January 16, 2026

David A. Bergantino
Auditor General
33 Broad Street
Suite 201
Providence, RI 02903

Re: Comments on Proposed Regulation 130-RICR-00-00-2 - Policies and Procedures for 340B Drug Program Reporting, Audit, Compliance and Enforcement

Dear Auditor General Bergantino,

On behalf of the Hospital Association of Rhode Island (HARI) and the Rhode Island Health Center Association (RIHCA), we appreciate the opportunity to submit comments on the proposed regulation 130-RICR-00-00-2 governing 340B program reporting, audit, compliance, and enforcement, including the proposed reporting schedules.

Our member hospitals and community health centers share a strong commitment to transparency, compliance, and stewardship of the 340B program. The program is an essential federal tool that enables safety net providers to stretch scarce resources to care for vulnerable patients and sustain critical services. We believe that well-designed reporting can strengthen public understanding of the program while ensuring that requirements are administratively feasible, operationally accurate, and consistent with existing legal obligations—including federal program rules and contractual confidentiality provisions.

Our comments focus specifically on Schedules B, C, E, G, and H of the proposed reporting schedule.

We offer targeted recommendations intended to enhance the clarity, accuracy, and usefulness of the data collected while avoiding unintended consequences.

Schedule B – Drug Purchasing Sources

Consideration:

Schedule B currently references purchases from “pharmacies/pharmacy.”

Proposed revision:

Strike references to “pharmacies/pharmacy.”

Rationale:

Covered entities do not purchase drugs from pharmacies. Drugs are purchased from manufacturers and wholesalers under existing pharmaceutical supply chain arrangements. Retaining the term “pharmacy” in this schedule creates confusion and does not reflect how drug purchasing occurs operationally.

Schedule C – Insurance Information

Consideration:

The current field requests “Insurer Company or Program Name.”

Proposed Revision:

Replace “Insurer Company or Program Name” with:
“Insurance Type – Medicare, Commercial (includes Medicare Supplemental), Medical Assistance, or Other.”

Rationale:

Requiring reporting by company and program would necessitate extensive interpretation, cross-walking, and reconstruction of data that is not captured in a standardized or reliable way. Covered entities do not report 340B data at this level of detail; attempting to do so would impose significant undue administrative burden and significantly increase the risk of inconsistent and inaccurate reporting, without improving transparency.

Covered entities can, however, reliably identify 340B-eligible claims by insurance type (e.g., Medicare, Medicaid, commercial). Aligning the requirement with these established categories reflects operational reality, supports data integrity, and continues to fulfill the regulation’s intent to promote transparency.

Schedule E – Vendor and Contractor Payments

Consideration:

The current form requires covered entities to individually list vendors/contractors and the amounts paid to them. This raises concerns related to contractual confidentiality, proprietary pricing, and potential antitrust implications.

Proposed Revision:

Provide in Schedule E the total aggregated payments for managing, administering, or facilitating any aspect of the 340B covered entity's drug program.

Provide in a separate Schedule, the names of all vendors, including split billing vendors, and contract pharmacies, with which the 340B covered entity contracted to provide services

associated with the covered entity's 340B program participation during the previous calendar year.

Rationale:

We fully support transparency regarding the types of services and functions associated with 340B program administration. However, requiring the identification of specific vendors and associated payment thresholds raises concerns regarding confidential business arrangements, competitive market dynamics, and antitrust sensitivities.

Schedule G – NDC-Level Reporting and Reimbursement Accuracy

We strongly support the goal of meaningful, accurate reporting that allows for appropriate comparison across covered entities. However, as currently drafted, Schedule G risks requiring data that cannot be produced reliably for all provider types due to fundamental differences in billing and reimbursement structures.

For reporting purposes, it is important to clarify that:

- "Prescription drugs" include both drugs dispensed through contract pharmacies and drugs administered in hospital settings, consistent with the scope of Schedule G.

- A covered entity's 340B program includes both hospital-based and contract pharmacy transactions.

However, there is a critical operational distinction:

- **Contract pharmacy drugs** are billed and reimbursed at the individual prescription (NDC) level.

- **Hospital-administered drugs** are frequently billed as part of a **bundled payment**, where the drug represents only one component of a larger service bundle that may include drug acquisition, clinical administration, supplies, overhead, and professional services.

As a result, the reimbursement associated with a hospital-administered drug **cannot be reliably isolated at the NDC level**. Hospitals receive a single, aggregated payment reflecting multiple services rather than discrete reimbursement tied to a specific drug code. There is no accurate methodology by which hospitals can extract true NDC-level reimbursement on these transactions.
Requiring such reporting would therefore compel covered entities to submit estimates or constructed figures that would appear precise but would, in fact, be misleading.

Proposed Revision:

We recommend that Schedule G focuses on uniform, reportable, and auditable data that will provide utilization transparency, as follows:

- Total claims amount of each 340B NDC that was dispensed or administered, and

- Remove the requirement to report reimbursement amounts at the NDC level.

This approach provides useful insight into program scope and utilization without introducing data that cannot be validated or meaningfully compared across covered entities.

Schedule H – Use of 340B Savings and Community Impact

We understand and respect the need for greater transparency around how 340B-related resources support patient care and community benefit. At the same time, the structure of Schedule H as currently drafted risks mischaracterizing how 340B operates and how savings function in practice.

Importantly, 340B savings do not create a one-to-one dollar equivalent that can be neatly allocated across discrete programmatic "buckets." The federal statute establishes that the purpose of the program is to enable covered entities to "stretch scarce federal resources as far as possible, reaching more eligible patients and providing more comprehensive services." That flexibility is foundational to the program's design and allows covered entities to respond to evolving community needs without creating programmatic "buckets".

The importance of preserving this flexibility is particularly acute in Rhode Island, where safety net providers serve an exceptionally high proportion of low-income and uninsured patients. According to Rhode Island Hospital Discharge Data, more than 40% of hospital 340B covered entities outpatient encounters involve patients covered by Medicaid or who are uninsured. Similarly, more than 55% of patients served by Rhode Island's community health centers are covered by Medicaid or lack insurance. These payer dynamics underscore that 340B participation directly supports providers caring for the state's most vulnerable populations and is deeply integrated into the financial viability of essential access points across the healthcare system.

Attempting to require overly prescriptive accounting of "savings allocation" may unintentionally create an artificial assessment of program impact that neither the federal statute contemplates nor state law can impose on a federally created program. More importantly, left as-is Schedule H creates a presumption, without meaning to, that 340B savings are required to conform to one or more of these line-items.

Proposed revision:

Rather than creating an entirely new accounting framework, we recommend that Schedule H permit covered entities to:

- Provide a narrative description of how 340B participation supports access, services, and community benefit;
- Include required aggregate information; and
- Reference existing reporting (e.g., Form 990 Schedule H, community benefit reports, impact profiles) where applicable.

This approach promotes meaningful transparency, reduces duplicative administrative burden, and avoids forcing covered entities into artificial accounting constructs that do not reflect how the program functions in practice.

We appreciate the Office of the Auditor General's attention to this important matter and its efforts to implement the statutory requirements thoughtfully. Our recommendations are intended to support the development of a reporting framework that advances transparency and accountability while ensuring accuracy, feasibility, and consistency with federal law and operational realities.

Respectfully submitted,

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