**Purpose:** This tool provides an example of a self-audit best practice for community health centers (CH/FQ/FQHC/FQHCLA/NH) to comply with 340B requirements regarding the prevention of diversion.

**Background:** Section 340B of the PHSA prohibits diversion – the resale or other transfer of a 340B drug to ineligible patients. To adhere to this requirement, a covered entity is responsible for the tracking and accountability of its 340B drugs to ensure that diversion has not occurred.

**This self-audit tool is part of a series focusing on three compliance elements:**

**1. Eligibility**

**2. Prevention of Diversion**

**3. Prevention of Duplicate Discounts**

Prior to completing the Eligibility Self-Audit Tool, covered entities are encouraged to:

* Map their 340B drug universe (this tool is available in [Word](https://www.340bpvp.com/Documents/Public/340B%20Tools/340B-universe-mapping-template.docx) and [Excel](https://www.340bpvp.com/Documents/Public/340B%20Tools/340B-universe-mapping-template.xlsx))
* Complete the Covered Entity [Self-Audit: Policy and Procedure](https://www.340bpvp.com/Documents/Public/340B%20Tools/self-audit-policy-and-procedure.docx).

**Instructions:** Covered entities should complete this tool at least quarterly, however exact parameters should be adjusted to meet entity-specific auditing needs.

The following data points are used to complete this tool:

1. Identify and collect relevant data for the most recent 3-month period, as follows:
2. List of eligible covered entity service locations (clinics/departments/service units including main site and associated sites registered on 340B OPAIS)
3. List of eligible providers
4. Proof of provider eligibility (contract/employment records, referral for consultation)
5. Patients’ health care records
6. 340B dispensing records
7. 340B purchasing invoices
8. NDC crosswalk (for virtual inventory)
9. Accumulation report (for virtual inventory)
10. Inventory report (for physical inventory)
11. Audit samples.
12. Select 20 invoices from 340B purchases, as follows: 10 invoices with the highest volume (number of lines) and 10 invoices with the highest total cost
13. Randomly select 20 ***different*** drugs from the 340B purchasing invoices identified in step 2a
(recommend one per invoice)
14. Randomly select one **340B** dispense/administration for each of the 20 drugs from step 2b
15. Randomly select 1 day of accumulations from the accumulation report

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| **CHC Diversion Self-Audit Tool** |
| 1. Entity’s name
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| 1. Entity’s 340B ID
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| 1. Entity’s physical address (including suite number, if applicable and associated sites)
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| 1. Date of the LAST self-audit
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| 1. Audit sample period of LAST self-audit
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| 1. Date of THIS self-audit
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| 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 individual completing THIS self-audit
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| 1. Signature of individual 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 impacted manufacturers and whether results are indicative of a material breach leading to a self-disclosure to HRSA.* Refer to [Establishing Material Breach Threshold Tool](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 impacted manufacturers
* Attach corrective action plan resolutions, including completion date, when finished
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| **Compliance Element: Prevention of Diversion***Section 340B of the Public Health Service Act prohibits the resale, or other transfer, of a 340B drug to a person who is not a patient of the entity. Covered entities are responsible for maintaining an accurate patient eligibility determination system, including tracking and accounting all of 340B drugs at the covered entity to ensure that diversion has not occurred.* |
| **PATIENT ELIGIBILITY VERIFICATION****Table 1*** For each of the 20 administrations/dispenses selected in step 2c of the instructions (page 1) and for the date range selected in step 1 of the instructions, verify patient eligibility by validating the dispense/administration record against the entity’s health care record
* Validate that the prescription/drug order is the result of a health care service included in the scope of grant and was provided to a covered entity patient at an eligible site by an eligible provider such that the covered entity documents its responsibility for care in its health care record
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| **Table 1****340B Eligibility Determination Verification Table****Time period tested: begin date\_\_\_\_\_ to end date\_\_\_\_\_.**(attach actual data to substantiate eligibility for each sample) |
| **(1)****Sample ID (prescription number or dispense tracking number)** | **(2)****Date****dispensed/****administered** | **(3)****Drug dispensed/****administered/ prescribed based on eligible CE service?** | **(4)****Drug dispensed/ administered/ prescribed from location with a****340B ID?** | **(5)****Drug dispensed/ administered as a result of a service included in the scope of grant?** | **(6)*****ELIGIBLE* Provider** | ***(7)******DRUG* and *VISIT* documented** **in covered entity’s health care record?** |
| **(A)****Employed/****contracted?** | **(B)****Documented referral?** |
| **YES** | **NO** | **YES** | **NO** | **YES** | **NO** | **YES** | **NO** | **YES** | **NO** | **YES** | **NO** |
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| **Table 1 Assessment Questions**  | **Yes** | **No** | **N/A** | **Unsure** |
| 1. **Did each of the administered/dispensed 340B drugs tested in Table 1 originate from an eligible CE service?**

