**Purpose:** This tool provides a sample self-audit for rural hospitals (CAH/RRC/SCH) 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 Prevention of Diversion Self-Audit Tool, covered entities are encouraged to:

* Map their 340B drug universe(this tool is available in [Word](https://docs.340bpvp.com/documents/public/resourcecenter/340b-universe-mapping-template.docx) and [Excel](https://docs.340bpvp.com/documents/public/resourcecenter/340b-universe-mapping-template.xlsx))
* Complete the [Covered Entity Self Audit: Policy and Procedure](https://docs.340bpvp.com/documents/public/resourcecenter/covered-entity-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 locations (clinics/departments/service units)
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. Select audit samples. Adjust sample size based on entity’s policies and procedures.
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

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| **Hospital Diversion Self-Audit Tool** |
| 1. Entity’s name (parent site, off-site outpatient facility,

 or entity-owned pharmacy) |  |
| 1. Entity’s 340B ID
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| 1. Entity’s physical address (including suite number, if applicable)
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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
 |  |
| 1. Signature of individual completing THIS self-audit
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| 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://docs.340bpvp.com/documents/public/resourcecenter/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 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 from *ELIGIBLE* location?** | **(4)****Drug dispensed/ administered/ prescribed from *LOCATION* with a****340B ID?** | **(5)****Patient was an OUTPATIENT?** | **(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** |

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| 1. **Did each of the administered/dispensed 340B drugs tested in Table 1 originate from an eligible location?**

*(An eligible location includes the parent entity and off-site outpatient locations included on the most recently filed Medicare Cost Report as a reimbursable clinic with associated costs/charges.)* * List eligible locations as determined by the Medicare Cost Report
* Identify location from which dispense/administration/prescription originated
* Compare location to list to determine eligibility of location.

Answer “Yes” to the question only if all answers are “YES” in column 3, “Drug dispensed/administered/prescribed from ELIGIBLE location?” |  |  |  |
| *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?**

*(A parent entity or off-site outpatient location registered on the entity’s 340B OPAIS record and included on the most recently filed Medicare Cost Report as a reimbursable clinic with associated costs/charges.)* * List locations registered on 340B OPAIS
* Identify location from which dispense/administration/prescription originated
* Compare location to 340B OPAIS record

Answer “Yes” to the question only if all answers are “YES” in column 4, “Drug dispensed/ administered/ prescribed from LOCATION with a 340B ID?” |  |  |  |
| *If response is “No” or “Unsure,” explain: (Identify and discuss each outlier)* |
| 1. **For each administered/dispensed 340B drug tested in Table 1, was each patient an outpatient at the time the medication was administered/dispensed, as defined by the covered entity’s policy and procedure?**

Answer “Yes” to the question only if all answers are “YES” in column 5, “Patient was an OUTPATIENT?” |  |  |  |
| *If response is “No” or “Unsure,” explain: (Identify and discuss each outlier)* |

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| 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 providing 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 a documented referral for consultation and a documented summary of the referral visit in the patient’s medical records
* Determine eligibility of providers

Answer “Yes” to the question only if a “YES” is documented in either column 6A or 6B, “Eligible provider.” |  |  |  |
| *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 encounter 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 covered entity’s health care record?” |  |  |  |
| *If response is “No” or “Unsure,” explain: (Identify and discuss each outlier)* |

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| **INVENTORY PURCHASE AND DISPENSATION 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 dispensation) or administered units (if entity charges upon administration)
* For physically separate inventory: Note that the “inventory units” refers to the number of units in stock (actually on the shelves if physical inventory)
* For virtual inventory: Note that the “inventory units” refers to either the number of units in the accumulator (if virtual replenishment)
* Any identified variance will need to be resolved and documented to demonstrate that the 340B drug was not diverted
* For virtual inventory: For column 3 “Billing unit per package,” review the ***actual*** billing units per package for the specific drug in column 1
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|  | **Table 2****Purchases and Dispensations Reconciliation Table****Time period tested: begin date\_\_\_\_\_ to end date\_\_\_\_\_.**(attach data to substantiate reconciliation for each sample) |
| **(1)****340B drug name and strength** | **(2)****NDC** **(if virtual inventory)** | **(3)****Billing unit per package (if virtual inventory)** | **(4)****Date range selected through today’s date** | **(5)****Beginning inventory****(units)** | **(6)****(–) Dispensed****(units)** | **(7)****(+) Purchased****(units)** | **(8)****(=)** **Ending** **inventory****(units)** | **(9)****Inventory units Reconciled?** | **(10)****Variance resolved?** |
| **YES** | **NO** | **YES** | **NO** |
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| **Table 2 Assessment Questions**  | **Yes** | **No** | **N/A** | **Unsure** |
| **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 9, “Inventory units reconciled?” |  |  |  |  |
| *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 were not the result of diversion)*Answer “Yes” to the question only if all answers are “YES” in column 10, “Variance resolved?” |  |  |  |  |
| *If response is “No” or “Unsure,” explain: (Identify and discuss each outlier)* |
|  **Virtual Inventory**  |
| 1. **If using a virtual inventory method, for each drug tested in column 3, is the**

**calculation of actual billing units per package accurate and does it match** **the split-billing software configuration/setup for each specific NDC?***(Variances due to billing unit discrepancies will prohibit the inventory from reconciling)*Answer “N/A” if a physical inventory is used.Answer “Yes” to the question only if the split-billing software contains the accurate billingunits per package for all drugs tested 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?**

Answer N/A if a virtual inventory is used.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: (Identify and discuss each outlier)* |

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| **VIRTUAL INVENTORY ACCUMULATION AND REPLENISHMENT RECONCILIATION** **Table 3*** Complete this table if using a virtual inventory (*not applicable for physical 340B inventories*)
* Randomly select one 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 actual 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 matches 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** |
| 1. **For each drug sample tested in Table 3, was the dispensed quantity correctly accumulated?**

Answer “Yes” to the question only if all the answers are “YES” in column 4, “Drug NDC and quantity dispensed matches quantity accumulated?” |  |
| *If response is “No” or “Unsure,” explain: (Identify and discuss each outlier)* |
|  | **Yes** | **No** |  **N/A Unsure** |
| 1. **For each drug sample tested in Table 3, did the 11-digit NDC billed match the 11-digit NDC accumulated?**

Answer “Yes” to the question only if all the answers are “YES” in column 5, “NDC billed matches NDC accumulated?” |  |  |  |
| *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 ordered on the pharmacy’s 340B account match the drug NDC and quantity deducted from the 340B accumulator?**

 *(Quantity in accumulator is based on billing units per package (BUPP).)*  Answer “Yes” to the question only if all the answers are “YES” in column 6,  “Drug NDC and quantity ordered matches drug NDC and quantity deducted from  340B accumulator?” |  |  |  |
| *If response is “No” or “Unsure,” explain: (Identify and discuss each outlier)* |

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| 1. **For each drug tested in Table 3, did the drug NDC and quantity received match the drug NDC and quantity ordered?**

Answer “Yes” to the question only if all the answers are “YES” in column 7, “Drug NDC and quantity received match drug NDC and quantity ordered?” |  |  |  |  |
| *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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