



Office of the Auditor General

State of Rhode Island - General Assembly

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The Rhode Island Office of the Auditor General has reviewed public comments provided relating to Proposed Regulation 130-RICR-00-00-2 - Policies and Procedures for 340B Drug Program Reporting, Audit, Compliance and Enforcement, and provide the following responses dated January 22, 2026, and when applicable, revisions to the proposed policies and procedures, specifically Appendix A, the 340B Drug Pricing Program – Mandated Covered Entity Reporting template, which was the focus of all comments submitted.

The following are the comments received relating to Appendix A of the policies and procedures, followed by the response and, when deemed appropriate and responsive, the remedy taken in the form of revisions to Appendix A. Appendix A has been attached to this narrative with the revised sections of the reporting template highlighted.

Comment 1: 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.

Response and remedy: Schedule B instructions and schedule content were revised to address this comment.

Comment 2: 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.

Response and remedy: Schedule C instructions and schedule content were revised to address this comment.

Comment 3 - 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.

Response and remedy: To address concern, identification of specific contracted entities has been removed and only reporting at the service contractor category will be required on Schedule E. Detailed information, if required, could be requested from the covered entity but is not deemed necessary to be incorporated in the public report to meet the reporting requirements in statute.

Comment 4 - 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.

Response and remedy: To address the concern cited, the instructions were changed to provide reporting based on dispensing or administration of the prescription drug during the period. In addition, the amount reported was modified to drug cost instead of the previously reported claim reimbursement amount.

Comment 5 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.

Response: We considered Comment 5 and do not believe it is consistent with federal program requirements for auditability. Covered entities are required to have detailed accounting and record-keeping to allow for auditing this program requirement and, in our opinion, requested information in Schedule H is consistent with that requirement.

The above public comments, considerations, responses, and, when applicable, remedies are respectfully submitted as required by the rulemaking requirements of the Office of the Secretary of State.

Sincerely,



David A. Bergantino, CPA, CFE
Auditor General



State of Rhode Island
340B Drug Pricing Program - Mandated Covered Entity Reporting
Mandated Reporting Cover Page

**Covered Entity 340B Drug Pricing Program Reporting Mandated by
RI General Law Section 5-19.3-6.**

Covered Entity Name:	<input type="text"/>
Covered Entity Corporate Address:	<input type="text"/>
340B ID Number(s)	<input type="text"/>
Reporting for Calendar Year:	<input type="text"/>

Covered Entity Required Information

Date of most recent recertification with the Health Resources and Service Administration	<input type="text"/>
Reporting Basis (i.e., Cash or Accrual)	<input type="text"/>

RHODE ISLAND



**340B DRUG PRICING
PROGRAM**



State of Rhode Island

Schedule B

340B Drug Pricing Program - Covered Entity Reporting
Schedule B - Acquisition Cost Detail Schedule

Covered Entity Name:

Reporting for Calendar Year:

Instruction: Provide detail for all vendors (e.g. manufacturers, wholesalers) where the covered entity procured \$5,000 or more of prescription drugs from an individual vendor/pharmacy under the 340B program. Provide an aggregated total for vendors where procurement was less than \$5,000.

Line No.	Vendor Name	Amount Paid	Unit
1			USD
2			USD
3			USD
4			USD
5			USD
6			USD
7			USD
8			USD
9			USD
10			USD
	Total for vendors under \$5,000	_____	USD
	Total Aggregated Acquisition Cost for all 340B Program Drugs - (Supports Schedule A, Line 1)	_____	USD
		=====	
		Schedule A - Line 1	



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Schedule C

340B Drug Pricing Program - Covered Entity Reporting

Schedule C - Claim Reimbursements For 340B

Dispensed / Administered Drugs

Covered Entity Name:

Reporting for Calendar Year:

Instruction: Provide detail (amount and number of individual claims) for all reimbursements relating to pharmaceuticals obtained under the 340B Drug Program from commercial insurance (including Medicare Supplemental plans), Medical Assistance, Medicare, and or other sources. This schedule should total all reimbursements relating to pharmaceuticals obtained under the 340B Drug Program.

Line No.	Reimbursement Source	Amount Reimbursed	Unit	Count	Unit
1	Commercial Insurance		USD		Claims
2	Medical Assistance (i.e., Medicaid)		USD		Claims
3	Medicare		USD		Claims
4	Other Sources		USD		Claims
Total Aggregated Payment Amount Received for Dispensed/Administered 340B Drugs (Supports Schedule A - Line 2)					
		<u>Schedule A - Line 2</u>		<u></u>	



State of Rhode Island

Schedule D

340B Drug Pricing Program - Covered Entity Reporting

Schedule D - Payment to Contract Pharmacy Detail Schedule

Covered Entity Name:

Reporting for Calendar Year:

Instruction: Provide detail for all payments made to contract pharmacies for dispensing 340B prescription drugs during the reporting period. Individually list any contract pharmacy paid \$5,000 or more. Aggregate payments to contract pharmacies paid less than \$5,000.

