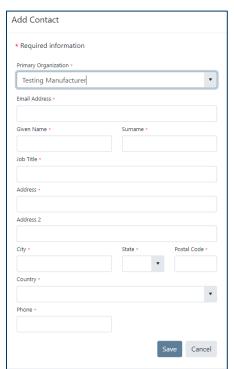
Add a Contact

By following the steps below, a reporting entity may add a contact:

1. On the "My Organization" page, click the "Contacts" tab and click the "Add" button.



2. In the window that appears, enter the contact information, and click the "Save" button.



Note: The "Primary Organization" field allows users to define the level of access a contact has to data and communications within the system based on the affiliate to which they are

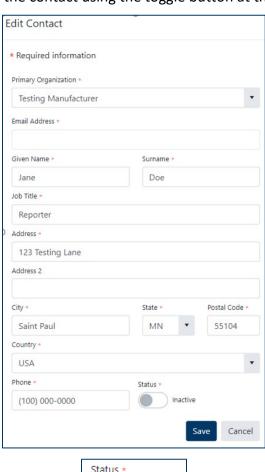
primarily assigned. Contacts will have access to submit and review information for the primary organization that is selected and any affiliates (children) of the primary organization; however, contacts will not be able to access information submitted for higher level (parent) organizations of the primary organization that is selected.

3. The newly added contact will appear in the "Contacts" tab. An activation email will be sent to the new contact and no additional approval will be required by MDH. Refer to "Activate Account" instructions.

Manage Contacts

By following the steps below, a reporting entity may edit the information of, activate, or inactivate contacts.

- 1. On the "My Organization" page, click the "Contacts" tab, identify the contact to modify, and click on the pencil-shaped icon to the left of the contact's name.
- 2. In the window that appears, a user may edit the contact information of the contact, as well as activate or inactivate the contact using the toggle button at the bottom of the window.





Note: If a contact does not appear in the user's list of contacts, they may be inactive and not displayed by default. To display all active and inactive contacts, use the toggle button on the right side of the page.

3. Click the "Save" button and any modifications to the contact's information or status will be saved.

Add and Manage Labeler Codes (Optional)

Once registered, a reporting entity (a manufacturer or a third-party administrator) has the option to add labeler codes.

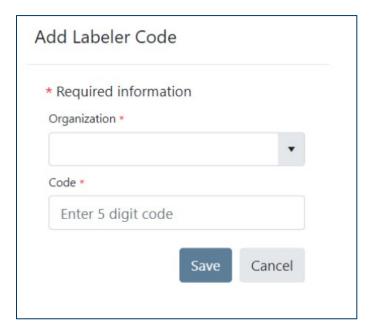
Add a Labeler Code

By following the steps below, a reporting entity may add a contact:

1. On the "My Organization" page, click the "Labeler Codes" tab and click the "Add" button.



2. In the window that appears, enter the Labeler Code information, and click the "Save" button.



3. The newly added labeler code will appear in the "Labeler code" tab.

Remove Labeler Codes

By following the steps below, a reporting entity may remove labeler codes.

- 1. On the "My Organization" page, click the "Labeler Code" tab, identify the Labeler Code to remove, and click on the garbage-can-shaped icon to the left of the labeler code.
- 2. Click the "Save" button and the labeler code will be removed.

Submit a Report

Report Submission Overview

Reporting entities must upload or manually enter data online and, once uploaded, certify the accuracy and completeness of their submissions. Additionally, reporting entities may assign Not Public / Trade Secret written statements and attach documents to their reports, as needed. Contacts associated with or working on behalf of a manufacturer may also collaborate, review, and edit data that has been uploaded but not yet certified.

Key considerations for reporting entities to know before beginning:

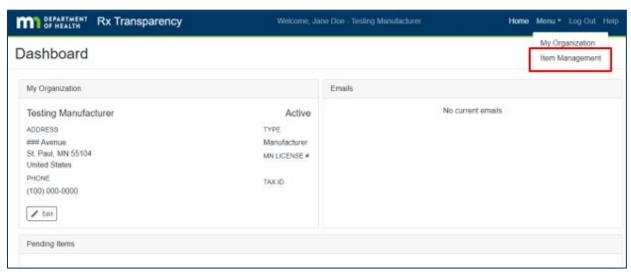
- When uploading batch reports, you will designate the manufacturer associated with the reports. You may prefer to upload separate batches for each manufacturer/affiliate for which you are reporting.
- The upload process checks NDCs against labeler codes associated with the reporting manufacturer and will warn about records that are not associated. While not required,

manufacturers may reduce warnings by associating labeler codes in the portal prior to submitting reports.

