130-RICR-00-00-2

TITLE 130 – AUDITOR GENERAL

CHAPTER 00 – N/A

SUBCHAPTER 00 – N/A

PART 2 – POLICIES AND PROCEDURES FOR 340B DRUG PROGRAM REPORTING AND AUDIT AND COMPLIANCE AND ENFORCEMENT PROVISIONS OF R.I. GEN. LAWS CHAPTER 5-19.3.

2.1 General

A. 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.

B. R.I. Gen. Laws § 5-19.3-7 also authorizes the Auditor General 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.

2.2 Authority

A. By the virtue of the authority vested in the Auditor General by R.I. Gen. Laws § 5-19.3-7, the Auditor General hereby issues the following rules and regulations relating to reporting and audit, and compliance and enforcement provisions within R.I. Gen. Laws Chapter 5-19.3.

2.3 Definitions

A. For purposes of this regulation and related Appendix A, the following terms are defined as provided in R.I. Gen. Laws § 5-19.3-2:

1. "340B contract pharmacy" means a pharmacy, as defined in R.I. Gen. Laws § 5-19.1-2, that dispenses 340B drugs on behalf of a 340B-covered entity under contract.

2. "340B covered entity" means an entity participating or authorized to participate in the federal 340B drug discount program, as described in 42 U.S.C. § 256b.

3. “340B Drug” means a drug that has been subject to any offer for reduced prices by a manufacturer pursuant to 42 U.S.C § 256b and is purchased by a covered entity as defined in 42 U.S.C § 256b(a)(4).

4. "Health insurer" means every nonprofit medical service corporation, hospital service corporation, health maintenance organization, or other insurer offering or insuring health services.

5. "Pharmaceutical manufacturer" means any person or entity that manufactures or sells prescription drugs, directly or through another person or entity, in this state.

6. "Pharmacy benefit manager" or "PBMs" means an entity doing business in the state that contracts to administer or manage prescription-drug benefits on behalf of any carrier that provides prescription-drug benefits to residents of this state.

2.4 Purpose and Scope

A. These rules and regulations supplement R.I. Gen. Laws Chapter 5-19.3 as authorized under R.I. Gen. Laws § 5-19.3-7.

2.5 Reporting - Policies and Procedures

A. To facilitate statutory reporting requirements, covered entities (as defined at § 2.3 of this part) must complete and submit the 340B Drug Pricing Program – Mandated Covered Entity Reporting (Annual Report), included as Appendix A to this policy.

B. The mandated annual report can be found at the website of the RI Auditor General (https://www.oag.ri.gov/) under the tab for 340B Drug Pricing Program Reporting. The annual report can also be obtained by request by emailing the Office of the Auditor General at ag@rioag.gov. The annual report is provided in excel to allow covered entities flexibility in expanding or adding data to meet their individual reporting needs. The annual report includes the minimum information required by R.I. Gen. Laws § 5-19.3-6, however, covered entities can include additional data or narratives within their annual reports when submitted.

C. R.I. Gen. Laws § 5-19.3-6 mandates that annual reports be submitted for the calendar year ending December 31st with the first report due for the period ending December 31, 2025.

D. Covered entities must submit reporting for the registered parent (corporate entity) authorized in the 340B program, inclusive of all provider locations participating in the 340B Drug Pricing Program.

E. Covered entities can elect to report amounts in the 340B reporting template on a cash or accrual basis of accounting.

F. Covered entities are required to submit the annual report on or before April 1st for the preceding calendar year.

G. The reporting template must be completed and submitted to the Office of the Auditor General by email (ag@rioag.gov) as a:

1. PDF file for purposes of public posting as the covered entity's annual report on the website of the Office of the Auditor General; and

2. Via the original excel template for Auditor General data compilation needed to administer its statutory duties relating to the law.

H. For reporting consistency, the Office of the Auditor General will communicate the availability of each covered entity's annual report on the website of the Office of the Auditor General to the Office of the Governor, the Speaker of the House, the President of the Senate and the respective covered entity officials upon posting as required by R.I. Gen. Laws § 5-19.3-6.

