**Purpose:** This tool is intended to provide considerations for compliant solutions for covered entities that utilize the Controlled Substances Ordering System (CSOS) to purchase 340B drugs.

**Background:** The Drug Enforcement Administration (DEA) requires that staff take specific actions when ordering Schedule II controlled substances (CII). Electronic ordering of controlled substances using the DEA’s Controlled Substances Ordering System (CSOS) has greatly improved the medication ordering process for pharmacies—especially those serving acute care facilities—enabling faster access to purchase products, along with improved security to track and document controlled substance purchases. The CSOS system also eliminates the need for issuing a hard-copy DEA form 222. For 340B covered entities, in addition to the DEA’s requirement for controlled substance ordering, covered entities must also adhere to HRSA’s 340B compliance requirements.

**Best Practices:**

* Document the CII ordering process within 340B policies and procedures
* Ensure auditable records are maintained for 340B CII purchases
* Include CII medications in routine self-audit processes

Covered entities subject to the GPO Prohibition (DSH/PED/CAN) have a unique process when using CSOS for ordering controlled substance medications. Entities must ensure that when purchasing CIIs via CSOS that the appropriate 340B, GPO, or non-GPO/WAC purchasing accounts are utilized to remain compliant with the GPO Prohibition requirement. The process for ordering CII medications through CSOS for an entity that is NOT subject to the GPO Prohibition, or has a separate inventory for 340B medications, would entail ordering the needed medications through the 340B or non-340B/GPO account accordingly. Some entities may only dispense to 340B eligible patients (and carve-in Medicaid) therefore purchase CII medications directly on a 340B account (e.g. closed door pharmacy serving only 340B eligible patients). The process outlined below applies to entities that purchase CII medications through a split-billing software.

**CSOS:**  Covered entities should understand their 340B split-billing software and wholesaler configuration for processing CSOS orders. Some software/wholesaler configurations allow buyers to submit CSOS orders directly from their split-billing software. Other configurations are set up where the buyer initiates the CSOS order from the wholesaler purchasing system then transmits the order to the split billing software. The split billing software splits the order based on available accumulations then the order is routed back to the wholesaler to fill. In either of these situations, the CSOS order requires the electronic signature of the authorized CSOS approver when submitting CII drug orders.

As an example, the controlled substances order may be placed using the following steps. However, entity-specific processes for CSOS ordering should be included in 340B policies and procedures.

1. **Use wholesaler system or CII storage system to create the order.** Create the order on the entities default account (non-GPO/WAC account for DSH/PED/CAN and GPO account for all other 340B covered entities).

*Note: It is possible to skip this step and enter the order directly into the split-billing software. In these instances, you may proceed to step 2. The benefit of entering the order into the wholesaler purchasing system initially is that you will have visibility to product availability and updated contract pricing.*

1. **Export your order to the split-billing software.** Once the order is complete, export the order to the split-billing software so it will separate to the appropriate 340B, GPO, or non-GPO/WAC account(s), as applicable. When the order is sent to the split-billing software, the split-billing system will determine whether accumulation in the 340B and GPO accounts (if applicable) has been reached for the individual products needed according to the 11-digit NDC match. It will then display the allowable order quantities for the respective accounts. For entities subject to the GPO Prohibition, if no accumulations are available on 340B or GPO, the software will purchase that NDC using the non-GPO/WAC account. Use a standard report available to review the CII accumulations that may be available. This enables the ability to enter in the drug quantity needed on the appropriate account without having to export the order.
2. **Upload split orders into the wholesaler system**. Now that the order has been split into the appropriate accounts, log in to the wholesaler purchasing system and enter the order. Using the split-billing software as a guide, ensure that the appropriate quantities are placed on the 340B, GPO and the non-GPO/WAC accounts (if applicable). During this step, the order may be edited or deleted.
3. **Send and approve CSOS orders.** The authorized CSOS individual may select each order by account and instruct the purchasing system to “submit” the order after it has been reviewed. During the review process the authorized CSOS approver will have the options to print, approve and/or deny the e222. After approving the e222, the order is submitted by way of the security certificate to the wholesaler.
4. **Transmit orders to wholesaler.** Once the order review and edit processes are completed the order(s) should be submitted through the wholesale purchasing software, which creates the electronic 222 (e222). When the ordered medications are delivered to the pharmacy, the order may be electronically verified with quantities actually received for each item delivered.

*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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