

Self-Audit: Policy and Procedure

340B Program Audit Template | Quantum 5D Consulting | 2026 Edition

Purpose

The purpose of this tool is to evaluate the content within a covered entity's 340B Program policy and procedure documents.

Background

HRSA has identified specific requirements to assist covered entities in developing their 340B-related policies and procedures. Policies and procedures standardize practices throughout an organization and are requested as part of the HRSA audit data request due prior to the on-site visit. Policies and procedures should include elements of program requirements, including methods for routine self-auditing and internal corrective action. Covered entities are strongly encouraged to review and update their policies and procedures for all facets of the 340B Program on a regular basis to improve program integrity within their organization.

340B Program Policy and Procedure Review

Entity Information

Parent 340B ID:

Parent Covered Entity Name:

Parent Physical Address:

Date of LAST Audit:

Date of THIS Audit:

Name/Title of Individual Completing This Audit:

Signature:

Summary of Results:

Actions to Be Taken:

Compliance Element Assessment

1. Does your organization have a policy and procedure for the registration/recertification process?

☐ Yes ☐ No ☐ N/A ☐ Unsure

Document name of the policy and procedure:

Document the section or page number that includes the following elements:

- a. Process for annual recertification in the Office of Pharmacy Affairs Information System (OPAIS)
- b. Process for registering new outpatient facilities/sites in OPAIS
- c. Process for updating changes in OPAIS (e.g., authorizing official, primary contact, 340B contact, address changes)
- d. Process for removing sites that no longer qualify as eligible from OPAIS

Date last reviewed/updated/approved:

If response is "No," "N/A," or "Unsure," explain:

3. Does your organization have a policy and procedure for determining eligible sites?

☐ Yes ☐ No ☐ N/A ☐ Unsure

Document name of the policy and procedure:

Document the section or page number that includes the following elements:

- a. Process for determining whether a site is reimbursable on a covered entity's Medicare cost report or is listed as a site on a scope of grant
- b. Process for determining whether a site is an eligible child site or an associated site
- c. Process for determining whether services rendered at a site are eligible outpatient services
- d. Process for ensuring that only eligible sites purchase or use 340B drugs

Date last reviewed/updated/approved:

If response is "No," "N/A," or "Unsure," explain:

5. Does your organization have a policy and procedure for the procurement process?

☐ Yes ☐ No ☐ N/A ☐ Unsure

Document name of the policy and procedure:

Document the section or page number that includes the following elements:

- a. Process for establishing and maintaining 340B purchasing accounts with wholesalers and/or manufacturers
- b. Process for ensuring that only authorized personnel can purchase drugs under the 340B Program
- c. Process for separating 340B purchasing accounts from non-340B (GPO) purchasing accounts
- d. Process for ensuring that drugs purchased under the 340B Program are used only for eligible patients at eligible sites

Date last reviewed/updated/approved:

If response is "No," "N/A," or "Unsure," explain:

8. Does your organization have a policy and procedure for GPO Prohibition violations (applicable to DSH, PED, CAN entity types)?

☐ Yes ☐ No ☐ N/A ☐ Unsure

Document name of the policy and procedure:

Document the section or page number that includes the following elements:

- a. Process for ensuring that covered outpatient drugs are not purchased through a group purchasing organization (GPO) or GPO-negotiated pricing arrangement
- b. Process for identifying and reviewing self-negotiated contracts versus GPO contracts for covered outpatient drugs
- c. Process for ensuring compliance with the Controlled Substances Ordering System (CSOS) requirements when ordering Schedule II drugs under 340B

Date last reviewed/updated/approved:

If response is "No," "N/A," or "Unsure," explain:

9. Does your organization have a policy and procedure for exclusions to covered outpatient drugs?

☐ Yes ☐ No ☐ N/A ☐ Unsure

Document name of the policy and procedure:

Document the section or page number that includes the following elements:

