**Purpose:** This tool is designed to assist covered entities with development and implementation of a consignment program that is compliant with 340B Program policy.

**Background:** Pharmaceutical consignment programs were developed to assist health care organizations with the management of high-cost, low-use medications that are essential to keep on hand. Under a consignment program, the financial ownership of the drug remains with the vendor until the product is dispensed to the patient. After the drug is used, the vendor bills the entity using either a 340B, wholesale acquisition cost (WAC), or group purchasing organization (GPO) account, depending on the patient’s eligibility. By not absorbing the cost of the drug until it is used, the entity minimizes the risk of drug expiration and lowers its total cost of inventory on hand.

**340B Program Considerations:** Covered entities using a mixed-use inventory must take special precautions when developing a consignment program because drugs are dispensed to both 340B eligible and ineligible patients. If an entity does not carefully coordinate the product use with the patient status and proper ordering account, there is an increased risk for 340B diversion or GPO Prohibition violation (for DSH/PED/CAN).

To support compliance, covered entities dispensing covered outpatient drugs through a consignment inventory should develop a 340B-compliant process for dispensing and replenishing these drugs. If electronic integration between the consignment vendor and split-billing software is not available, it may be necessary to manually enter consignment utilization and purchase data into the split-billing software. It is important to include the consignment inventory process in the covered entity’s policies and procedures and train all staff members who work with consignment inventory on 340B-compliant practices and documentation. Incorporating the consignment program within internal self-audits may help to identify and correct any gaps.

**Implementation Checklist:**

1. Select a consignment vendor that supports 340B Program compliance and integrates with your pharmacy model.
2. Prior to implementation, identify staff members who will access the consignment inventory and ensure that they receive adequate 340B training, including inventory management and reordering practices.
3. Develop a process for determining patient status either before the drug is removed from consignment or retroactively, depending on the selected consignment program.
4. Outline a detailed process for consignment inventory documentation that helps confirm that consignment drugs are billed and repurchased on the appropriate accounts based on patient status.
5. Create a regular self-auditing process to ensure that all compliance elements are consistently met.

**Considerations When Selecting a Vendor:**

1. Which of the models listed in the following table does the vendor support? Which of these models works best for your site’s operations and 340B compliance controls?
2. What reporting is available from the vendor? Is there integration with split-billing software?
3. How is inventory reconciled? What processes (manual or otherwise) is the covered entity responsible for?
4. Does the vendor have a process for making corrections through a credit-and-rebill process to support compliance?
5. How often is invoicing done (weekly, monthly)? Does this timing correspond with the covered entity’s ability to gather necessary patient eligibility information and submit to the vendor?

In this tool, we outline consignment program operations and address 340B compliance considerations for the different types of inventory tracking models available.

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|  | **Replenishment/Neutral Inventory Model** | | **Physical Inventory Model** | |
| **Operational Considerations** | **Compliance Considerations** | **Operational Considerations** | **Compliance Considerations** |
| **Radio Frequency Identification (RFID) Active or Passive** | Initial neutral inventory is ordered by customer and inventory is managed by vendor.  Refrigerators or storage units come with continuous or intermittent monitoring trackers of inventory.  Active RFID tracking identifies usage upon removal from storage unit; passive RFID tracking uses snapshot monitoring.  Requires returning unused products to the storage unit, within a specified period, to avoid being invoiced for unused product. | A usage report based on RFID tracking is provided to the consignment vendor prior to invoicing.  The customer identifies the account(s) (WAC/ GPO/340B) to be invoiced based on patient eligibility and/or accumulations; selection should be defendable and auditable.  Accumulations may need to be updated manually to maintain compliant purchasing.  Wasted products that cannot be tracked back to a patient should be invoiced to a neutral account.  A routine audit should be conducted to ensure that accumulator counts reconcile with dispenses and purchases. | Inventory is segregated and labeled to indicate inventory type (WAC/ GPO/340B).  Patient status is known upon dispense and corresponding inventory type is selected.  Refrigerators or storage units come with continuous or intermittent monitoring trackers of inventory.  Active RFID tracking identifies usage upon removal from storage unit; passive RFID tracking uses snapshot monitoring.  Requires returning unused products to the storage unit, within a specified period, to avoid being invoiced for unused product. | Patient status should be known upon dispense.  Training is imperative; document patient and product information for each dispense.  A routine audit should be conducted to ensure that account-specific dispenses and purchases reconcile. |

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|  | **Replenishment/Neutral Inventory Model** | | **Physical Inventory Model** | |
| **Operational Considerations** | **Compliance Considerations** | **Operational Considerations** | **Compliance Considerations** |
| **Non-RFID** | Initial neutral inventory is ordered by customer and inventory is managed by entity and/or vendor.  No refrigerator, storage units, or equipment are provided for consignment storage/tracking.  Physical inventory reconciliation is performed routinely by customer or vendor. | Vendor keeps track of product usage and sends billing report to customer prior to invoicing.  The customer identifies the account(s) (WAC/ GPO/340B) to be invoiced based on patient eligibility and/or accumulations; selection should be defendable and auditable.  Accumulations may need to be updated manually to maintain compliant purchasing.  Wasted products that cannot be tracked back to a patient should be invoiced to a neutral account.  A routine audit should be conducted to ensure that accumulator counts reconcile with dispenses and purchases. | Inventory is segregated and labeled to indicate inventory type (WAC/ GPO/340B).  No refrigerator, storage units, or equipment are provided for consignment storage/tracking.  Patient status is known upon dispense and corresponding inventory type is selected.  Physical inventory reconciliation is performed routinely by customer or vendor. | Patient status should be known upon dispense.  Training is imperative; document patient and product information for each dispense.  A routine audit should be conducted to ensure that account-specific dispenses and purchases reconcile. |

*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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