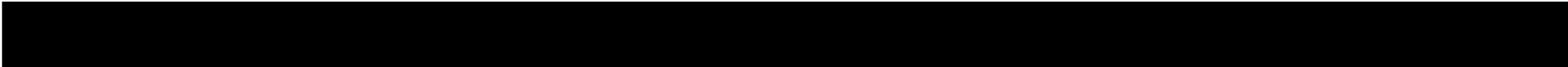


MHDO

Maine Health
Data Organization

Information | Insight | Improvement



Chapter 570 - Uniform Reporting System for Prescription Drug Price Data Sets

2023 Requirements

March 15, 2023

3:00 – 4:00 pm EST

Participant Reminders



Please mute your audio.



Please submit questions via the webinar chat feature.



We will address as many questions as possible at the end of today's webinar. For those questions we are unable to get to, answers will be available in the FAQ posted in the portal.



A recording of the webinar will be distributed after the webinar and made available on the MHDO website.

Agenda



- Welcome & Review of Agenda
- Introduction to MHDO
- Chapter 570 Requirements
- Timeline
- Prescription Drug Pricing Portal Demo
- Resources and Questions

Introductions

MHDO Maine Health
Data Organization
Information | Insight | Improvement



Karynlee Harrington
Karynlee.Harrington@maine.gov
Executive Director, MHDO

Philippe Bonneau
Philippe.Bonneau@maine.gov
Compliance Officer, MHDO

Kate Mullins
kmullins@hsri.org
Director Project & Product
Management, HSRI

The Maine Health Data Organization (MHDO) is required by Public Law 2019, Chapter 470, to collect data from prescription drug manufacturers, wholesale drug distributors and pharmacy benefit managers (reporting entities).

90-590 CMR Chapter 570: *Uniform Reporting System for Prescription Drug Price Data Sets* defines the data collection requirements. Recent changes made to Chapter 570 were provisionally adopted December 2022.

A copy of the rule can be found here: <https://mhdo.maine.gov/rules.htm>

Registration Requirements

[c. 570 sec 2(A)]



Action Required by January 30, 2023:

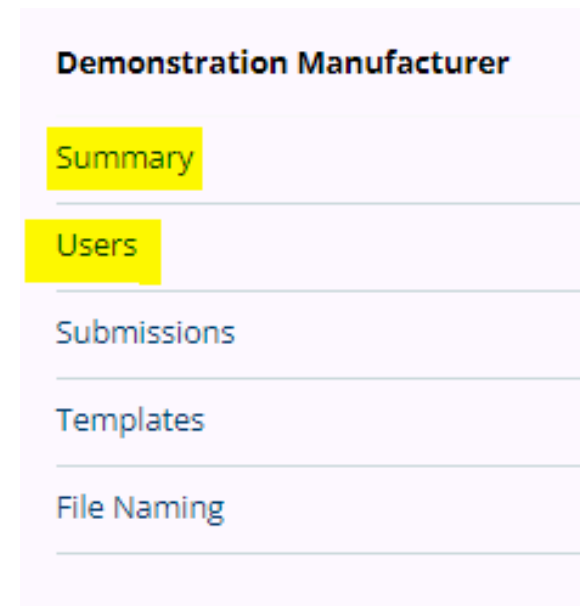
Review and update Summary and Users information via the MHDO Prescription Drug Price Data Portal.



If your organization was not registered in 2022 or you need help with your user account, please contact the MHDO Help Desk (mhdohelp@hsri.org).

Chapter 570 Annual Registration

- Confirmation of company Summary information and company Users.
- User information is used for communications from the MHDO and should be updated as often as needed to maintain timely, focused communication.



Manufacturer Notifications

[PL 2021, c. 305, secs 4 & 5
and c. 570 sec 2(B)]



No longer required



As of reporting year 2022, MHDO is responsible for the notifications described on the next slide.

MHDO Notifications

[c. 570 secs 2 (B) and 2(C)(1,
2, 3)]



No later than January 30th of each year, the MHDO posts on its publicly accessible website NDCs that hit one of the triggers during the prior calendar year as defined in 90-590 CMR Chapter 570.



On or before February 15th of each year, the MHDO produces and posts on its publicly accessible website a list of drug product families for which it intends to request pricing component data.



Not sooner than 30 days after publicly posting the list of drug product families, the MHDO notifies reporting entities via e-mail whether or not pricing component data is required.

