Maine Primary Care Association | MHA Maine Hospital Association | mshp Maine Society of Health System Pharmacists | Maine Pharmacy Association

Coalition to Protect Health Care for Rural and Underserved Communities

340B Program Integrity

The 340B program is heavily regulated with both state and federal oversight. It includes compliance mechanisms, penalties for noncompliance or abuse and a dispute resolution process. Covered entities that participate in the program may only purchase 340B discounted drugs for patients who qualify and may not receive duplicative 340B discounts and Medicaid rebates for the same drug. Additionally, covered entities may not engage in diversion of covered outpatient drugs defined by Health Resources and Services Administration (HRSA) as the resale or other transfer of a 340B drug to ineligible patients.

Compliance & Audits

- Both the Secretary of U.S. Department of Health and Human Services (DHHS) and drug manufacturers are authorized to audit covered entities to ensure compliance with the diversion and duplicate discount provisions.
- Covered entities that fail to comply may be fined and/or removed from the program.

Federal Preemption & Oversight

- No state has adopted redundant program integrity provisions and any attempt to enforce the provisions in the 340B program raise federal preemption concerns.
- In the words of a federal district court in Mississippi, the 340B Program has "comprehensive enforcement mechanisms."
- When it was alleged that federal oversight of the 340B program needed enhancement, even the Supreme Court agreed that enforcement of the 340B program is robust.

Key Components of 340B Program Integrity in Maine

Details on reverse

Federal Oversight	State Oversight
1 HRSA is the lead federal agency providing the bulk of oversight of this program.	3 MaineCare provides some regulatory oversight to the extent that it overlaps with MaineCare drug discount programs.
2 HRSA has specific provisions for FQHC providers.	4 MHDO has specific transparency regulations for hospital providers.

For over 30 years, the 340B Program has increased access to care for rural and underserved communities. Efforts to restrict this program only serve to increase profits for pharmaceutical companies at the expense of patient care across Maine.

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Key Components of 340B Program Integrity in Maine

Federal Oversight

1 HRSA is the lead federal agency providing the bulk of oversight of this program.

HRSA, an agency of the U.S. DHHS, has national responsibility for the 340B Program. This includes annual recertification and a program-specific audit process for 340B covered entities. The compliance audits are conducted by highly trained auditors in accordance with HRSA policies and procedures include:

- Review of relevant policies and procedures and how they are operationalized.
- Verification of eligibility (including the GPO prohibition, maintaining auditable records, and outpatient clinic eligibility).
- Verification of internal controls to prevent diversion and duplicate discounts, including how the covered entity defines whether a patient is considered inpatient or outpatient, HRSA Medicaid Exclusion File designations, and accuracy of covered entity's 340B OPAIS record.
- Review compliance at covered entity, outpatient or associated facilities, and contract pharmacies.
- Testing of 340B drug transaction records on a sample or judgmental basis.

2 HRSA has specific provisions for Federally Qualified Health Centers (FQHCs).

Federal law enables 340B covered entities to stretch scarce federal resources to reach more eligible patients and provide more comprehensive services. FQHCs, also know as Community Health Centers, have additional federal laws and regulations that require health centers to invest all 340B savings into activities that support their federally approved goal of expanding access to care for medically underserved patients. FQHCs are subject to additional program integrity audits by HRSA to ensure statutory and regulatory compliance.

State Oversight

3 MaineCare provides some regulatory oversight to the extent that it overlaps with MaineCare drug discount programs.

All 340B providers who submit claims to MaineCare must determine whether they will use 340B drugs for their MaineCare patients (carve-in to the program) or whether they will purchase drugs for these patients through other mechanisms (carve-out of the program). In alignment with existing MaineCare policy, 340B providers are responsible for enrolling with the HRSA Office of Pharmacy Affairs, confirming the HRSA Medicaid Exclusion File (MEF) accurately represents their current Medicaid Exclusion status, completing the MaineCare 340B Provider Agreement (found on the MIHMS Health PAS Online Portal), and including a full list of service locations that will dispense 340B drugs on their 340B Provider Agreement.

4 Maine Health Data Organization (MHDO) has specific transparency regulations for hospital providers.

The State of Maine directed MHDO to adopt a program (found at Chapter 340) to require hospitals to submit extensive information about their participation in the 340B program. Maine is one of the first states to adopt such legislation enhancing transparency into the value the 340B program brings to our State and our commitment to program integrity.