**Purpose:** This tool provides a sample self-audit for covered entities to comply with 340B requirements, including the prevention of diversion and duplicate discounts, in contract pharmacy arrangements.

**Background:** In a contract pharmacy arrangement, the covered entity retains responsibility to prevent diversion and duplicate discounts, maintain auditable records, and meet all other 340B Program requirements. Visit the [HRSA OPA June 2015 Update](https://www.hrsa.gov/opa/updates/2015-june) to review best practices for resolving noncompliance in the contract pharmacy setting.

**Instructions:** As a best practice, covered entities should complete this self-audit process at least quarterly; however, exact parameters should be adjusted to meet entity-specific auditing needs. In addition, HRSA recommends that covered entities use annual independent audits of their contract pharmacies as part of fulfilling their ongoing obligation of ensuring 340B Program compliance.

Collect relevant data points to complete this tool, which may include the following:

1. All fully executed contract pharmacy service agreements
2. Utilization reports for all qualified 340B dispenses from contract pharmacies, including payer information
3. Pharmacy accumulation report (if using virtual inventory model)
4. Pharmacy inventory on-hand report (if using physical inventory model)
5. Purchase reports or invoices for all 340B drugs purchased for dispensing at contract pharmacies
6. Contract pharmacy Medicaid billing policies and procedures (fee-for-service and managed care) and state Medicaid requirements/communications, if applicable
7. Select audit samples from utilization reports (*select a representative sample*)
	1. Random: from each contract pharmacy arrangement (e.g., 30 from large chain, 10 from small-volume independent)
	2. Targeted: select dispenses of drugs (1) with a high likelihood of being miscalculated, (2) with a high financial impact should an infraction be identified (e.g., specialty drugs), and (3) any 340B drugs billed to Medicaid

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| **Contract Pharmacy Self-Audit Tool** |
| 1. Entity name
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| 1. Entity 340B ID
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| 1. Name(s) of contract pharmacy organization(s) being audited

*(This could be a chain or independent pharmacy and have multiple service site addresses.)* | *Example:**1. National Chain Pharmacy 1**2. National Chain Pharmacy 2**3. Independent Pharmacy* |
| 1. Date of the LAST self-audit
 |  |
| 1. Audit sample period of LAST self-audit
 |  |
| 1. Date of THIS self-audit
 |  |
| 1. Audit sample period of THIS self-audit

*(Note: 1st day of audit sample period should be the day after the last day of the previous audit sample)* |  |
| 1. Name and title of person completing THIS self-audit
 |  |
| 1. Signature of person completing THIS self-audit
 |  |
| 1. Summary of results:

**Note areas for improvement identified**Review results with 340B steering committee and determine next steps to resolve issues with affected manufacturers and whether results are indicative of a material breach leading to a self-disclosure to HRSA.* Refer to <https://www.340bpvp.com/Documents/Public/340B%20Tools/establishing-material-breach-threshold.docx> as a resource.
 |
| 1. Actions to be taken:

Develop a corrective action plan, if applicable.* Attach corrective action plan that addresses the compliance issues identified in this self-audit and resolution procedure with affected manufacturers.
* Attach corrective action plan resolutions, including completion date, when finished.
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| **Compliance Element: Contract Pharmacy Agreement and 340B OPAIS Record**A covered entity may elect to dispense 340B drugs to its patients through a contract pharmacy arrangement. A covered entity should have in place a written contract pharmacy agreement that accurately identifies the covered entity locations, either by name and address as listed in 340B OPAIS, or by an inclusive statement of all covered entity locations participating in the contract pharmacy arrangement. The written agreement should identify the name and address of all contract pharmacy locations participating in the arrangement. Participating contract pharmacy locations should be registered in 340B OPAIS after the written agreement is in place. |
| **Table 1:**Complete Table 1 (page 4) by using all fully executed contract pharmacy service agreements from data point 1 (page 1) and 340B OPAIS records:* List the name and store number of each location used by the covered entity (column 1).
* List the address of each contract pharmacy location used by the covered entity (2).
* List the covered entity 340B IDs served by the contract pharmacy location (3).
* Document whether the information in columns 1–3 is contained in the executed contract pharmacy agreement (4).
* Document whether the contract pharmacy is registered in the covered entity’s 340B OPAIS record (5).
* Document whether the contract pharmacy information in 340B OPAIS matches the written agreement (6).
* Document whether the contract pharmacy agreement accurately lists all covered entity locations participating in the contract (7).
* Document whether the contract pharmacy agreement including all applicable amendments is signed and dated by both the covered entity and contract pharmacy (8).

