

Contract Pharmacy Prevention of Diversion

340B Audit Template | Quantum 5D Consulting | 2026

Purpose: This template is designed to assist covered entities in conducting a comprehensive contract pharmacy audit to assess compliance with 340B program requirements. The contract pharmacy audit evaluates three key compliance elements: (1) Eligibility, (2) Prevention of Diversion, and (3) Prevention of Duplicate Discounts. This template addresses the **Prevention of Diversion** element.

340B Contract Pharmacy Compliance Elements:

1. Eligibility

2. Prevention of Diversion

3. Prevention of Duplicate Discounts

Instructions for Completing This Audit

1. **Identify the audit period.** Determine the time frame to be reviewed (e.g., quarterly, semi-annually, or annually). The audit period should align with the covered entity's

internal audit schedule and any applicable regulatory or contractual requirements.

2. **Select a representative sample of prescriptions.** Choose a statistically significant sample of prescriptions dispensed through the contract pharmacy during the audit period. The sample should be large enough to provide confidence in the results. A recommended minimum is 30 prescriptions, though a larger sample may be warranted depending on volume and risk factors. The sample should include a mix of:
 - Payer types (Medicaid, commercial, uninsured/cash)
 - Drug categories (brand, generic, specialty)
 - Prescribers (multiple providers across eligible sites)
 - Time periods (spread across the audit period)
3. **Gather documentation.** For each sampled prescription, collect the prescription record, patient eligibility documentation, dispensing records, purchasing records, and any TPA (third-party administrator) reports relevant to the transaction.
4. **Complete the information form.** Fill in the Covered Entity and Contract Pharmacy Information section with accurate identifying data for both the covered entity and the contract pharmacy under review.
5. **Complete each audit table.** For each sampled prescription, enter the required data into the corresponding audit table. Use the column headers as a guide for what data to record. Leave columns blank if the data element is not applicable to a specific prescription.
6. **Answer all assessment questions.** After completing each audit table, answer the corresponding assessment questions. Use the sub-bullets under each question to guide your response. If the answer is "No" or "Unsure," document the prescription number(s) and provide an explanation in the highlighted response area.
7. **Compile findings and corrective actions.** Upon completion of all audit sections, summarize findings, identify areas of non-compliance or risk, and develop corrective action plans with assigned owners and target completion dates.

Covered Entity & Contract Pharmacy Information

Covered Entity Name:	340B ID:
Entity Type (FQHC, DSH, etc.):	Contract Pharmacy Name:
Contract Pharmacy Address:	Contract Pharmacy NPI:
TPA (Third-Party Administrator):	Audit Period:
Auditor Name / Title:	

Section 1: Patient Eligibility Verification

For each sampled prescription, verify that the patient meets the covered entity's 340B patient definition. Record the following information for each prescription in the audit sample.

Table 1 — Patient Eligibility Verification

Rx #	Patient Name / ID	Date of Service	Drug Name & NDC	Prescriber Name	Prescriber NPI	Eligible CE Site	Encounter Date	Encounter Location
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Rx #	Patient Name / ID	Date of Service	Drug Name & NDC	Prescriber Name	Prescriber NPI	Eligible CE Site	Encounter Date	Encounter Location
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Patient Eligibility Assessment Questions

1.1 Does each patient in the sample have a documented relationship with the covered entity that meets the entity's 340B patient definition?

- **Yes:** Each patient has a qualifying encounter with an eligible provider at a registered covered entity site, and the encounter is documented in the medical record.
- **No:** One or more patients do not have a documented qualifying encounter, or the encounter does not meet the entity's patient definition criteria.
- **N/A:** Not applicable to this audit.
- **Unsure:** Unable to determine based on available documentation.

☐ Yes ☐ No ☐ N/A ☐ Unsure

If response is "No" or "Unsure," indicate Rx # and explain:

1.2 Was the prescription written by a provider who is registered or affiliated with the covered entity and authorized to prescribe under the entity's 340B program?

- **Yes:** Each prescriber is credentialed, employed by, or has a contractual relationship with the covered entity, and is listed as an eligible prescriber.
- **No:** One or more prescriptions were written by providers not affiliated with the covered entity or not authorized under its 340B program.
- **N/A:** Not applicable to this audit.
- **Unsure:** Unable to verify prescriber affiliation based on available records.