Pricing
Component Data
Requirements,
Template
Download,
Completion &
Submission

[c. 570 secs 2(C)(4) and
2(D, E and G)]



If required, download pre-populated template(s) beginning **March 17, 2023**, from the MHDO Prescription Drug Price Data Portal.



Complete template(s) within your own environment.



Submit completed template(s) **by May 16, 2023**, via the MHDO Prescription Drug Price Data Portal.

Timeline



| Task Name | Date |
|---|-------------|
| MHDO Prescription Drug Price Data Portal 2023 registration must be completed | Mon 1/30/23 |
| The MHDO produces and posts on its publicly accessible website a list of prescription drugs for which the manufacturer has met any of the three criteria during the prior calendar year | Mon 1/30/23 |
| The MHDO produces and posts on its publicly available website a list of drug product families for which it intends to request pricing component data from manufacturers, wholesale drug distributors and pharmacy benefits managers | Wed 2/15/23 |
| HSRI, MHDO's data vendor, notifies manufacturers, wholesale distributors and PBMs via email that prepopulated Pricing Component Data templates, including specific NDCs for which reporting is required, are available for download from the MHDO Prescription Drug Price Data Portal | Fri 3/17/23 |
| Completed Pricing Component Data templates are due | Tue 5/16/23 |

Pricing Component Data Templates

Pre-Populated Excel Templates

| | | | | | |
|----|---|--|--------------|------|-------------|
| 1 | Manufacturer Report | | | | |
| 2 | Version 3.0 | | | | |
| 3 | <i>INSTRUCTIONS: This worksheet has been intentionally protected from the addition of tabs, rows, and columns. All yellow shaded areas in the NDC_Details tab must be completed. Review the Data Element Definitions and then proceed to fill out the NDC_Details tab. Each row should be populated with the information for each NDC your organization is required to report on. Each column is required for all NDCs except where noted. Failure to supply valid values for all fields will result in the rejection of submission.</i> | | | | |
| 4 | Organization Name | Demonstration Manufacturer | | | |
| 5 | Organization TIN/FEIN | 11-111111 | | | |
| 6 | Year | 2023 | | | |
| 7 | | | | | |
| 8 | Data Element Definitions | | | | |
| 9 | Data Element | Description from MHDO Chapter 570 | Format | Size | Example |
| 10 | NDC (Prepopulated) | The national drug code maintained by the FDA for the drug product that includes the labeler code, product code, and package code. A drug's NDC is typically expressed using 11 digits in a 5-4-2 format (xxxx-yyy-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. Do not leave blank. Do not include dashes or spaces. | Alphanumeric | 11 | 12345678910 |
| 11 | Drug Indicator | Select from Drop-down: 1 - Brand Name; 2 - Generic | Drop-down | N/A | 1 - Brand |

MHDO Prescription Drug Price Data Portal Demo

Login

Username

Password

Log In

Forgot your username or password?
[Recover an Existing Account](#)

Other questions? Contact the Help Desk at
mhdohelp@hsri.org

Resources

MHDO website: [MHDO Home Page \(maine.gov\)](#)

- [MHDO Rules and Statutes \(maine.gov\)](#)
- [Trigger NDCs' \(maine.gov\)](#)
- [List of Drug Product Families \(maine.gov\)](#)
- [Pricing Component Data \(maine.gov\)](#)
- [MHDO Prescription Drug Price Portal - Log In \(maine.gov\)](#)

Technical Support

The MHDO Help Desk is available for any technical/system issue you may encounter in the MHDO Prescription Drug Price Data Portal. Key information:

- **Hours of Operation** (8 a.m. – 5 p.m. ET, Monday – Friday).
- **Toll-free Phone:** (866) 451-5876
- **Email:** mhdohelp@hsri.org

You will receive a call back from the Help Desk or an e-mail follow-up within two hours of the request. Please include the organization name and U.S. Tax ID associated with the issue or request in all communications with the Help Desk.

COMPLIANCE AND ASSESSMENTS: Questions related to requirements for registration and data submissions, extension requests, and assessments should be directed to:

Philippe Bonneau, Ph.D.

Compliance Officer

Maine Health Data Organization

151 Capitol Street, 102 SHS

Augusta, ME 04333-0102

philippe.bonneau@maine.gov

Questions?



Please submit questions via the webinar chat feature.



We will address as many questions as possible at this time. For those questions we are unable to get to, answers will be provided in the FAQ available in the portal.