**Table 1** |
|  **(1)****Name and store # of contract pharmacy** | **(2)****Contract pharmacy address** | **(3)****Covered entity locations served by contract pharmacy** | **(4)****Contract pharmacy name, store # and address listed on current contract pharmacy agreement?** | **(5)****Contract pharmacy registered in 340B OPAIS as written in the contract pharmacy agreement?** | **(6)****Contract pharmacy name/address in 340B OPAIS matches name/address listed in contract pharmacy agreement?** | **(7)****Contract pharmacy contract lists name and address of each participating covered entity location, or an inclusive statement of all covered entity locations?** | **(8)****Contract pharmacy agreement including all applicable amendments is signed and dated by the covered entity and contract pharmacy?** |
| **YES** | **NO** | **YES** | **NO** | **YES** | **NO** | **YES** | **NO** | **YES** | **NO** |
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|  **Table 1 Assessment Questions** | **Yes** | **No** | **N/A** | **Unsure** |
| 1. **Does an executed agreement exist between the covered entity and the contract pharmacy organization?**

*(Executed agreements must be signed by all parties and dated. Answer “Yes” only if all responses are “Yes” in column 8.)*Attach a copy of the agreement to this self-audit or identify location(s) where document(s) is/are maintained. |  |  |  |
| *If “No” or “Unsure,” explain:*  |
| 1. **Is each contract pharmacy location listed in the current contract pharmacy agreement?***(Answer “Yes” only if all responses are “Yes” in column 4.)*
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| *If “No” or “Unsure,” explain:*  |

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| 1. **Is each contract pharmacy location registered in 340B OPAIS?**

*(Answer “Yes” only if all responses are “Yes” in column 5.)*Attach a copy of the 340B OPAIS record to this self-audit. |  |  |  |  |
| *If “No” or “Unsure,” explain:*  |

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| 1. **Does each contract pharmacy name and address in 340B OPAIS match the contract pharmacy name and address in the executed written contract pharmacy agreement?**

*(Answer “Yes” only if all responses are “Yes” in column 6.)*  |  |  |  |
| *If “No” or “Unsure,” explain:*  |
| 1. **Does each contract pharmacy contract list the name and address of each participating covered entity location, or an inclusive statement of all covered entity locations?**

*(Answer “Yes” only if all responses are “Yes” in column 7.)* |  |  |  |
| *If “No” or “Unsure,” explain:*  |
| 1. **Has the covered entity performed an annual independent audit of its contract pharmacy operations?**

If so, document the date and name of independent organization that performed the audit. |  |  |  |
| *If “No” or “Unsure,” explain:*  |

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| **Compliance Element: Prevention of Diversion***Covered entities are responsible for ensuring compliance of their contract pharmacy arrangement(s) with all 340B Program requirements. The contract pharmacy, with the assistance of the covered entity, will establish and maintain a tracking system suitable to prevent diversion of 340B drugs and duplicate discounts on the drugs.**NOTE: You will need a copy of Table 2 for each contract pharmacy organization audited.* |
| **Table 2**Complete Table 2 (page 7) using information from data points 2–7 (page 1):* Fill in the contract pharmacy organization name and date of audit.
* For each dispense selected from the audit sample, record Rx# (1), date filled (2), and name and store # of contract pharmacy that dispensed the drug (3).*Note: Add more rows as needed to accommodate your audit sample size from data point 7a/b (page 1).*
* Identify if the prescription was dispensed to a patient of the entity (4).
* Locate the encounter in the medical record where the patient received an eligible service for the prescription; confirm service eligibility, including appropriate auditable records/documentation (5) and provider eligibility (6).
* *For grantees only*: Evaluate whether the service provided in the encounter was consistent with the scope of grant (7).
* If using a replenishment inventory model, confirm that appropriate quantities were accumulated (8).
* Confirm that the 340B purchase/replenishment order was correct and received by the contract pharmacy (9).

In other words, did the 340B purchase deduct appropriately from available accumulations (11-digit NDC level) and was it physically received by the contract pharmacy? |
| **Table 2** | **Contract Pharmacy Organization:** | *Example: Pharmacy Chain Name* |
| **Sample Number** | **(1)****Rx number** | **(2)****Date filled** | **(3)****Name and store # of contract pharmacy** | **(4)****Dispensed to patient of the entity?**  | **(5)****From eligible entity service/ encounter and documented in health care record?** | **(6)****Written by eligible provider?**  | **(7)*****GRANTEES ONLY*****Services included in scope of grant?**  | **(8)****Quantity accumulated correctly?** | **(9)****Appropriate quantities purchased for replenishment and received by contract pharmacy?** |
| **YES** | **NO** | **YES** | **NO** | **YES** | **NO** | **YES** | **NO** | **YES** | **NO** | **YES** | **NO** |
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| **Table 2 Assessment Questions** | **Yes** | **No** | **N/A** | **Unsure** |
| 1. **Were all prescriptions filled at a contract pharmacy location registered on 340B OPAIS?**

