MHDO Maine Health Data Organization

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90-590 Maine Health Data Organization

Chapter 340: Uniform Reporting System for Reporting 340B Drug Program Data Sets

(New Routine Technical Rule)

Section I. Basis Statement

The Maine Health Data Organization is authorized by statute to collect health care data.

PL 2023, Chapter 276, "An Act to Increase Transparency Regarding Certain Drug Pricing Programs", requires the Maine Health Data Organization to collect data in a standardized way from Maine hospitals participating in the federal drug pricing program under Section 340B of the federal Public Health Service Act, 42 United States Code, Section 256b, referred to in this document as the 340B program.

This new proposed chapter governs the provisions for filing 340B Drug Program data sets from participating Maine hospitals. The provisions include identification of the organizations required to 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.

The MHDO Board met on September 7, 2023, and authorized the MHDO to initiate rulemaking for this new routine technical rule. The MHDO held a public hearing on May 1, 2024, with a May 13, 2024, deadline for written comments. The MHDO Board met on September 5, 2024, and voted unanimously to adopt the changes as amended and presented below and in the corresponding rule.

Section II. Names of Individuals that Submitted Comments

The following is a list of individuals and affiliations that made oral comments at the public hearing and/or submitted written comments to the Maine Health Data Organization (MHDO) regarding the new proposed rule:

1. David Winslow, Maine Hospital Association

2. Melody Calkins, Biotechnology Innovation Organization (BIO)
3. Rachel Cottle Latham, The Pharmaceutical Research & Manufacturers of America (PhRMA)

Section III. Summary of Comments Received by Submitter with Proposed Agency Response & Action

- **The Maine Hospital Association submitted the following comment(s):**

Comment 1: This proposed rule requires hospitals to submit National Drug Code (NDC) numbers and the 340B drug acquisition cost associated with those NDC numbers. This is a problem for hospitals. This requirement was in the original bill (LD 1395) and was removed by the Legislative Committee and remained removed from the enacted law. In addition to NDC numbers not even being referenced in Chapter 276, the requirement also doesn't exist in the American Hospital Association's Good Stewardship Principles that this law is based on and is referenced in section 2 of Chapter 276.

More specifically, the requirement in section 1 of the template to provide the NDC and the "340B Drug Acquisition Cost" (as opposed to section 3 of the template to provide "Total 340B Drug Acquisition Cost") would have a hospital in non-compliance with federal law and could result in the hospital being terminated from the 340B program. (Note: Links to various federal documents were included in the testimony).

As such, we request that the template be amended to reflect Chapter 276 and only require hospitals to provide names and estimated savings associated with the 3 costliest 340B drugs, the names and estimated savings associated with the 3 top drugs purchased through the 340B program, the total 340B drug acquisition cost (all 340B drugs) and total annual estimated savings from the 340B program.

MHDO Staff Response:

Chapter 276 section 2(c) requires hospitals to include examples of the top drugs purchased through the 340B program. MHDO's proposed rule is structured so that the way in which the hospital identifies examples of their top drugs purchased through the 340B program, is by the universal drug identification code. The National Drug Code (NDC) is a unique 11-digit number that identifies a drug. The first five digits indicate the manufacturer or the labeler; the next four digits indicate the ingredient, strength, dosage form and route of administration; and the last two digits indicate the packaging. A uniform data set relies on standards and codes when defining data elements. All of MHDO's prescription drug reporting mandates require submitters to identify drugs by the drugs NDC.

The intent of Section 2(F) and Appendix A: Sample Template-340B Drug Program Data Set, of the proposed Rule, is to collect the aggregate total 340B Drug Acquisition Cost

for the calendar year for each NDC reported. The MHDO agrees that the current data element labels and descriptions in Section 2(F) and Appendix A are vague in this regard and should be updated for clarity.

Recommended Board Action:

Relabel Section 2(F) data element "340B Acquisition Cost" as "Total 340B Drug Acquisition Cost (NDC)"

Update the description under Section 2(F) for relabeled data element "Total 340B Drug Acquisition Cost (NDC)" to read "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".

