90-590 MAINE HEALTH DATA ORGANIZATION

Chapter 340: UNIFORM REPORTING SYSTEM FOR REPORTING 340B DRUG PROGRAM DATA SETS

SUMMARY: This Chapter contains the provisions for filing 340B Drug Program data sets from participating Maine hospitals.

The provisions include:

Identification of the organizations required to register and report;

Establishment of requirements for the content, format, method, and time frame for filing 340B Drug Program data;

Establishment of standards for the data reported; and

Compliance provisions.

1. Definitions

Unless the context indicates otherwise, the following words and phrases shall have the following meanings:

A. **340B Drug Program.** "340B Drug Program" means Section 340B of the Public Health Service Act that requires pharmaceutical manufacturers participating in Medicaid to sell outpatient drugs at discounted prices to health care organizations that care for many uninsured and low-income patients. These organizations include federal grantee organizations and several types of hospitals, including critical access hospitals (CAHs), sole community hospitals (SCHs), rural referral centers (RRCs), and public and nonprofit disproportionate share hospitals (DSH) that serve low-income and indigent populations.

B. **340B Acquisition Cost.** "340B Acquisition Cost" means the cost to the hospital and, where applicable, its Contract Pharmacies and 340B Third Party Administrators, to purchase a prescription drug product with a unique NDC under the 340B Drug Program.

C. **340B Third Party Administrator.** "340B Third Party Administrator" means an entity contracted by a Hospital to administer tasks related to purchasing, inventory management, reporting, billing, or other administration for its 340B Drug Program.

D. **Contract Pharmacy.** "Contract Pharmacy" means a pharmacy contracted by a Hospital to dispense 340B drugs to patients, that is registered for the 340B Drug Program, and listed as active on the 340B Office of Pharmacy Affairs Information System (OPAIS), whether or not such pharmacy is located in the State.

E. **Hospital.** "Hospital" means an acute care institution licensed and operating in this State as a hospital under section 1811 or the parent of such institution; or a hospital subsidiary or hospital affiliate in the State that provides medical services or medically related diagnostic and laboratory services or engages in ancillary activities supporting those services.

F. **MHDO.** "MHDO" means the Maine Health Data Organization.

G. **M.R.S.** "M.R.S." means Maine Revised Statutes.

H. **National Drug Code (NDC).** "National Drug Code" means the three-segment code maintained by the federal Food and Drug Administration that includes a labeler code, a product code, and a package code for a drug product and that has been converted to an 11-digit format consisting of five digits in the first segment, four digits in the second segment, and two digits in the third segment. A three-segment code shall be considered converted to an 11-digit format when, as necessary, at least one "0" has been added to the front of each segment containing less than the specified number of digits such that each segment contains the specified number of digits.

2. Registration and Submission Requirements

Hospitals participating in the 340B Drug Program shall submit to the MHDO or its designee complete 340B Drug Program data sets in accordance with the requirements of this section.

A. **Registration.** Each Hospital participating in the 340B Drug Program shall complete an online registration form, or update an existing one, via the MHDO Hospital Data Portal web interface (https://mhdo.maine.gov/hospital_portal/ by December 1st of each year. It is the responsibility of the reporting entity to complete, as needed, all company and contact information.

B. **Submission Method.** Each Hospital participating in the 340B Drug Program shall annually complete a MHDO Standardized template as presented in Appendix A, that will be available in the MHDO Hospital Data Portal web interface (https://mhdo.maine.gov/hospital_portal/). E-mail attachments shall not be accepted.

C. **Submission Deadline.** The annual submission of 340B data shall cover the previous fiscal year and shall be due not later than six months after its most recent fiscal year end in accordance with the following schedule:

Fiscal Year End Date	**Filing Deadline**
January 31	July 31
February 28	August 31
March 31	September 30
April 30	October 31
May 31	November 30
June 30	December 31
July 31	January 31
August 31	February 28
September 30	March 31

October 31	April 30
November 30	May 31
December 31	June 30

D. **Rejection of Submissions**. Failure to conform to the requirements of subsections B and C of this Section shall result in the rejection of the data submissions. All rejected data must be corrected and resubmitted in the MHDO Hospital Data Portal within 30 days of the rejection.

E. **Replacement of Data Files.** A Hospital may replace data submitted to the MHDO with updated data within 90 days of the updated information becoming available if that date is no longer than 18 months after the hospital's fiscal year end.

F. **Reporting Specifications.** Each Hospital must report the following data.

For the top three drugs with a unique NDC having the highest acquisition costs and the top three drugs with a unique NDC that were dispensed most often, and acquired by the hospital (or its Contract Pharmacies and 340B Third Party Administrators) under the 340B Drug Program during the fiscal year, the following data elements:

Data Element Name	**Description/Codes/Sources**
NDC	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.
Drug Name	A description of the drug including the product name, dosage form, strength, and package size.
Total 340B Drug Acquisition Cost (NDC)	The total cost in whole dollars to the hospital and, where applicable, its Contract Pharmacies and 340B Third Party Administrators, to purchase the drug under the 340B Drug Program.
Total 340B Estimated Savings (NDC)	The total cost that would have otherwise been paid to acquire the drug had a 340B discount not been applied (based on the average acquisition cost paid for the same drug outside the 340B program on a per unit basis), reduced by the 340B Acquisition Cost.