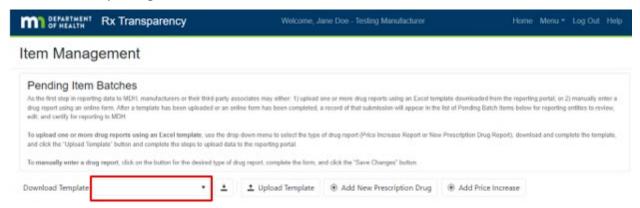
Enter Reports Using MDH-Provided Excel Template

By following the steps below, a reporting entity may upload data for one or more drug reports using an Excel template:

1. From the home page dashboard, click on the drop-down "Menu" located in the upper-right of the window and click "Item Management."



2. Using the drop-down menu located to the right of the words "Download Template" select the type of drug report to use for uploading. The options are: "New Prescription Drug" for New Prescription Drug Price Reporting and "Price Increase" for Prescription Drug Price Increase Reporting.



3. Once the report type is selected, click on the download icon located to the right of the drop-down menu.



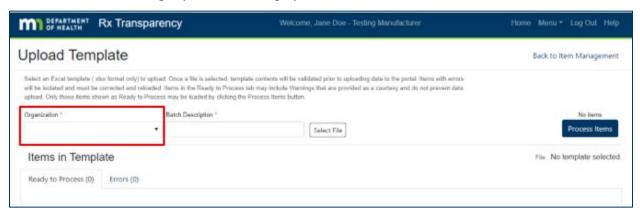
- 4. Depending on the browser and computer settings, the file may appear within the browser window and/or in your computer's Downloads folder. Open the file, and if applicable, click "Enable Editing" in the yellow banner at the top of the Excel file window.
- 5. Add data to the Excel file for all drug reports, with each drug report on a single row. Questions about the data elements to report may be answered in a second tab labeled "Help," which provides a description of the Format, Size, and Description of each data element, along with examples.

Note: Do not edit, add to, or change the row position of the column headers on the Items tab of the workbook.

6. When ready to upload, save the file and navigate to the Item Management page. Once on the page, click the "Upload Template" button.



7. Once on the Upload Template page, use the Organization drop down to identify which manufacturer's drug reports are being uploaded.

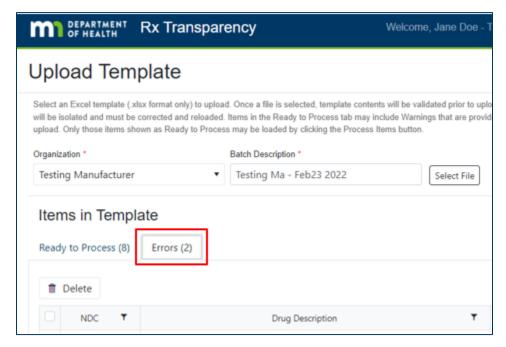


Note: All records uploaded will be associated with the selected Organization. To associate records with different manufacturers, upload separate files. Additionally, the Batch Description is pre-populated with the Manufacturer name and a timestamp; users may edit the Batch Description, as desired.

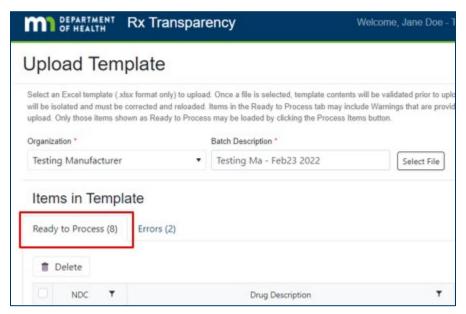
8. Click the "Select File" button, select the file to upload, and click "Open." Once a file is selected, the file contents will be validated prior to uploading data to the portal. Items with errors will be isolated and must be corrected and reloaded.

Note: Data will not be retained within the system at this stage; additional steps are required to upload data for further review, revision and/or certification for final submission to MDH.

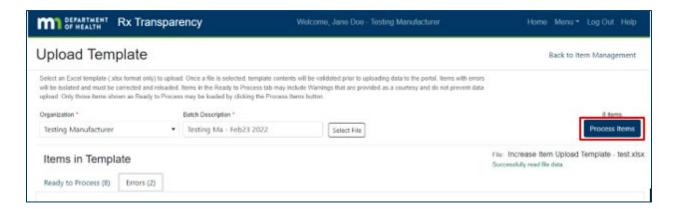
9. To review errors, click on the "Errors" tab. Items with Errors cannot be processed and must be corrected and reloaded.



10. To review warnings, click on the "Ready to Process" tab and review descriptions of any Warnings indicated. The filter button on the Warnings column may be used to only present records with selected warning statuses. Warnings will not prevent the upload of drug reports.



11. When one or more drug reports are ready to upload, click the "Process Items" button. When records are successfully uploaded, a confirmation window will appear.