Line No.	Contract Pharmacy Name	Amount Paid	Unit
1			USD
2			USD
3			USD
4			USD
5			USD
6			USD
7			USD
8			USD
9			USD
10			USD

Total for contract pharmacies under \$5,000

Total Aggregated Payments to Contract Pharmacies for 340B Program Prescription Drugs (Supports Schedule A - Line 3

Schedule A - Line 3



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Schedule E

340B Drug Pricing Program - Covered Entity Reporting
Schedule E - Payments to Outside Entities (Vendors) for 340B Program
Management, Administration, or Facilitation

Covered Entity Name:

Reporting for Calendar Year:

Instruction: Aggregate detail by service/contractor category for all payments made to vendors/contractors relating to the management, administration, and/or facilitation of any aspect of the Covered Entity's participation in the 340B Program. Examples of services/contractors to be aggregated include contracted pharmacies, split billing vendors, consultants, third-party administrators, and other vendors. For consultants and other vendors, provide a brief description of service provided. Aggregate payments for service/contractor categories individually paid less than \$5,000.

Line No.	Program Management, Administration, or Facilitation Category	Description For Other / Consultants	Amount	Unit
1				USD
2				USD
3				USD
4				USD
5				USD
6				USD
7				USD
8				USD
	Total Vendor Categories individually under \$5,000		_____	
	Total Aggregated Payments to Outside Entities (Vendors) for 340B Program Management, Administration, or Facilitation (Supports Schedule A - Line 4)		_____	
			=====	Schedule A - Line 4



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Schedule F

340B Drug Pricing Program - Covered Entity Reporting
Schedule F - Administrative Expenses for 340B Program

Covered Entity Name:

Reporting for Calendar Year:

Instruction: Provide detail for all covered entity expenses (noncontracted) relating to the administration of the 340B program including staffing, operational, and administrative expenses. Detail individual expense categories with expenses of \$5,000 or more. Aggregate expense categories individually less than \$5,000.

Line No.	Expense Category Description	Amount/Value	Unit
1			USD
2			USD
3			USD
4			USD
5			USD
6			USD
7			USD
8			USD
9			USD
10			USD
	Total for expense categories individually under \$5,000	_____	
	Total Aggregated Administrative Expenses for 340B Program	=====	
		Schedule A - Line 5	



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Schedule G

340B Drug Pricing Program - Covered Entity Reporting

Schedule G - Detail of Prescription Drugs Relating to Covered Entity Participation in the 340B Program Dispensed or Administered During the Period.

Covered Entity Name:

Reporting for Calendar Year:

Instruction: List all prescription drugs relating to Covered Entity participation in the 340B Program during the period. Detail the total amount (cost of prescription drug obtained through the 340B program) and count of individual prescription drug claims dispensed or administered during the period. Aggregate all prescription drugs where reimbursements for the particular drug were less than \$5,000.

Line No.	Prescription Drug Name	National Drug Code Number	Cost Amount	Unit	Count	Unit
1				USD		Claims
2				USD		Claims
3				USD		Claims
4				USD		Claims
5				USD		Claims
6				USD		Claims
7				USD		Claims
8				USD		Claims
9				USD		Claims
10				USD		Claims
	Total Prescription Drugs individually under \$5,000		_____	USD	_____	Claims
	Total Prescription Drugs Obtained Through 340B Program Dispensed or Administered During the Period		=====		=====	

Mandated by RIGL § 5-19.3-6



State of Rhode Island

Schedule H

340B Drug Pricing Program - Covered Entity Reporting

Schedule H - 340B Program Savings Usage by Covered Entity to Benefit Patients and/or its Community Through Programs, Projects, and/or Services.

Covered Entity Name:

Reporting for Calendar Year:

Instruction: List all programs, projects, and/or services provided by the Covered Entity through 340B Program savings that benefited patients and/or its community. Detail individual programs, projects, and/or services provided and the related costs incurred by the covered entity. Individually list programs, projects, and services with costs of \$5,000 or more. Aggregate all other programs, projects, and services where costs totaled less than \$5,000.

<u>Line No.</u>	<u>340B Net Revenue Usage Description</u>	<u>Amount/Value</u>	<u>Unit</u>
1	Health Services Expansion		USD
2	Community and Public Health Programs		USD
3	Improving Patient Access		USD
4	Facility Upgrades		USD
5	Technology Upgrades		USD
6	Subsidize Losses - Medicaid and Medicare Program Underpayments		USD
7	Research and Innovation		USD
8	Community Programs		USD
9	Charity Care/Uncompensated Care		USD
10	Other		USD
	Other programs, projects, and services where costs totaled less than \$5,000.		USD

Total Aggregate Costs of Programs, Projects, and/or Services Supported by 340B Net Revenue

Mandated by RIGL § 5-19.3-6.



State of Rhode Island

340B Drug Pricing Program - Covered Entity Reporting

Schedule I - Covered Entity Certification Page

Schedule I

Covered Entity Name:

Reporting for Calendar Year:

Two empty rectangular boxes for entering the Covered Entity Name and Reporting for Calendar Year.

Line No.	Covered Entity Certification	YES	NO	If Yes, explain any noncompliance noted.
1	During the reporting period, did the covered entity conduct a self-audit of their participation in the 340B Program as required by the Health Resources and Services Administration (HRSA)?			
2	During the reporting period, was the covered entity audited by HRSA or subject to a drug manufacturer audit approved by HRSA?			

I certify, to the best of my knowledge and belief, that the information reported in this reporting package is materially complete and accurate?

Signature

Date

Name and Title

Email