☐ Yes ☐ No ☐ N/A ☐ Unsure

If response is "No" or "Unsure," indicate Rx # and explain:

1.3 Does the patient's encounter date fall within the covered entity's defined eligibility window relative to the prescription date of service?

- **Yes:** The patient's qualifying encounter occurred within the entity's defined look-back period (e.g., within 12 months prior to the date of service).
- **No:** One or more patients had encounter dates outside the allowable eligibility window.
- **N/A:** Not applicable to this audit.
- **Unsure:** Unable to determine the encounter date or confirm it falls within the eligibility window.

☐ Yes ☐ No ☐ N/A ☐ Unsure

If response is "No" or "Unsure," indicate Rx # and explain:

1.4 Was the prescription dispensed at a contract pharmacy that is registered in the 340B OPAIS and has a current contract pharmacy agreement with the covered entity?

- **Yes:** The dispensing pharmacy is listed in OPAIS as a registered contract pharmacy for this covered entity and the contract pharmacy agreement is current and executed.
- **No:** The dispensing pharmacy is not registered or the agreement has lapsed.
- **N/A:** Not applicable to this audit.
- **Unsure:** Unable to verify registration status or agreement currency.

☐ Yes ☐ No ☐ N/A ☐ Unsure

If response is "No" or "Unsure," indicate Rx # and explain:

1.5 Is the covered entity maintaining an accurate and current list of eligible prescribers whose prescriptions qualify for 340B pricing at the contract pharmacy?

- **Yes:** The entity maintains a prescriber list that is reviewed and updated at least quarterly, and all prescribers in the sample are on the current list.
- **No:** The prescriber list is outdated, incomplete, or includes providers no longer affiliated with the covered entity.
- **N/A:** Not applicable to this audit.
- **Unsure:** Unable to locate or verify the prescriber list.

☐ Yes ☐ No ☐ N/A ☐ Unsure

If response is "No" or "Unsure," indicate Rx # and explain:

1.6 Are the TPA's patient eligibility determinations consistent with the covered entity's 340B policies and procedures?

- **Yes:** The TPA's eligibility logic and look-back periods match the covered entity's documented policies, and the TPA accurately identified eligible and ineligible patients in the sample.
- **No:** Discrepancies exist between the TPA's determinations and the entity's policies, or the TPA incorrectly classified patients.
- **N/A:** No TPA is used, or TPA eligibility determinations are not part of this audit scope.
- **Unsure:** Unable to compare TPA logic against entity policies.

☐ Yes ☐ No ☐ N/A ☐ Unsure

If response is "No" or "Unsure," indicate Rx # and explain:

1.7 For any prescriptions identified as ineligible during this audit, has the covered entity taken appropriate corrective action (e.g., reversing the 340B claim, replenishing non-340B inventory)?

- **Yes:** Ineligible prescriptions were identified, and the entity has documented corrective actions including reversal of 340B credit, notification to the TPA, and inventory adjustment.
- **No:** Ineligible prescriptions were identified but no corrective action has been taken or documented.
- **N/A:** No ineligible prescriptions were identified in the sample.

- ☐
- Yes
- ☐
- No
- ☐
- N/A
- ☐
- Unsure

For each sampled prescription, reconcile the dispensation record with the corresponding purchase and replenishment records. This section verifies that 340B-purchased drugs are dispensed only to eligible patients and that non-340B inventory is not diverted into the 340B channel.

Rx #	Drug Name & NDC	Qty Dispensed	Date Dispensed	340B or Non-340B	Purchase Order / Invoice #	Purchase Date	Supplier / Wholesaler

Rx #	Drug Name & NDC	Qty Dispensed	Date Dispensed	340B or Non-340B	Purchase Order / Invoice #	Purchase Date	Supplier / Wholesaler
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Inventory Purchase and Dispensation Assessment Questions

2.1 For each prescription in the sample, does the dispensation record match a corresponding 340B purchase or replenishment order for the same drug (NDC) and quantity?

- **Yes:** Each dispensation has a traceable, matching 340B purchase or replenishment record with the correct NDC and quantity.
- **No:** One or more dispensations cannot be matched to a 340B purchase or replenishment order, or there are NDC or quantity discrepancies.
- **N/A:** Not applicable to this audit.
- **Unsure:** Documentation is insufficient to confirm a match.