- a. Process for identifying drugs that are excluded from the definition of covered outpatient drugs (e.g., vaccines, drugs used during inpatient stays, drugs provided free of charge by manufacturers)
- b. Process for ensuring excluded drugs are not purchased at 340B pricing

Date last reviewed/updated/approved:

If response is "No," "N/A," or "Unsure," explain:

10. Does your organization have a policy and procedure for contract pharmacy oversight?

☐ Yes ☐ No ☐ N/A ☐ Unsure

Document name of the policy and procedure:

Document the section or page number that includes the following elements:

- a. Process for conducting internal audits of contract pharmacy arrangements
- b. Process for requiring and reviewing independent audits of contract pharmacies
- c. Process for addressing findings from internal and independent audits, including corrective action plans

Date last reviewed/updated/approved:

If response is "No," "N/A," or "Unsure," explain:

11. Does your organization have a policy and procedure for inventory management to prevent diversion?

☐ Yes ☐ No ☐ N/A ☐ Unsure

Document name of the policy and procedure:

Document the section or page number that includes the following elements:

- a. Process for physically or virtually separating 340B inventory from non-340B inventory
- b. Process for tracking 340B drug inventory from receipt through dispensing
- c. Process for reconciling 340B inventory on a routine basis
- d. Process for investigating and resolving inventory discrepancies

Date last reviewed/updated/approved:

If response is "No," "N/A," or "Unsure," explain:

12. Does your organization have a policy and procedure for tracking 340B drugs via accumulation in a virtual replenishment model?

☐ Yes ☐ No ☐ N/A ☐ Unsure

Document name of the policy and procedure:

Document the section or page number that includes the following elements:

- a. Process for configuring accumulator settings within the split-billing software
- b. Process for ensuring that accumulations are generated only for eligible 340B prescriptions
- c. Process for matching NDC numbers between dispensed drugs and replenishment orders
- d. Process for monitoring accumulation balances and preventing over-accumulation
- e. Process for reconciling accumulations against actual replenishment purchases

Date last reviewed/updated/approved:

If response is "No," "N/A," or "Unsure," explain:

13. Does your organization have a policy and procedure for ensuring accumulations and replenishment occur at the 11-digit NDC level?

☐ Yes ☐ No ☐ N/A ☐ Unsure

Document name of the policy and procedure:

Document the section or page number that includes the following elements:

- a. Process for maintaining a CDM (charge description master) crosswalk that maps charge items to specific 11-digit NDC numbers
- b. Process for reviewing and updating the CDM crosswalk when new drugs are added, removed, or when NDC numbers change

Date last reviewed/updated/approved:

If response is "No," "N/A," or "Unsure," explain:

14. Does your organization have a policy and procedure for the prevention of diversion at the parent entity and off-site outpatient facilities (child sites)?

☐ Yes ☐ No ☐ N/A ☐ Unsure

Document name of the policy and procedure:

Document the section or page number that includes the following elements:

- a. Definition of an eligible 340B patient at the covered entity
- b. Process for verifying patient eligibility at the point of care or point of dispensing
- c. Process for ensuring prescriptions are generated from an eligible outpatient encounter at a registered 340B site
- d. Process for ensuring prescribers are employed by or have a contractual arrangement with the covered entity
- e. Process for reviewing and validating 340B claims captured by the split-billing software
- f. Process for identifying and addressing referral prescriptions and their 340B eligibility
- g. Process for handling discharge prescriptions and determining 340B eligibility
- h. Process for routine auditing of dispensing records to detect and prevent diversion

Date last reviewed/updated/approved:

If response is "No," "N/A," or "Unsure," explain:

15. Does your organization have a policy and procedure for monitoring 340B split-billing software for diversion prevention?