*Compare location where prescription was dispensed to the covered entity’s contract pharmacy listing.**Answer “Yes” only if all audited contract pharmacy locations are listed in 340B OPAIS.* |  |  |  |
| *If “No” or “Unsure,” explain:*  |
| 1. **Were all prescriptions dispensed to a patient of the entity and written pursuant to encounters from 340B eligible services documented in the patients’ health care records?**

*CHCs/grantees: An eligible service may include services provided by any associated sites of the health center or a location included in the scope of grant or FQHC-LA designation. Consider whether the service is consistent with the scope of grant and how the covered entity defines an eligible service in its policies and procedures.* *Hospitals: An eligible service may include those provided by the parent hospital or offsite outpatient locations of the covered entity. Consider how the covered entity defines an eligible service in its policies and procedures.* *Any purchase, dispense, or administration elsewhere should be evaluated to ensure that there are auditable records maintained for each patient receiving a 340B drug.* *Referral prescriptions (if applicable):* *Does the covered entity maintain a record of the patient’s health care demonstrating its responsibility for the care provided that resulted in the referral prescription, consistent with the 340B patient definition guideline?**Answer “Yes” only if all responses are “Yes” in columns 4 and 5 in Table 2.* |  |  |  |
| *If “No” or “Unsure,” explain:*  |

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| **Table 2 Assessment Questions** | **Yes** | **No** | **N/A** | **Unsure** |

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| 1. **Were all prescriptions written by 340B-eligible providers?**

For each sample, review a copy of the documentation (e.g., credentialing, contract,or other arrangement) that demonstrates the provider’s relationship with the covered entity.*Answer “Yes” only if all responses are “Yes” in column 6 in Table 2.* |  |  |  |  |
| *If “No” or “Unsure,” explain:*  |

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| 1. **(Grantees only) Were all prescriptions written pursuant to an encounter for a service consistent with the scope of grant?**

*Answer “Yes” only if all responses are “Yes” in column 7 in Table 2.* |  |  |  |
| *If “No” or “Unsure,” explain:*  |
| 1. **Was the appropriate drug quantity accumulated (replenishment models only) and, if quantities were sufficient, was the subsequent 340B purchase/replenishment order correct and received by the contract pharmacy?**

*Answer “Yes” only if all responses are “Yes” in columns 8 and 9 in Table 2.* |  |  |  |
| *If “No” or “Unsure,” explain:*  |
| **Compliance Element: Prevention of Duplicate Discounts for Medicaid FFS Carve-Out***Contract pharmacies may not dispense 340B drugs to Medicaid fee-for-service (FFS) patients (i.e., are required to carve out Medicaid FFS) unless the covered entity, contract pharmacy, and state Medicaid agency have established an arrangement to prevent duplicate discounts. Any such arrangement shall be reported to HRSA OPA by the covered entity. Contract pharmacy carve-in requests are reviewed by HRSA, and, if approved, are listed with a carve-in effective date on 340B OPAIS.**For information on seeking contract pharmacy carve-in approval from HRSA, review the Contract Pharmacy Medicaid Carve-In Checklist* [https:/www.340bpvp.com/Documents/Public/340B%20Tools/contract-pharmacy-medicaid-carve-in-checklist.docx](https://www.340bpvp.com/Documents/Public/340B%20Tools/contract-pharmacy-medicaid-carve-in-checklist.docx)*Note: HRSA encourages covered entities to work with states and their respective Medicaid managed care organizations (MCOs) to develop strategies to prevent duplicate discounts. In some cases, states have placed certain requirements on covered entities regarding the prevention of duplicate discounts for drugs billed to MCOs. Additional PVP resources available to help covered entities locate state-specific requirements for carving in and for use of 340B for Medicaid patients can be found at* <https://www.340bpvp.com/resource-center/medicaid>*Complete this section if Medicaid FFS is carved out for contract pharmacy arrangements.* |
| **Assessment Questions for Medicaid FFS CARVE-OUT** | **Yes** | **No** | **N/A** | **Unsure** |
| 1. **For contract pharmacies that carve out, is Medicaid FFS ever the payer for 340B dispenses?**