*(An eligible clinic includes services provided by the main health center or an outpatient offsite location included in the scope of grant or FQHC-LA designation.)*Answer “Yes” to the question only if all answers are YES the column 3, “340B eligible location,” in Table 1.  |  |  |  |  |
| *If response is “No” or “Unsure,” explain: (Identify and discuss each outlier)* |
| 1. **Did each of the administered/dispensed 340B drugs tested in Table 1 originate from an eligible location registered on the entity’s 340B OPAIS record?**

*(The eligible clinic location is registered on 340B OPAIS as the main health center or associated site. Sites must be operational in the HRSA Electronic Handbook prior to being registered in 340B OPAIS.)*Answer “Yes” to the question only if all answers are YES in column 4, “Location with 340B ID,” in Table 1. |  |  |  |  |
| *If response is “No” or “Unsure,” explain: (Identify and discuss each outlier)* |
| 1. **For each administered/dispensed 340B drug tested in Table 1, was the drug dispensed/administered as a result of a service included in the scope of grant or FQHC-LA designation (if applicable)?**

Answer “Yes” to the question only if all answers are YES in column 5, “Drug dispensed/administered as a result of a service included in the scope of grant?” in Table 1. |  |  |  |  |
| *If response is “No” or “Unsure,” explain: (Identify and discuss each outlier)* |
| 1. **For each administered/dispensed 340B drug in Table 1, did each patient receive health care from providers who were employed or contracted by the covered entity, or provided care under other arrangements (such as a referral for consultation)?**
* List providers who prescribed the drug deemed 340B eligible
* Compare this list to the entity’s eligible provider list
* Identify providers who are employed or contracted
* Identify providers providing care as a result of a referral for consultations and locate documentation of referral for consultation including record of the prescribed medication
* Determine eligibility of providers

Answer “Yes” to the question only if a YES is documented in either column 6a or 6b, “Eligible provider?” in Table 1.  |  |  |  |  |
| *If response is “No” or “Unsure,” explain: (Identify and discuss each outlier)* |
| 1. **Were each of the administered/dispensed 340B drugs tested in Table 1 part of an episode of care documented in the patient’s health care record maintained by the entity?**

*(Demonstrates that the covered entity maintains responsibility for the care of the patient)* Answer “Yes” to the question only if all answers are YES in column 7, “Drug and visit documented in the entity’s health care record?” in Table 1. |  |  |  |
| *If response is “No” or “Unsure,” explain: (Identify and discuss each outlier)* |

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| **INVENTORY PURCHASE AND DISPENSE RECONCILIATION** **Table 2*** As a best practice, this table can be used for both **physically separate inventory** and **virtual inventory models**. The covered entity should have inventory management procedures in place to prevent diversion of 340B drugs to ineligible patients, which may involve a different process than this table based on the entity.
	+ - Best Practices
			* Inventory process is outlined from the receipt of the medication to the dispensation/administration of the medication
			* Routine inventory counts
			* Reconcile inventory counts with inventory system
			* Adjusting and reconciling variances (including documentation of outcome)
* In this example, for each of the 20 drug audit samples selected in step 2b of the instructions (page 1) and for the date range in step 1 of the instructions, use purchasing, dispensing, and inventory records to reconcile inventory units
	+ Note that “dispensed units” refers to either dispensed units (if entity charges upon dispense) or administered units (if entity charges upon administration)
	+ For physically separate inventory: Note that “inventory units” refers to the number of units in stock (actually on the shelves)
	+ For virtual inventory: Note that “inventory units” refers to the number of units in the accumulator
	+ Any identified variance will need to be resolved and documented to demonstrate that the 340B drug was not diverted
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| **Table 2****Purchases and Dispenses Reconciliation Table****Time period tested: begin date\_\_\_\_\_ to end date\_\_\_\_\_.**(Attach data to substantiate reconciliation for each sample) |