☐ Yes ☐ No ☐ N/A ☐ Unsure

Document name of the policy and procedure:

Document the section or page number that includes the following elements:

- a. Process for routinely reviewing software qualification logic and rules to ensure accuracy
- b. Process for validating that the software correctly identifies 340B-eligible versus non-eligible transactions
- c. Process for documenting and resolving software errors or discrepancies

Date last reviewed/updated/approved:

If response is "No," "N/A," or "Unsure," explain:

16. Does your organization have a policy and procedure for the prevention of diversion at contract pharmacies?

☐ Yes ☐ No ☐ N/A ☐ Unsure

Document name of the policy and procedure:

Document the section or page number that includes the following elements:

- a. Process for ensuring that contract pharmacies dispense 340B drugs only to eligible patients of the covered entity
- b. Process for verifying that the prescription originated from an eligible outpatient encounter at a registered 340B site
- c. Process for ensuring that the contract pharmacy agreement includes compliance and audit provisions
- d. Process for monitoring contract pharmacy 340B utilization data for unusual patterns or anomalies
- e. Process for conducting routine audits of contract pharmacy dispensing records
- f. Process for addressing identified instances of diversion at contract pharmacies, including corrective action
- g. Process for terminating contract pharmacy arrangements when compliance cannot be maintained

Date last reviewed/updated/approved:

If response is "No," "N/A," or "Unsure," explain:

17. Does your organization have a policy and procedure for monitoring split-billing software at contract pharmacies?

☐ Yes ☐ No ☐ N/A ☐ Unsure

Document name of the policy and procedure:

Document the section or page number that includes the following elements:

- a. Process for validating that the split-billing software at contract pharmacies correctly identifies 340B-eligible transactions
- b. Process for reviewing and reconciling contract pharmacy 340B claims against covered entity patient records
- c. Process for documenting and resolving discrepancies between contract pharmacy software and covered entity records

Date last reviewed/updated/approved:

If response is "No," "N/A," or "Unsure," explain:

18. Does your organization have a policy and procedure for the prevention of duplicate discounts at the entity and off-site outpatient facilities?

☐ Yes ☐ No ☐ N/A ☐ Unsure

Document name of the policy and procedure:

Document the section or page number that includes the following elements:

- a. Process for identifying Medicaid fee-for-service (FFS) claims and ensuring they are excluded from 340B pricing to prevent duplicate discounts
- b. Process for identifying Medicaid managed care organization (MCO) claims and determining whether 340B pricing or Medicaid rebates apply
- c. Process for utilizing the Medicaid Exclusion File (MEF) and ensuring it is current and accurately loaded into the split-billing software
- d. Process for carving out Medicaid FFS prescriptions from 340B replenishment
- e. Process for billing Medicaid at the 340B ceiling price or actual acquisition cost when applicable
- f. Process for monitoring state Medicaid program changes that affect duplicate discount prevention
- g. Process for documenting and resolving any identified instances of duplicate discounts

Date last reviewed/updated/approved:

If response is "No," "N/A," or "Unsure," explain:

19. Does your organization have a policy and procedure for the prevention of duplicate discounts at contract pharmacies?

☐ Yes ☐ No ☐ N/A ☐ Unsure

Document name of the policy and procedure:

Document the section or page number that includes the following elements:

- a. Process for implementing carve-out or carve-in models at contract pharmacies to prevent duplicate Medicaid discounts
- b. Process for ensuring contract pharmacies correctly apply the Medicaid Exclusion File and exclude Medicaid FFS prescriptions from 340B claims

Date last reviewed/updated/approved:

If response is "No," "N/A," or "Unsure," explain:

20. Does your organization have a policy and procedure that defines material breach and the self-disclosure process?

☐ Yes ☐ No ☐ N/A ☐ Unsure

Document name of the policy and procedure:

Document the section or page number that includes the following elements:

- a. Definition of what constitutes a material breach of 340B Program requirements
- b. Process for identifying and investigating potential material breaches
- c. Process for self-disclosing identified violations to HRSA, including timelines and required documentation
- d. Process for implementing corrective action plans following a material breach or self-disclosure

Date last reviewed/updated/approved:

If response is "No," "N/A," or "Unsure," explain:

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