Identify the billing codes (BIN, PCN, and/or group numbers) used by the contract pharmacy to bill Medicaid FFS. Ensure that all the claims in the 340B utilization file do not list a Medicaid FFS billing code (including primary, secondary, and tertiary payers, as applicable).*Answer “No” only if Medicaid was* ***never*** *the payer for any contract pharmacy prescriptions.**If Medicaid FFS claims are identified in the 340B utilization report, determine corrective action.* |  |  |  |
| *If “Yes” or “Unsure,” explain:*  |

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| **Compliance Element: Prevention of Duplicate Discounts for Medicaid FFS Carve-In***Contract pharmacies are prohibited from using 340B drugs to dispense Medicaid FFS prescriptions and must carve out unless the covered entity, contract pharmacy, and state Medicaid agency have established an arrangement to prevent duplicate discounts reported and approved by HRSA. Contract pharmacy carve-in requests are reviewed by HRSA and, once approved, the arrangement is listed with a carve-in effective date on 340B OPAIS. A covered entity may not dispense 340B drugs to Medicaid FFS patients at the contract pharmacy until the carve-in effective date is listed on 340B OPAIS. Note: this type of arrangement is uncommon.**Complete this section if Medicaid FFS is carved in for contract pharmacy arrangements.*  |
| **Table 3**Complete Table 3 (page 12) by identifying a sample of Medicaid FFS claims dispensed from each contract pharmacy organization in which the covered entity carves in Medicaid FFS.* Fill in the contract pharmacy organization name and date of audit.
* For each Medicaid FFS dispense selected from the audit sample, record prescription number (1), date filled (2), and name and store number of contract pharmacy that dispensed the product (3). Add additional rows as needed for sample size.
* List the covered entity location and corresponding 340B ID (if applicable) where the patient received an eligible service for the prescription (4).
* List the Medicaid payer’s BIN/PCN/group number(s) (5).
* Compare the information in columns 3 and 4 to the 340B OPAIS to complete (6).
* To complete (7), compare the prescription billing record to the state’s requirements for billing 340B drugs dispensed at contract pharmacy to Medicaid FFS.
	+ Medicaid billing requirements should be listed in the documented arrangement between covered entity, the contract pharmacy, and the state Medicaid agency and align with the state plan amendment (SPA).
		- For information on contract pharmacy carve-in arrangements, download the [Contract Pharmacy Medicaid Carve-In Checklist](https://www.340bpvp.com/Documents/Public/340B%20Tools/contract-pharmacy-medicaid-carve-in-checklist.docx).
		- For information on reported state Medicaid requirements, visit [www.340bpvp.com/resource-center/medicaid](https://www.340bpvp.com/resource-center/medicaid). Stakeholders are encouraged to contact the states to verify current policy/requirements.

Note: You will need a copy of Table 3 for each contract pharmacy organization in which the covered entity carves in Medicaid FFS. |
| **Table 3** | **Contract Pharmacy Organization:** | *Example: Pharmacy Chain Name* |
| **Sample Number** | **(1)****Rx number** | **(2)****Date filled** | **(3)****Name and store # of contract pharmacy** | **(4)****Covered entity location and 340B ID (if applicable) of eligible service for prescription** | **(5)****BIN/PCN/group # for Medicaid FFS payer** | **(6)****Does the entity location (4) have the contract pharmacy location (3) registered on 340B OPAIS with a Medicaid FFS carve-in effective date?** | **(7)****Was the 340B drug billed according to state Medicaid requirements?** |
| **YES** | **NO** | **YES** | **NO** |
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| **Table 3: Assessment Questions for Medicaid FFS CARVE-IN** | **Yes** | **No** | **N/A** | **Unsure** |
| 1. **Were all Medicaid FFS prescriptions dispensed from a contract pharmacy location on 340B OPAIS with a carve-in effective date?**

*Answer “Yes” to this question only if all responses in column 6 are “Yes.”* |  |  |  |
| *If “No” or “Unsure,” explain:*  |

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| 1. **For each prescription tested in Table 3, was Medicaid FFS billed according to state Medicaid requirements?**

*Answer “Yes” only if all dispenses met the state requirements.* |  |  |  |  |
| *If “No” or “Unsure,” explain:*  |

*This tool is written to align with Health Resources and Services Administration (HRSA) policy, and is provided only as an example for the purpose of encouraging 340B Program integrity. This information has not been endorsed by HRSA and is not dispositive in determining compliance with or participatory status in the 340B Drug Pricing Program. 340B stakeholders are ultimately responsible for 340B Program compliance and compliance with all other applicable laws and regulations. Apexus encourages all stakeholders to include legal counsel as part of their program integrity efforts.*

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