RHODE ISLAND GOVERNMENT REGISTER

PUBLIC NOTICE OF PROPOSED RULEMAKING

AUDITOR GENERAL

Title of Rule: Policies And Procedures For 340b Drug Program Reporting And Audit And Compliance And Enforcement Provisions Of R.I. Gen. Laws Chapter 5-19.3.

Rule Identifier: 130-RICR-00-00-2

Rulemaking Action: Proposed Adoption

Important Dates:

Date of Public Notice: December 17, 2025

End of Public Comment: January 16, 2026

Rulemaking Authority:

R.I. Gen. Laws § 5-19.3

Summary of Rulemaking Action:

R.I. Gen. Laws Chapter 5-19.3 entitled “Defending Affordable Prescription Drug Costs Act” mandates specific reporting requirements in R.I. Gen. Laws § 5-19.3-6 for covered entities of Rhode Island that participate in the federal 340B program. Those reporting requirements mandate the submission to the Office of the Governor, the Speaker of the House, the President of the Senate, and the Auditor General a report that includes a minimum of the following information:
1.The aggregated acquisition cost for all prescription drugs that the 340B covered entity obtained through the 340B program during the previous calendar year;
2.The aggregated payment amount that the 340B covered entity received for drugs, under the 340B program and dispensed or administered to patients enrolled in commercial and Medicare Supplemental plans;
3.The aggregated payment amount that the 340B covered entity made:
a.To contract pharmacies to dispense drugs to its patients under the 340B program during the previous calendar year;
b.To any other outside vendor for managing, administering, or facilitating any aspect of the 340B covered entity's drug program during the previous calendar year; and
c.For all other expenses related to administering the 340B program, including staffing, operational, and administrative expenses, during the previous calendar year.
4.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;
5.The number of claims for all prescription drugs the 340B covered entity obtained through the 340B program during the previous calendar year, including the total number of claims and the number of claims reported by commercial and Medicare Supplemental plans;
6.A description of the ways in which the 340B entity uses savings from its participation in the 340B program to benefit patients and/or its community through programs, projects, and services funded in whole or in part by savings from the 340B program;
7.A description of any and all material breaches, changes in 340B eligibility status, and/or the U.S. Department of Health and Human Services, Health Resources and Services Administration's ("HRSA") 340B program or manufacturer audits during the previous calendar year;
8.A description of the 340B covered entity's self-audit and oversight of its participation in the 340B program in compliance with the HRSA 340B program rules and guidance; and
9.Such additional information as the General Assembly or Auditor General may request.

Additional Information and Public Comments:

All interested parties are invited to request additional information or submit written or oral comments concerning the proposed adoption until January 16, 2026 by contacting the appropriate party at the address listed below:

David A. Bergantino
Auditor General
33 Broad Street
Suite 201
Providence, RI 02903
david.bergantino@rioag.gov

In accordance with R.I. Gen. Laws § 42-35-2.8, an oral hearing will be granted if requested by twenty-five (25) persons, by a governmental agency or by an association having at least twenty-five (25) members. A request for an oral hearing must be made within ten (10) days of the publication of this notice.

Regulatory Analysis Summary and Supporting Documentation:

Auditor General Regulatory Analysis – Policies and Procedures Relating to 340B Drug Pricing Program Reporting and Enforcement

(a) An agency shall prepare a regulatory analysis for a proposed rule. The analysis must be completed before notice of the proposed rulemaking is published. The summary of the analysis prepared under subsection (c) must be published with the notice of proposed rulemaking.

(b) A regulatory analysis must contain:

(1) An analysis of the benefits and costs of a reasonable range of regulatory alternatives reflecting the scope of discretion provided by the statute authorizing the proposed rule;

Under R.I. Gen. Laws § 5-19.3-7. Compliance and enforcement, the Office of the State Auditor General shall have the authority to (1) Investigate complaints and take appropriate actions to ensure compliance with this chapter, and (2) Promulgate rules and regulations necessary to carry out the provisions of this chapter. The proposed policies and procedures were designed to avoid creation of new costs and the costs of initial implementation, which are not significant, will be funded through the Office of the Auditor General's budget.

(2) Demonstration that there is no alternative approach among the alternatives considered during the rulemaking proceeding which would be as effective and less burdensome to affected private persons as another regulation. This standard requires that an agency proposing to write any new regulation must identify any other state regulation that is overlapped or duplicated by the proposed regulation and justify any overlap or duplication; and

To our knowledge, there is no alternative approaches or other state regulations that relate to this rulemaking as the legislation created new requirements and authority in statute.

(3) A determination whether:

(i) The benefits of the proposed rule justify the costs of the proposed rule; and

The proposed policies and procedures were designed to avoid creation of new costs and the costs of initial implementation, which are not significant, will be funded through the Office of the Auditor General's budget. The main implementation cost for the Office of the Auditor General relates to website design to allow for covered entity report posting. This cost will be funded by the budget of the Office of the Auditor General.

(ii) The proposed rule will achieve the objectives of the authorizing statute in a more cost-effective manner, or with greater net benefits, than other regulatory alternatives.

The proposed rules and regulations are for a new statute (R.I. Gen. Laws Chapter 5-19.3, Defending Affordable Prescription Drug Costs Act) promulgating reporting and enforcement requirements for the Office of the Auditor General and there are no preexisting regulatory alternatives.

(c) An agency preparing a regulatory analysis under this section shall prepare a concise summary of the analysis.

Not applicable, see above analysis comments.

For full regulatory analysis or supporting documentation contact the agency staffperson listed above.