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| **(1)****340B drug name and strength** | **(2)****NDC** | **(3)****Date range selected through today’s date** | **(4)****Beginning inventory****(units)** | **(5)****(–) Dispensed****(units)** | **(6)****(+) Purchased****(units)** | **(7)****(=)** **Ending** **inventory****(units)** | **(8)****Inventory Units Reconciled?** | **(9)****Variance Resolved?** |
| **Yes** | **No** | **Yes** | **No** |
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| **Table 2 Assessment Questions**  | **Yes** | **No** | **N/A** | **Unsure** |

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| **For each of the drugs tested in Table 2 during the defined time period, does the number of units purchased and dispensed reconcile to the number of units left in inventory?**Answer “Yes” to the question only if all answers are YES in column 8, “Inventory units reconciled?” in Table 2. |  |  |  |  |
| *If response is “No” or “Unsure,” explain: (Identify and discuss each outlier)* |
| 1. **For each of the drugs tested in Table 2 during the defined time period, were all identified variances resolved and documented?**

*(Demonstrates that variances in drugs dispensed versus purchased were not the result of diversion)*Answer “Yes” to the question only if all answers are YES in column 9, “Variance resolved?” in Table 2.  |  |  |  |  |
| *If response is “No” or “Unsure,” explain: (Identify and discuss each outlier)* |
| **Physical Inventory** |
| 1. **If using a physical inventory method, are the 340B drugs distinguishable from the non-340B drugs on the shelves?**

To answer this question, the reviewer will be required to visit the medication storage area(s) involved in this self-audit. |  |  |  |  |
| *If response is “No” or “Unsure,” explain:*  |

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| **VIRTUAL INVENTORY ACCUMULATION AND REPLENISHMENT RECONCILIATION****Table 3** * Randomly select 1 day of accumulations for each of the 20 drugs selected in step 2b of the instructions

(page 1)* Use the NDC crosswalk and pharmacy accumulation report to ensure that the accumulation and replenishment process uses an exact 11-digit NDC match for each drug
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| **TABLE 3** **Accumulation and Replenishment Reconciliation Table****Time period tested: begin date\_\_\_\_\_\_ to end date\_\_\_\_\_**(attach data to substantiate reconciliation for each sample) |
| **(1)****Sample ID**  | **(2)****Accumulation identifier or record associated with prescription number or dispense tracking number** | **(3)****Date****Of accumulation** | **(4)****Drug NDC and quantity dispensed matches quantity accumulated?**  | **(5)****NDC billed matches NDC accumulated?** | **(6)****Drug NDC and quantity ordered match drug NDC and quantity deducted from 340B accumulator?** | **(7)****Drug NDC and quantity received match drug NDC and quantity ordered?** |
| **YES** | **NO** | **YES** | **NO** | **YES** | **NO** | **YES** | **NO** |
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| **Table 3 Assessment Questions** | **Yes** | **No** | **N/A** | **Unsure** |
| **For each drug sample tested in Table 3, was the dispensed quantity correctly accumulated?**Answer N/A if a physical inventory is used.Answer “Yes” to the question only if all answers are YES in column 4, “Drug NDC quantity dispensed matches quantity accumulated?” in Table 3. |  |  |  |  |
| *If response is “No” or “Unsure,” explain: (Identify and discuss each outlier)* |
| 1. **For each drug sample tested in Table 3, did the 11-digit NDC billed match the 11-digit NDC accumulated?**

Answer N/A if a physical inventory is used.Answer “Yes” to the question only if all the answers are YES in column 5, “NDC billed matches NDC accumulated?” in Table 3. |  |  |  |  |
| *If response is “No” or “Unsure,” explain: (Identify and discuss each outlier)* |
| 1. **For each drug sample tested in Table 3, did the drug NDC and quantity ordered on the entity’s 340B account match the drug NDC and quantity deducted from the 340B accumulator?**

 Answer N/A if a physical inventory is used.Answer “Yes” to the question only if all answers are YES in column 6, “Drug NDC and quantity ordered match drug NDC and quantity deducted from 340B accumulator?” in Table 3. |  |  |  |  |
| *If response is “No” or “Unsure,” explain: (Identify and discuss each outlier)* |
| 1. **For each drug tested in Table 3, did the drug NDC and quantity received match the drug NDC and quantity ordered?**

Answer N/A if a physical inventory is used.Answer “Yes” to the question only if all the answers are YES in column 7, “Drug NDC and quantity received matches drug NDC and quantity ordered?” in Table 3. |  |  |  |  |
| *If response is “No” or “Unsure,” explain: (Identify and discuss each outlier)* |

*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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