Relabel Section 2(F) data element "340B Estimated Savings" as "Total 340B Estimated Savings (NDC)"

Update the description under Section 2(F) for relabeled data element "Total 340B Estimated Savings (NDC)" to read "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."

Relabel Appendix A data element "340B Drug Acquisition Cost" as "Total 340B Drug Acquisition Cost (NDC)"

Relabel Appendix A data element "340B Drug Program Estimated Savings" as "Total 340B Estimated Savings (NDC)"

Comment 2: We request that the second section of the template also be amended to reflect the language in Chapter 276. The current language of the proposed template asks hospitals to provide the *3 Most Frequently Prescribed 340B Drugs*. The word prescribed is confusing and imprecise because not all drugs that have been prescribed are actually used. The language in Chapter 276 says *examples of the hospital's top drugs purchased through the 340B program* and that language should be duplicated on the template.

MHDO Staff Response:

The MHDO agrees that not all prescribed drugs are actually dispensed.

Recommended Board Action:

Relabel Appendix A section header "Top 3 Most Frequently Prescribed 340B Drugs" as "Top 3 Most Frequently Purchased (Dispensed) 340B Drugs."

Comment 3: We believe that the Hospital Internal Review and Oversight section is unclearly worded. This is a federal program and there is a federal requirement where hospitals need to attest to compliance every year. It would be much simpler to just say the hospital needs to submit the attestation that it provides to the federal government so we would request that change.

MHDO Staff Response:

The data element in Appendix A of the proposed rule specific to the hospitals internal review and oversight of the 340B program is derived from the language in §1728.2. D. *A description of the hospital's internal review and oversight of the 340B program, which must meet the federal Department of Health and Human Services, Health Resources and Services Administration's program rules and guidance for compliance.*

For the first reporting period MHDO will require hospitals to submit a description of the hospital's internal review and oversight of the 340B program. Once the description has been provided, MHDO will accept a copy of the hospital's annual attestation that they meet all the federal 340B program requirements as required by the Office of Pharmacy Affairs within HRSA (Health Resources and Services Administration).

Recommended Board Action:

The following language will be added to Appendix A.
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.

- **The Biotechnology Innovation Organization (BIO) submitted the following comment(s):**

BIO recommends that the MDHO adopt the following changes to the 340B Proposed Chapter designed to ensure consistent and effective oversight of the Program.

Comment 1: BIO strongly opposes the codification of contract pharmacy arrangements within the 340B Proposed Chapter, which will create significant program integrity risks when oversight of these arrangements is already lacking. Contract pharmacies originated as a creation by HRSA via sub-regulatory guidance rather than by statute and have grown

far beyond Congress' vision for when the program was created. While HRSA issued additional guidance in 2010 which covered entities have used to authorize covered entity arrangements with unlimited numbers of contract pharmacies, the U.S. Court of Appeals for the Third Circuit has ruled there is nothing in the statute that requires manufacturers to distribute 340B drugs to an unlimited number of contract pharmacies.

Codifying the practice of contract pharmacies creates perverse incentives in an already opaque program, ultimately making it harder to uphold transparency in the program. In recent years, the growth of contract pharmacies has led to significant diversion of medications to non-eligible recipients; more than half of the entities audited by HRSA showed adverse findings. The GAO and the OIG have also found that the complexity of contract pharmacy arrangements leads to statutorily prohibited duplicate discounts. Meanwhile, the growth of contract pharmacy arrangements has provided considerable profits for intermediary contract pharmacies rather than helping vulnerable patients. A contract pharmacy's average gross profit margin on a 340B medicine dispensed at a contract pharmacy is estimated at 72%, compared to just 22% when dispensed by an independent pharmacy. Studies have found that disproportionate share hospitals (DSH) have utilized contract pharmacies to expand their reach into more affluent areas, while decreasing their use of contract pharmacies in low-income medically underserved areas. **Accordingly, MDHO should not codify contract pharmacy arrangements in the definition of the proposed Chapter.**