☐ Yes ☐ No ☐ N/A ☐ Unsure

If response is "No" or "Unsure," indicate Rx # and explain:

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2.2 Are 340B-purchased drugs being dispensed only to patients who meet the covered entity's 340B patient definition, and are non-340B drugs being dispensed to all other patients?

- **Yes:** The contract pharmacy and TPA correctly segregate 340B and non-340B dispensations, and no 340B-purchased drugs were dispensed to ineligible patients.
- **No:** Evidence of diversion exists where 340B drugs were dispensed to non-eligible patients, or non-340B inventory was incorrectly credited to the 340B program.
- **N/A:** Not applicable to this audit.
- **Unsure:** Unable to determine whether segregation is properly maintained.

☐ Yes ☐ No ☐ N/A ☐ Unsure

If response is "No" or "Unsure," indicate Rx # and explain:

2.3 Is the timing of 340B replenishment orders consistent with dispensation activity (i.e., replenishment occurs after dispensation to an eligible patient, not before)?

- **Yes:** Replenishment orders are placed after the eligible dispensation event and within the entity's documented replenishment timeframe.
- **No:** Replenishment orders precede dispensation events, or the timing gap exceeds the entity's documented standards, suggesting potential accumulation or diversion risk.
- **N/A:** The contract pharmacy uses a physical inventory (non-replenishment) model.
- **Unsure:** Unable to determine replenishment timing from available records.

☐ Yes ☐ No ☐ N/A ☐ Unsure

If response is "No" or "Unsure," indicate Rx # and explain:

Section 3: Virtual Inventory Accumulation and Replenishment Reconciliation

This section evaluates the virtual inventory model used at the contract pharmacy. In a virtual inventory (replenishment) model, the contract pharmacy dispenses from its own stock and the TPA identifies eligible 340B claims, generating a replenishment order for 340B-priced drugs. This reconciliation verifies that virtual inventory accumulations and replenishments are accurate and timely.

Table 3 — Virtual Inventory Accumulation and Replenishment Reconciliation

[illegible]

Drug Name & NDC	Accumulated Qty (TPA Report)	Replenishment Qty Ordered	Replenishment Date	Wholesaler / Supplier	Variance (Accumulated vs. Replenished)
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Virtual Inventory Assessment Questions

3.1 Does the quantity of drugs accumulated in the virtual inventory (as reported by the TPA) match the quantity of 340B replenishment orders placed with the wholesaler?

- **Yes:** Accumulated quantities and replenishment order quantities match for all drugs reviewed, with no unexplained variances.
- **No:** Variances exist between accumulated quantities and replenishment orders that have not been explained or resolved.
- **N/A:** The contract pharmacy does not use a virtual inventory / replenishment model.
- **Unsure:** Unable to obtain or reconcile TPA accumulation reports with wholesaler order records.

☐ Yes ☐ No ☐ N/A ☐ Unsure

If response is "No" or "Unsure," indicate drug(s) and explain:

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3.2 Are replenishment orders being placed within the covered entity's defined timeframe (e.g., within 7 days, 14 days, or 30 days of accumulation)?

- **Yes:** All replenishment orders in the sample were placed within the entity's documented timeframe.
- **No:** One or more replenishment orders were placed outside the defined timeframe, creating risk of inventory accumulation or diversion.
- **N/A:** The contract pharmacy does not use a virtual inventory / replenishment model.
- **Unsure:** Unable to determine the timing of replenishment orders relative to accumulation.

☐ Yes ☐ No ☐ N/A ☐ Unsure

If response is "No" or "Unsure," indicate drug(s) and explain:

3.3 Is the covered entity monitoring for over-accumulation of virtual inventory (i.e., accumulating more 340B credit than can reasonably be replenished based on dispensing volume)?

- **Yes:** The entity has a process to identify and investigate instances where accumulated virtual inventory exceeds replenishment capacity or expected dispensing patterns.
- **No:** No monitoring process exists, or over-accumulation has been identified without corrective action.
- **N/A:** The contract pharmacy does not use a virtual inventory / replenishment model.
- **Unsure:** Unable to determine whether the entity monitors for over-accumulation.

☐ Yes ☐ No ☐ N/A ☐ Unsure

If response is "No" or "Unsure," explain:

3.4 Are 340B replenishment orders being placed through the correct 340B purchasing account (not the contract pharmacy's own GPO or WAC account)?