I. As mandated by R.I. Gen. Laws § 5-19.3-6, all submitted reports will be posted on the Auditor General's website. The Auditor General will post a minimum of the 5 most recent annual report submissions for each covered entity.

J. Any questions regarding 340B Drug Pricing Program – Mandated Covered Entity Reporting can be submitted to the Office of the Auditor General at ag@rioag.gov.

2.6 Compliance, Audit, and Enforcement - Policies and Procedures

A. The Office of the Auditor General will perform the following relative to compliance and enforcement pursuant to R.I. Gen. Laws Chapter 5-19.3:

1. Monitor covered entity compliance with mandated reporting requirements and report to the General Assembly.

2. Take appropriate actions to ensure compliance with mandated reporting requirements. Failure to submit the Annual Report in the format described above will be deemed non-compliance with R.I. Gen. Laws § 5-19.3-6 and may subject the covered entity to compliance action, which may include but shall not be limited to, posting a record of the noncompliance on the Auditor General's website, reporting the noncompliance to the General Assembly, referring the covered entity to the responsible state licensing

body and/or the Department of the Attorney General for any further action they deem warranted.

B. Requirements for covered entities subject to compliance audits or inquiries in relation to their participation in the 340B Drug Pricing Program:

1. Covered entities are required to provide to the Auditor General supporting data and documentation in connection with compliance or performance audits, or inquiries by the Office of the Auditor General.

2. Covered entities are required to provide supporting data and documentation requested by the Auditor General or contracted auditors in the performance of audits or inquiries authorized under R.I. Gen. Laws Chapter 5-19.3.

C. Processing of Complaints Alleging Violations of R.I. Gen. Laws § 5-19.3-6:

1. Complaints alleging violation of the reporting and audit requirements mandated by R.I. Gen. Laws § 5-19.3-6 shall be filed with the Rhode Island Office of the Auditor General at ag@rioag.gov who shall investigate complaints and refer violations to the appropriate enforcement authorities, when appropriate.

2. Complaints shall specify in sufficient detail the facts in supporting the alleged violation and shall cite the specific section of R.I. Gen. Laws § 5-19.3-6, which is alleged to have been violated. Each complaint shall identify the name, address, and full contact information of the complainant and shall be signed and notarized.

3. The complainant shall provide any and all documents and other evidence that form the basis of the complaint.

D. Processing of Complaints Alleging Discriminatory Actions in Violation of R.I. Gen. Laws §§ 5-19.3-3 and 5-19.3-5:

1. Complaints alleging violation of R.I. Gen. Laws § 5-19.3-3 (Prohibition of certain discriminatory actions related to reimbursement of 340B covered entities and 340B contract pharmacies) and R.I. Gen. Laws § 5-19.3-5 (Prohibition on certain discriminatory actions by a pharmaceutical manufacturer, agent, or affiliate of such manufacturer related to 340B entities), shall be filed with the Rhode Island Department of the Attorney General, which may investigate such complaints and take any action it deems necessary to effectuate the purposes of R.I. Gen. Laws Chapter 5-19.3.

2. Complaints shall specify in sufficient detail the facts in support of the alleged violation and shall cite the specific sections of R.I. Gen. Laws §§ 5-19.3-3 and/or 5-19.3-5 alleged to have been violated. Each complaint

shall include the name, address, and full contact information of the complainant, and shall be signed and notarized.

3. The complainant shall provide any and all documents and other evidence that form the basis of the complaint.

E. Nothing in these policies and procedures shall preclude the complainant from exercising any other rights or remedies that may be available under state or federal law.

F. Nothing in these policies and procedures shall preclude the Rhode Island Department of the Attorney General from enforcing any provision of R.I. Gen. Laws Chapter 5-19.3, or from seeking other relief authorized by the statute or common law.

G. Nothing in these policies and procedures shall be construed or applied in a manner that conflicts with any applicable federal law or regulatory guidance.