MHDO Staff Response:

The HRSA (Health Resources & Services Administration) website includes language on its page titled *340B Drug Pricing Program*, which states, A *340B covered entity may sign a written contract with one or more pharmacies to provide pharmacy services and 340B drugs to authorized patients. A covered entity should decide if it needs pharmacy services and the appropriate distribution mechanism for those services, when choosing to use contract pharmacy services. A covered entity should identify all pharmacy locations and all covered entity locations that will use 340B drugs in a written contract.* As such, the proposed rule provides a definition for a 340B Contract Pharmacy so that the hospital's 340B drug acquisition costs and estimated savings include when applicable the costs and savings of their Contract Pharmacies (and 340B Third Party Administrators) that provide 340B services on behalf of the hospital.

Recommended Board Action:

None.

Comment 2: As outlined above, MDHO should not include contract pharmacies within the definition of 340B Acquisition Cost and instead limit the definition strictly to 340B covered entities. In addition, before including any reference to TPAs within proposed

definitions, MDHO should outline a separate definition for TPAs. It is critical that MDHO facilitate further discussion around the role of TPAs and how any costs associated with TPAs or fees collected by TPAs should be treated.

MHDO Staff Response:

The proposed rule is structured to capture the hospital's 340B Drug Acquisition Costs and 340B Drug Program Estimated Savings in the hospital's fiscal year. A hospital's 340B drug acquisition costs and estimated savings include, when applicable, the costs and savings of their Contract Pharmacies and 340B Third Party Administrators that provide 340B services on behalf of the hospital. The proposed rule provides a definition in section 1. C. for 340B Third Party Administrator (TPA).

Recommended Board Action:

None.

Comment 3: Within the Chapter, there are multiple proposed data elements relating to aggregate data on 340B acquisition cost and expenditures. However, this aggregate data is not sufficient to prevent drug diversion, statutorily prohibited duplicate discounts, or address other program integrity concerns. Accordingly, BIO recommends that MDHO include within the annual report a requirement to use a claims modifier to identify all claims for reimbursement for a unit of covered outpatient drug that is purchased at or below the ceiling price specified in in section 340B (a)(1) of the Public Health Service Act, as specified in rulemaking. This requirement is essential to properly identify 340B claims to ensure that an eligible patient receives the 340B discounted drug and prevent the drug from being diverted to a non-eligible patient. A claims modifier is also essential to prevent duplicate discounts, which require bottle or unit level data that a drug was subject to a 340B discount. Requiring only the reporting of aggregate data is insufficient to properly identify individual 340B claims and effectively address program integrity concerns.

Furthermore, the use of claims modifiers is already a common practice among hospital systems with other payers due to new requirements in the Medicare program and regulations implementing the Inflation Reduction Act. Specifically, it is now prohibited for manufacturers to pay 340B discounts on drugs also subjected to the inflation rebate, CMS has now required claims modifiers on all Part B drugs for all Medicare covered entities included in the Outpatient Prospective Payment System. In 2024, this requirement is extended to all covered entities, including critical access hospitals. In addition, it will also be prohibited for manufacturers to be subjected to 340B drug discounts on drugs that are subject to negotiation under the provisions of the maximum fair price and inflation rebates in Medicare Part D. Accordingly, claims modifiers should be likewise applied to the commercial marketplace.

MHDO Staff Response:

The reporting requirement in Public Law 2023, Chapter 276, does not include information specific to the prevention of drug diversion, duplicate discounts, or other program integrity concerns. The law does however include a requirement that the hospitals provide MHDO with a description of their internal review and oversight of the 340B program, which must meet the federal Department of Health and Human Services, Health Resources and Services Administration's program rules and guidance for compliance.

The reporting requirement in Public Law 2023, Chapter 276, does not include data collection at a claim level.

Recommended Board Action:

None.