- **Yes:** All replenishment orders in the sample were placed through the covered entity's designated 340B purchasing account with the wholesaler.
- **No:** One or more replenishment orders were placed through a non-340B account, resulting in incorrect pricing or potential duplicate discount.
- **N/A:** Not applicable to this audit.
- **Unsure:** Unable to verify the purchasing account used for replenishment orders.

☐ Yes ☐ No ☐ N/A ☐ Unsure

If response is "No" or "Unsure," indicate drug(s) and explain:

Section 4: Physical Inventory

If the contract pharmacy maintains a physical (segregated) 340B inventory, assess the following. If the contract pharmacy uses a virtual inventory model only, these questions may be marked N/A.

Physical Inventory Assessment Questions

4.1 If the contract pharmacy maintains a physically separate 340B inventory, is the inventory clearly labeled, segregated, and stored separately from non-340B stock?

- **Yes:** 340B inventory is physically separated from non-340B inventory with clear labeling, dedicated shelving or storage areas, and documented segregation procedures.

- **No:** 340B and non-340B inventory are commingled or not clearly labeled, creating a risk of diversion.
- **N/A:** The contract pharmacy does not maintain a physical 340B inventory (virtual inventory model only).
- **Unsure:** Unable to verify physical inventory segregation based on available documentation or site visit.

☐ Yes ☐ No ☐ N/A ☐ Unsure

If response is "No" or "Unsure," explain:

4.2 Does the contract pharmacy conduct periodic physical inventory counts of 340B stock, and are the results reconciled against purchasing and dispensing records?

- **Yes:** Physical inventory counts are conducted at defined intervals (e.g., monthly, quarterly), and the results are reconciled with purchasing invoices and dispensation records with variances documented and investigated.
- **No:** Physical inventory counts are not conducted, are irregular, or results are not reconciled against purchasing and dispensing records.
- **N/A:** The contract pharmacy does not maintain a physical 340B inventory (virtual inventory model only).
- **Unsure:** Unable to determine the frequency or accuracy of physical inventory counts.

☐ Yes ☐ No ☐ N/A ☐ Unsure

If response is "No" or "Unsure," explain:

Section 5: Return to Stock Verification

[illegible]

5.1 When a 340B-eligible prescription is returned to stock at the contract pharmacy, is the 340B credit properly reversed by the TPA, and is the

drug returned to the appropriate inventory (non-340B stock)?

- **Yes:** For all return-to-stock events in the sample, the TPA reversed the 340B credit and the drug was returned to non-340B inventory, with documentation supporting each reversal.
- **No:** One or more return-to-stock events did not result in a 340B credit reversal, or the drug was not returned to the correct inventory channel, creating a diversion risk.
- **N/A:** No return-to-stock events occurred during the audit period.
- **Unsure:** Unable to verify whether 340B credits were reversed or inventory was correctly reclassified.

☐ Yes ☐ No ☐ N/A ☐ Unsure

If response is "No" or "Unsure," indicate Rx # and explain:

Section 6: Contract Pharmacy Purchasing Accounts

This section verifies that the contract pharmacy's 340B purchasing accounts are properly established, authorized, and segregated from the pharmacy's own non-340B purchasing accounts. Improper account setup can lead to diversion, duplicate discounts, or GPO prohibition violations.

Table 5 — Contract Pharmacy Purchasing Accounts

Wholesaler / Supplier	Account Number	Account Type (340B / GPO / WAC)	Authorized Covered Entity
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Wholesaler / Supplier	Account Number	Account Type (340B / GPO / WAC)	Authorized Covered Entity

Purchasing Accounts Assessment Question

6.1 Does the contract pharmacy maintain separate and clearly identified 340B purchasing accounts for each covered entity it serves, and are these accounts distinct from the pharmacy's own GPO or WAC purchasing accounts?

- **Yes:** The contract pharmacy has dedicated 340B purchasing accounts for each covered entity, the accounts are clearly labeled, and they are separate from the pharmacy's non-340B accounts. Account documentation is on file and current.
- **No:** The contract pharmacy commingles 340B and non-340B purchases in the same account, or does not have separate accounts for each covered entity, creating a risk of diversion and duplicate discounts.
- **N/A:** Not applicable to this audit.
- **Unsure:** Unable to verify account setup or segregation based on available documentation.

☐ Yes ☐ No ☐ N/A ☐ Unsure

If response is "No" or "Unsure," explain:

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