**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 healthcare 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 upon the patient eligibility. By not absorbing the cost of the drug until it is used, the entity minimizes the risk of drug expiration and lowers their total cost of inventory on hand.

If your entity is considering a consignment program, here are a few decision points that should be evaluated prior to implementation:

* Consider how your entity financially values pharmacy inventory and how a consignment program would impact inventory management
* If expiration of certain high-cost medications is causing a significant financial impact to your entity, consider how a consignment program would reduce the financial impact of waste by shifting risk from the entity to the vendor
* Certain vendors charge a fee for consignment inventory, so it’s advisable to request estimated costs and benefits from the vendor before committing to the program

**340B Program Considerations:** Covered entities using a mixed-use inventory must take special precautions when developing a consignment program since 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 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 in 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 that 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.

In this tool, we highlight the most prevalent consignment programs in the market and address 340B compliance considerations.

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| Program Details | 340B Considerations |
| ASD Healthcare | |
| * Cubixx refrigerator with active (continuous monitoring) radio frequency identification (RFID) * Active RFID will require returning unused product to the refrigerator within 3 hours to avoid being invoiced for product * For non-340B covered entities, invoicing is the following day after product is removed from Cubixx | * For 340B covered entities, a usage report is provided to the consignment site prior to invoicing * Site selects whether to invoice product to 340B, WAC, or the GPO account. Selection should be defendable and auditable. * Cubixx will process corrections through a credit and rebill process to support compliance. Corrections must be requested as soon as an error is discovered. |
| BDI Pharma | |
| * Initial inventory is ordered by customer and inventory is managed virtually by BDI; physical inventory performed monthly by customer * No refrigerator or equipment provided specifically for consignment | * Customer keeps track of product usage and tells BDI which account(s) to bill on: GPO, WAC, and/or 340B (selection should be defendable and auditable) * Must have process in place to alert the buyer that product was removed and the account it should be billed under * All invoicing is done retroactively; therefore a process will need to be established to determine the patient status and communicating it to BDI prior to billing the entity |
| BioCARE | |
| * No refrigerator or equipment provided specifically for consignment * BioCARE representative performs physical inventories monthly to determine product usage * Customer is invoiced monthly for product used | * BioCARE physically counts the inventory monthly, so a process will need to be established to identify the patient status on the drugs that were dispensed and a communication plan to bill the drugs accurately * Customer keeps track of product usage and tells BioCARE which account(s) to bill on: GPO, WAC, and/or 340B |

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| Program Details | 340B Considerations |
| Cardinal Health | |
| * Cardinal Health-supplied refrigerator with passive (snapshot monitoring) RFID * Inventory is shipped on non-GPO/WAC account, but not invoiced at the time of ordering * Billing report is sent to customer and they determine what account the product should be invoiced after the drug is dispensed | * All products are ordered on WAC account so the pharmacist or technician does not necessarily need to know patient status upon dispense * Must have process in place to alert the buyer that product was removed and the account it should be billed under |
| FFF Enterprises | |
| * Verified Inventory Program – Consignment (VIPc) refrigerator with passive RFID * Inventory is segregated and labels are color coded:   Blue = 340B, Black = GPO, Green = Non-GPO/WAC   * Invoices are processed weekly for removed items that have been out of the refrigerator for two-midnights | * It is preferred that the pharmacist or technician know the status of the patient upon dispense of the drug to ensure that the appropriate product is pulled based on patient status * As an alternative to knowing patient status upon dispense of the product, the covered entity could pull product based on current accumulations in split-billing software * A major consideration with this approach is training and access to split-billing software during off-hours when the buyer or 340B coordinator is unavailable * An audit schedule should be created to ensure that products are pulled from appropriate stock |
| McKesson Plasma & Biologics | |
| * No refrigerator or equipment provided * Initial inventory is ordered by customer and inventory is managed virtually by McKesson; physical inventory performed monthly by customer * Billing report is sent to customer and they determine what account the product should be invoiced after the drug is dispensed | * Initial inventory is systematically held under the WAC account * All invoicing is done retroactively; therefore a process will need to be established to determine the patient status and communicating it to McKesson prior to McKesson billing the entity |

*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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