Comment 4: BIO urges the MDHO to fully consider how hospitals will enforce the statutory prohibition on duplicate discounts. The current sample template lacks the necessary detail to enable the detection of potential noncompliance with the prohibition on duplicate discounts, potential drug diversion, and other program integrity concerns. To this end, BIO recommends that the question "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" be replaced with the following targeted questions that will provide more detailed insight into potential program integrity violations:

- Please list the specific mechanisms that are employed to avoid duplicate discounts across all settings utilizing 340B, including at the hospital, pharmacies, and off-site clinics.
- Please ensure all child sites report aligned financial assistance policy as well as clinical and financial integration with its parent.
- Please state how a 340B eligible patient is defined within the hospital's policies and procedures, including whether covered entity ensures patient is listed on 340B OPAIS database.
- Please list specific services and dates of services provided by covered entity associated with each 340B prescriptions that a patient receives.
- Please list the calendar year in which 340B prescriptions are received.

MHDO Staff Response:

The reporting requirement in Public Law 2023, Chapter 276, includes the requirement that hospitals participating in the 340B program must submit to MHDO a description of

their internal review and oversight of the 340B program, which must meet the federal Department of Health and Human Services, Health Resources and Services Administration's program rules and guidance for compliance. Hospitals must recertify annually with the federal government their eligibility to participate in the 340B program and attest to meeting all program requirements. Lastly, it is the responsibility of the federal government to assess whether there are potential program integrity violations with this federal program.

Recommended Board Action:

None.

Comment 5: In addition, the question "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" does not specifically address how 340B savings are being utilized to service the needs of underserved and vulnerable patients in community. A report by the Alliance for 340B Integrity & Reform found that DSH hospitals earned an estimated $44.1billion in 340B profit in 2022, compared to only $18.5 billion in charity costs reported. Recently, the State Treasurer of North Carolina found that 340B hospitals billed the State Health Plan 5.4 times their discounted acquisition costs, collecting an 84.8% higher average price markup than hospitals outside of the program. For one treatment of a cancer drug used to treat melanoma, 340B hospitals in the state reaped an average $13,617 profit off the State Health Plan, billing $21,512 for a drug they acquired for an estimated $7,985. Given these concerning trends, all states should demand 340B covered entity transparency with targeted reporting requirements to ensure that 340B hospitals pass on savings to patients.

Accordingly, BIO recommends that the question "Please list the programs and services which are funded in whole or in part from 340B Drug Program savings that provide community benefit, including services that support community access to care that the hospital could not continue without savings from the 340B Drug Program" should be replaced with the following more targeted questions:

- Percentage of Total 340B Revenue Used to Provide Charity Care;
- Percentage of Total 340B Revenue Used to Provide Discounts on Covered Outpatient Drugs;
- Percentage of Total 340B Revenue Used to Provide Services Outside of Covered Outpatient Drugs;

•Total number of patients accessing prescriptions through 340B program at covered entity in a calendar year;
•Average distance between covered entity and child sites where prescriptions are filled.

MHDO Staff Response:

The reporting requirement in Public Law 2023, Chapter 276, requires each hospital *to report in a standardized format as agreed upon by the Maine Health Data Organization and the hospitals.* The content of the proposed rule was vetted with the Maine Hospital Association and the largest health systems in the State prior to the proposed rule being published. Several of the questions above were discussed during the early stages of developing the rule. It was determined that for the initial rulemaking the structure as proposed is sufficient.

Recommended Board Action:

None.

- **The Pharmaceutical Research & Manufacturers of America (PhRMA) submitted the following comment(s):**

Comment 1: Our comments are focused on Section 2(F) and corresponding Appendix A of the Proposed Rule. Section 2(F) would require each hospital to report drug-specific cost information to the MHDO. Specifically, Section 2(F) would require each hospital to report an individual drug's 340B acquisition cost in whole dollars to the hospital, and to its contract pharmacies and 340B third-party administrators, along with estimated savings for the fiscal year, for the top three drugs with a unique national drug code (NDC) having the highest acquisition costs and the top three drugs with a unique NDC that were dispensed most often. PhRMA is concerned that Section 2(F) and Appendix A do not adequately protect against the inadvertent disclosure of confidential and proprietary pricing information.