For all drugs acquired by the hospital (or its Contract Pharmacies and 340B Third Party Administrators) under the 340B Drug Program during the fiscal year, the aggregated total across all drugs for the following data elements:

Data Element Name	**Description/Codes/Sources**
Total 340B Drug Acquisition Cost (All 340B Drugs)	The sum total in whole dollars of all drugs under the 340B Drug Program, purchased by a hospital, and where applicable, its Contract Pharmacies and 340B Third Party Administrators.
Total Drug Expenditures (All Drugs)	The sum in whole dollars of all drugs purchased by a hospital, and where applicable, its Contract Pharmacies and 340B Third Party Administrators.
Total 340B Drug Program Estimated Savings (All 340B Drugs)	The cost that would have otherwise been paid to acquire drugs purchased under the 340B Drug Program had a 340B discount not been applied (based on the average acquisition cost paid for the same drugs outside the 340B program on a per unit basis), reduced by: 1. the 340B Acquisition Cost; and 2. the total amount of payments made to Contract Pharmacies, including any share of 340B savings retained by Contract Pharmacies, for dispensing drugs obtained under the 340B program; and 3. the total amount of payments made to 340B Third Party Administrators, including any share of 340B savings retained by 340B Third Party Administrators, for 340B program administration tasks; and 4. any additional administrative costs associated with the 340B program.
Program or Service Name / Category	The name of any program or service which is funded in whole or in part from Estimated Savings from the 340B Drug Program and provide community benefits.
Description of Program or Service	A description of any program or service which is funded in whole or in part from Estimated Savings from the 340B Drug Program and provide community benefits.
Hospital Internal Review and Oversight	A description of the Hospital's internal review and oversight of the 340B Drug Program, which meets the federal DHHS, HRSA's program rules and guidance for compliance.

3. Evaluation; Notification; Response

A. **Evaluation.** The MHDO or its vendor shall evaluate each file in accordance with the following standards:

1) When applicable, only an eligible code value for a specified data element shall be accepted;

2) Coding values indicating "data not available", "data unknown", or the equivalent shall not be used for individual data elements unless specified as an eligible value for the element.

B. **Notification.** Upon completion of the data evaluation, the MHDO or its designee will promptly notify each Hospital whose data submissions do not satisfy the standards for any filing period. This notification will identify the specific file and the data elements within them that do not satisfy the standards.

C. **Response.** Each Hospital notified under subsection 3(B) will respond within 30 days of the notification by making and reporting the changes necessary to satisfy the standards.

4. Compliance

A. **Certification of accuracy.** Hospitals will be required to attest to the accuracy of their data submissions through the MHDO Hospital Data Portal web interface.

B. **Enforcement.** The failure to file, report, or correct 340B Drug Program data sets when required in accordance with the provisions of this Chapter may be considered a civil violation under 22 M.R.S. § 8705-A and Code of Maine Rules 90-590, Chapter 100: *Enforcement Procedures*.

5. Extensions to Data Submission Requirements

If a Hospital, due to circumstances beyond its control, is temporarily unable to meet the terms and conditions of this Chapter, a written request must be made to the Compliance Officer of the MHDO as soon as it is practicable after the reporting entity has determined that an extension is required.

6. Annual Report Requirement

Information provided to the MHDO as required by this rule shall be used by the MHDO to:

A. Produce and post on MHDO's publicly accessible website, a report that includes a summary of the aggregate information received from Hospitals required to report under 22 M.R.S. § 1728 subsection 2, *and*

B. Submit the reports required by this subsection to the Office of Affordable Health Care, as established in Title 5, section 3122, the Maine Prescription Drug Affordability Board, as established in Title 5, section 12004-G, subsection 14-I, and the joint standing committee of the Legislature having jurisdiction over health data reporting and prescription drug matters.

STATUTORY AUTHORITY: 22 M.R.S. §§ 8703(1), 8704(1) & (4) and PL 2023, Ch. 276 [22 M.R.S. § 1728]

EFFECTIVE DATE: September 17, 2024

Appendix A: Sample Template - 340B Drug Program Data Set

Hospital Name:			
Fiscal Year:			
NDC	**Drug Name**	**Total 340B Drug Acquisition Cost (NDC)**	**Total 340B Estimated Savings (NDC)**
Top 3 Costliest 340B Drugs			
Top 3 Most Frequently Purchased (Dispensed) 340B Drugs			
Totals			
Total 340B Drug Acquisition Cost (All 340B Drugs)			
Total Drug Expenditures (All Drugs)			
Total 340B Drug Program Estimated Savings (All 340B Drugs)			
Please list the programs and services which are funded in whole or in part from 340B Drug Program savings that provide community benefits, including services that support community access to care that the hospital could not continue without savings from the 340B Drug Program.			
Program or Service Name/Category		**Description of Program or Service**	
Please describe the hospital's internal review and oversight of the 340B Drug Program, which meets the federal DHHS, HRSA's program rules and guidance for compliance. For Hospitals that have previously provided to the MHDO a description of the Hospital's internal review and oversight of the 340B Drug Program, the Hospital may alternatively submit a copy of the Hospital's annual attestation that the Hospital meets all federal 340B program requirements as required by the Health Resources and Services Administration, Office of Pharmacy Affairs.			