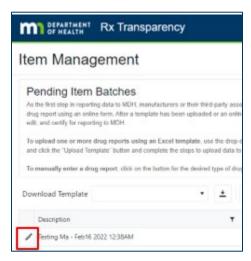


Note: Upon completing an upload, data is now available for reporting entities to review prior to submission. Reporting entities must certify the data, which they may do after reviewing, editing, attaching documents, or assigning Not Public / Trade Secret written statements as desired and applicable.

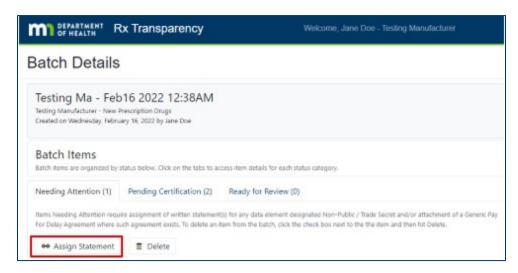
Assign NPTS Written Statements

By following the steps below, a reporting entity may provide a written statement providing the legal basis for designating data as Non Public / Trade Secret (NPTS):

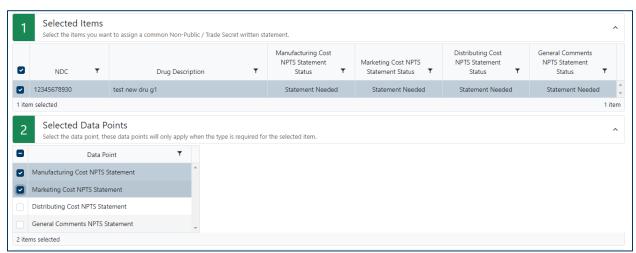
1. Once on the Item Management page, identify the uploaded batch that contains the record(s) to which to add NPTS written statements and click on the edit icon to the left of the file description.



2. Once on the Batch Items page, click "Assign Statement."



3. Once on the "Assign Non-Public / Trade Secrets Reasons" page, identify the NDCs and data points for which to provide an NPTS written statement by clicking on the check box to the left of the NDC(s) in section 1 of the page and clicking the check box to the left of the data point(s) in Section 2.



Note: A manufacturer may provide unique written statements for each data point of each report or provide the same written statement for multiple reports and/or data points, as desired.

4. Once all NDCs and data points are indicated in Sections 1 and 2 of the page, provide the written statement in Section 3 and click the "Save" button.

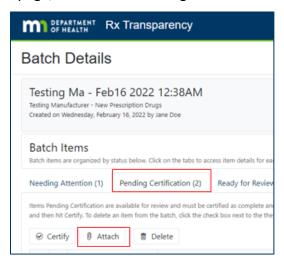


5. Repeat the process of selecting specific data points and providing written statements until all NPTS-identified data elements have a legal basis for this designation assigned to them.

Attach Documents

By following the steps below, a reporting entity may attach a pay for delay agreement or other documents to a drug report:

- 1. Once on the Item Management page, identify the uploaded batch that contains the record(s) to which to attach a document and click on the edit icon to the left of the file description.
- 2. Once on the Batch Items page, click on the Pending Certification tab and click "Attach."



3. Once on the Attach Documents page, use Section 1 of the page to check the box to the left of NDCs to which the documents are to be attached.



4. Under Section 2 of the page, determine whether the document being attached is a pay for delay agreement or other documentation and click the appropriate "Choose File" button to find, select, and open the file.

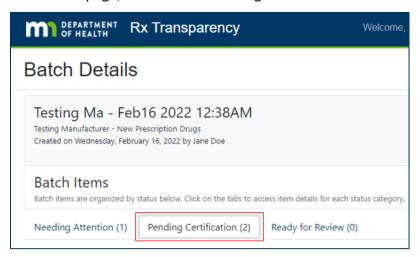


5. When all documentation has been selected, click "Save" to attach the documentation to the report.

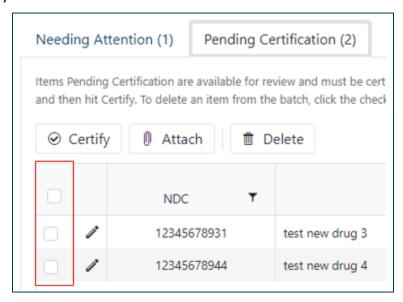
Certify Data (Required)

By following the steps below, a reporting entity may certify and submit a drug report:

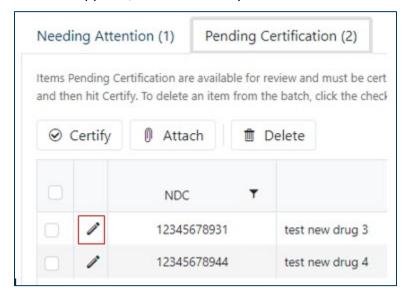
1. Once on the Batch Items page, click on the "Pending Certification" tab.