Under federal law, 340B drug-specific prices are confidential and proprietary information and may not be disclosed publicly or accessed by anyone other than authorized personnel at a covered entity or a manufacturer. In fact, the Health Resources and Services Administration (HRSA), which oversees the 340B drug program, places significant restrictions on access to 340B drug-specific pricing information in the 340B Office of Pharmacy Affairs Information System ("340B OPAIS"), only permitting access to a limited number of employees per covered entity and manufacturer. 340B drug-specific prices are available only to certain eligible covered entities specified in federal law. These prices are calculated using Medicaid pricing metrics that federal law also requires

be kept confidential. Given the sensitivity of drug manufacturers' pricing information, it is critical to protect the confidentiality of 340B drug-specific prices and to ensure that competitors and other stakeholders in the340B supply chain, such as pharmacy benefit managers and contract pharmacies, do not have access to this information, which if disclosed, could undercut competition.

MHDO Staff Response:

The intent of Section 2(F) and Appendix A of the Rule is to collect the aggregate total 340B Drug Acquisition Cost for the calendar year for each NDC reported. The MHDO agrees that the current data element labels and descriptions in Section 2(F) and Appendix A are vague in this regard and should be updated for clarity.

Recommended Board Action:

Relabel Section 2(F) data element "340B Acquisition Cost" as "Total 340B Drug Acquisition Cost (NDC)"

Update the description under Section 2(F) for relabeled data element "Total 340B Drug Acquisition Cost (NDC)" to read "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".

Relabel Section 2(F) data element "340B Estimated Savings" as "Total 340B Estimated Savings (NDC)"

Update the description under Section 2(F) for relabeled data element "Total 340B Estimated Savings (NDC)" to read "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."

Relabel Appendix A data element "340B Drug Acquisition Cost" as "Total 340B Drug Acquisition Cost (NDC)"

Relabel Appendix A data element "340B Drug Program Estimated Savings" as "Total 340B ~~Drug Program~~ Estimated Savings (NDC)"

Comment 2: At the virtual public hearing convened by the MHDO on May 1, 2024, the MHDO clarified that it is not asking for any detail in this Proposed Rule by volume, quantity, or at the unit level. PhRMA emphasizes the importance of protecting the confidentiality of all confidential, proprietary, and trade secret information submitted to the MHDO. Therefore, to guard against any inadvertent disclosure of such information,

PhRMA urges the MHDO to make clear in the Proposed Rule and Appendix A that each hospital must report the above-identified drug-specific cost information to the MHDO as an aggregated sum total in whole dollars.

MHDO Staff Response:

The MHDO reaffirms that it is not asking for any detail in this Proposed Rule by volume, quantity, or at the unit level. The intent of Section 2(F) and Appendix A of the Rule is to collect the aggregate total 340B Drug Acquisition Cost for the calendar year for each NDC reported. The MHDO agrees that the current data element labels and descriptions in Section 2(F) and Appendix A are vague in this regard and should be updated for clarity.

Recommended Board Action:

Relabel Section 2(F) data element "340B Acquisition Cost" as "Total 340B Drug Acquisition Cost (NDC)"

Update the description under Section 2(F) for relabeled data element "Total 340B Drug Acquisition Cost (NDC)" to read "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".

Relabel Section 2(F) data element "340B Estimated Savings" as "Total 340B Estimated Savings (NDC)"

Update the description under Section 2(F) for relabeled data element "Total 340B Estimated Savings (NDC)" to read "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."

Relabel Appendix A data element "340B Drug Acquisition Cost" as "Total 340B Drug Acquisition Cost (NDC)"

Relabel Appendix A data element "340B Drug Program Estimated Savings" as "Total 340B Estimated Savings (NDC)"

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

Effective Date: TBD