Purpose: This document provides background, challenges, and solutions to support compliance when using the Controlled Substances Ordering System (CSOS) with 340B drugs.

340B Challenge: 340B compliance for hospitals using the CSOS is a challenge in mixed-use areas that use a virtual inventory. Because of the Drug Enforcement Administration's (DEA's) requirements for ordering of Schedule II controlled substances (CII), pharmacy staff must take specific actions in the ordering process to ensure compliance with 340B requirements.

Instructions:

1. Read this summary of suggestions for purchasing CII medications to ensure 340B compliance.
2. Ensure that standard operating procedures address the process for ordering CIIs.
3. Check to see that the entity maintains auditable records of CIIs purchased under 340B, and, for hospitals subject to the GPO Prohibition, that a group purchasing organization (GPO) is not used to purchase covered outpatient drugs.
4. Include CII medications as samples in the routine self-audit process.

Background: 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. Using the CSOS system also eliminates the need for issuing the hard-copy DEA form 222. Ordering controlled substance medications must be performed in a way that remains compliant with the requirements of the 340B Program. Covered entities subject to the GPO Prohibition have special concerns when using CSOS for ordering controlled substance medications: they must ensure that purchasing of medications via CSOS is done using the appropriate purchasing accounts to ensure that the institution remains compliant with the GPO Prohibition. Although the ordering processes may vary somewhat among institutions and according to variations in drug distributors' systems and pharmacies' split-billing software systems, the following procedures provide an example of how the ordering process may proceed in a pharmacy using a mixed-use inventory in an entity subject to the GPO Prohibition. 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 be different and would entail only ordering the needed medications through the 340B account.

CSOS: The pharmacist (or designated non-pharmacist) authorized to purchase controlled substance medications for the pharmacy must first enroll in the CSOS program. Information on enrolling can be obtained at the DEA website: http://www.deaecom.gov/. The DEA has a technical assistance customer support help line to assist in setting up the CSOS process. An electronic CSOS security certificate must be obtained from the DEA and installed on a computer that will be used by the authorized pharmacist for ordering. Once the CSOS enrollment has been completed and the security certificate has been installed, orders can be processed electronically. In some situations, the split-billing software will be able to transmit the CII order electronically to the wholesaler for placement. There are specific requirements for the split-billing software vendor and the wholesaler for this configuration to be allowable. In these situations, the process will be similar to a typical drug order; however, it will require the electronic signature of the authorized CSOS approver.

In most scenarios, the CSOS order will need to be entered manually into the wholesaler ordering system, after it has been split by the split-billing software. The controlled substances order may be placed using the following steps:

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1. **Log in to the wholesaler's purchasing system to initiate the order.** Create the order on the account that is normally used when exporting to split-billing software, either the GPO or the WAC account. The order will not necessarily be placed on this account; you are just building the order on this account. *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 in the order into the wholesaler purchasing system initially is that you will have visibility to product availability and updated contract pricing.*

2. **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. When the order is sent to the split-billing software, the split-billing system will determine whether accumulation in the 340B and GPO accounts 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 340B and the GPO account. If no accumulations are available on 340B or GPO, the software will suggest to purchase that NDC on the non-GPO/WAC account. *Note: Depending on the split-billing software vendor, there may be a standard report available to review the CII accumulations available. If this report is available, it would be possible to enter in the drug quantity needed on the appropriate account without having to export the order.*

3. **Enter the order into the wholesaler purchasing 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 and the GPO accounts.

4. **Process the split orders through CSOS.** The authorized CSOS individual may select each specific order by account and instruct the purchasing system to "submit" the order after it has been reviewed. During this step, the order may be edited or deleted. The ordering individual may edit the order and reduce the ordering quantity of the individual medication listed in the WAC account to an amount that has been accumulated if the amount of the drug ordered through the 340B and GPO accounts is adequate to meet patient needs.

5. **Review and submit the orders.** Once the order review and edit processes are completed, the order should be submitted through the purchasing software. Once submitted, the order will link to the DEA software, and an electronic form e222 will automatically be generated as an on-screen pop-up.

6. **Approve the e222 and maintain auditable records.** The authorized ordering individual will have the option to either print or approve, or print and approve, the e222. After approving the e222, the order is submitted by use of the security certificate. When the ordered medications are delivered to the pharmacy, the order may be electronically verified with quantities actually received designated electronically for each item delivered and then the e222 may be electronically signed.

Maintain 340B Compliance: To maintain full 340B Program compliance, the pharmacy must ensure that all ordering of medications, including Schedule II controlled substances, is done in compliance with the GPO Prohibition. Medications must be purchased using the appropriate WAC, GPO, and 340B accounts according to the 11-digit replenishment model to fully comply with program guidelines.

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