2. **To certify one or more NDCs at a time**, check the box to the left of the NDC(s) and click the "Certify" button. A confirmation window will appear that confirms item certification. Click "Ok" to certify.



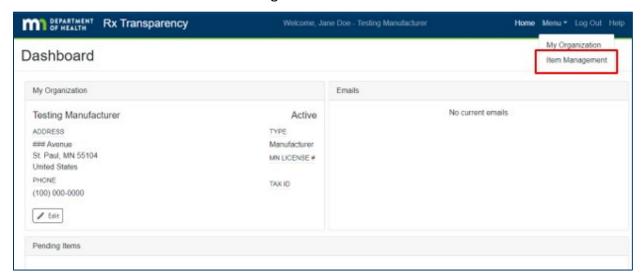
3. **To review the data and certify one NDC at a time**, click the edit icon to the left of the NDC and, in the window that appears, click the "Certify" check box and click "Save".



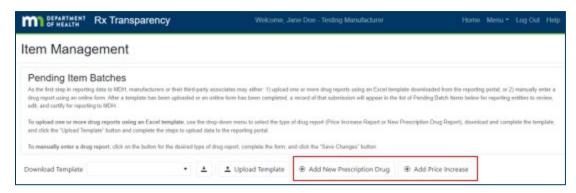
Enter a Report with an Online Form

By following the steps below, a reporting entity may enter data for a drug report using the online form:

1. From the home page dashboard, click on the drop-down "Menu" located in the upper-right of the window and click "Item Management."



2. Click on the "Add New Prescription Drug" button to submit a New Prescription Drug Price Report or the "Add Price Increase" button to submit a Prescription Drug Price Increase Report.



3. On the page that appears, identify the manufacturer of the drug, and complete all required data fields as specified in the Form & Manner document.



Note: The Batch Description field is where reporting entities provide a name for the record they are entering. This name will appear on the main Item Management page.

4. When all required fields are populated, click the button "Save Changes" to save the data in the system.



Note: Reporting entities can check the certify check box when entering a drug report to automatically certify an item or certify at a later time.

Assign NPTS Written Statements

By following the steps below, a reporting entity may provide a written statement providing the legal basis for designating data as Not Public / Trade Secret (NPTS):

1. On the page where the user completes data fields for a drug report using the online form, identify the data elements as NPTS by checking the box below the data field and to the right of "NPTS" so that the box is checked and "Assign Statement" appears.



- 2. For each data element identified as NPTS, click on the "Assign Statement" button, and in the window that appears, enter the legal basis for designating data as NPTS. When complete, click "Update Statement." The "Assign Statement" link updates to "View Statement." Users may review and edit previously entered statements by clicking "View Statement."
- 3. Once all desired NPTS written statements have been entered, click the "Save Changes" button to save data in the system.

Note: If a user needs to access a report previously saved in the system, they may access it by navigating to the Item Management page and clicking on the edit icon to the left of the appropriate item batch, followed by clicking on the edit icon to the left the desired NDC.

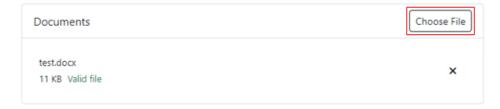
Attach Documents

By following the steps below, a reporting entity may attach a pay for delay agreement document or other documents to a drug report:

1. **To attach a Generic Delay Agreement**, click on the Choose File button to the right of "Generic Delay Document(s)." Select the file to attach in the window that appears and click Open. Reporting entities may attach more than one document by repeating this process, if necessary.



2. **To attach other documentation,** click on the Choose File button to the right of "Documents." Select the file to attach in the window that appears and click Open. Reporting entities may attach more than one document by repeating this process, as desired.



Certify Data (Required)

By following the steps below, a reporting entity may certify and submit a drug report:

- 1. On the page where the user completes data fields for a drug report using the online tool, check the box at the bottom of the form next to the question "Do you want to certify this record?" so that the word "Yes" displays next to a checked box.
- 2. Once the record has been marked as certified, click "Save Changes" and the report will be submitted to MDH. The submitted drug report will be available in the "Pending Item Batches" list under the Ready for Review tab.



Collaborate with Other Users, Review, and Edit Data (Optional)

By following the steps below, one or more contacts associated with the manufacturer of a drug being reported on may collaborate, review and edit data previously saved but not yet certified:

- 1. Once on the Item Management page, identify the uploaded batch that contains the record(s) requiring review and click on the edit icon to the left of the file description.
- 2. Once on the Batch Items page, identify the NDC to review or edit and click on the edit icon to the left of the NDC.
- 3. In the form that appears, review the data and edit as needed. When all edits are made, click the "Save Changes" button.

Minnesota Department of Health Health Economics Program 651-201-4520 health.Rx@state.mn.us www.health.state.mn.us

02/23/22

To obtain this information in a different format, call: 651-201-4520.