

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

2022 Requirements

January 11, 2022

1:00 – 2:00 pm EST

Participant Reminders



Participant audio has been muted.



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.

Introductions

MHDO Maine Health
Data Organization

Information | Insight | Improvement



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Agenda



Welcome & Review of Agenda
5 minutes

Introduction to MHDO
5 minutes

Chapter 570 Requirements

- Registration
- Pricing Component Data Submission

25 minutes

Implementation Timeline
5 minutes

Resources/Technical Support
10 minutes

Questions
10 minutes

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 were made to Ch. 570 that became effective December 2021.

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

Legislature enacted LD 686, PL 2021, Ch. 305, An Act to Increase Prescription Drug Price Transparency, which became effective October 18, 2021

Chapter 570, Notes

There are several provisions in Chapter 570 that are inconsistent with the new law (PL 2021, Ch. 305). When this happens, the statute overrides inconsistencies in the rule.

The final version of Ch. 570 includes notes that address the inconsistencies in the new law and in the rule.

Note: As of reporting year 2022, the MHDO will be posting a list of NDCs and the manufacturers will no longer have to make such notifications to MHDO. PL 2021, c. 305, Sections 4 & 5.

Chapter 570, Enforcement Update

Board of Directors of MHDO voted to partially suspend enforcement of 90-590 CMR Chapter 570, Section 2(J)(3) so that the MHDO shall enforce collection of the pricing component data from Pharmacy Benefits Mangers **only** for the data relevant to Maine, rather than the United States, including for each NDC the Pricing Units Administered, the Total Pharmacy Reimbursement, the Total Payment Received, the Total Rebate Receivable, the Total Rebate Payable Amount and any additional information, if applicable.

Updates to Ch. 570 & New Requirements

1. Definitions
2. Registration and Submission Requirements
3. Reporting Specifications

Registration Requirements

[90-590 Chapter 570 Sec 2(A)]



Action Required by January 30, 2022:
Review and update Summary and Users information via the MHDO Prescription Drug Price Data Portal



If your organization was not registered in 2021 or you need help with your user account, please contact the MHDO Help Desk (mhdohelp@hsri.org).

PL 2021, Chapter 305-New Requirement

Public notice of substantial drug price change or introduction. **No later than January 30, 2022**, and annually thereafter, MHDO shall produce and post on its publicly accessible website a list of NDCs for which the manufacturer has during the prior calendar year:

- A. Increased the wholesale acquisition cost of a brand-name drug by more than 20% per pricing unit;
- B. Increased the wholesale acquisition cost of a generic drug that costs at least \$10 per pricing unit by more than 20% per pricing unit; or
- C. Introduced a new drug for distribution in this State when the wholesale acquisition cost is greater than the amount that would cause the drug to be considered a specialty drug under the Medicare Part D program. For the purposes of this paragraph, "Medicare Part D" has the same meaning as in section 254-D, subsection 1, paragraph F.

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

Notifications

Not sooner than 30 days after publicly posting the list of drug product families pursuant to sub-section C(2), the MHDO will notify 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](#).

Pricing Component Data

Prescription drug manufacturers, wholesale drug distributors and pharmacy benefits managers shall report pricing component data to MHDO **no later than 60 days** after notification from the MHDO, as described in Chapter 570, section 2(C).

[90-590 Chapter 570 Sec 2(G)]

Pricing Component Data Template Download, Completion & Submission



Download pre-populated template(s) beginning March 17, 2022 from the MHDO Prescription Drug Price Data Portal.



Complete template(s) within your own environment.



Submit completed template(s) **by May 16, 2022** via the MHDO Prescription Drug Price Data Portal.

Pre-Populated Excel Templates

Pricing Component Data Templates

	A	B	C	D	E
1	Manufacturer Report for New Drugs				
2	Version 2.0				
3	INSTRUCTIONS: This worksheet has been intentionally protected from the addition of tabs, rows, and columns. All yellow shaded areas 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.				
4	Organization Name	Demonstration Manufacturer			
5	Organization TIN/FEIN	11-1111111			
6	Year	2022			
7					
8	Data Element Definitions				
9	Data Element	Description	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 (xxxxx-yyyy-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; 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

Timeline



Task Name	Start	Finish
Webinar to review Chapter 570 2022 registration and reporting requirements	Tue 1/11/22	Tue 1/11/22
MHDO Prescription Drug Price Data Portal 2022 registration must be completed	Sat 1/1/22	Sun 1/30/22
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	Sun 1/30/22	Sun 1/30/22
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	Tue 2/1/22	Tue 2/15/22
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	Thu 3/17/22	Thu 3/17/22
Completed Pricing Component Data templates are due	Mon 5/16/22	Mon 5/16/22

Resources

MHDO website:

<https://mhdo.maine.gov/index.aspx>

- Rules and Statutes

<https://mhdo.maine.gov/rules.htm>

- Pricing Component Data

https://mhdo.maine.gov/pharma_data_submitters.htm

- MHDO Prescription Drug Price Data Portal:

https://mhdo.maine.gov/pharma_portal

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 and U.S. Tax ID associated with your issue or request in all communications with the Help Desk.

COMPLIANCE AND ASSESSMENTS: Questions relating to deadlines for data submissions, extension requests and assessments can be directed to:

Philippe Bonneau, Ph.D.

Compliance Officer

Maine Health Data Organization

151 Capitol Street, 102 SHS

Augusta, ME 04333-0102

Tel: (207) 287-6743

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Questions?



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