340B Program Group Purchasing Prohibition – Changes in Patient Status

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The 340B section of the Public Health Services Act was enacted to establish the 340B Drug Pricing Program (Program). This act limits the prices of drugs that can be charged by drug manufacturers to qualifying covered entities (certain types of hospitals, Federally Qualified Health Centers, and public health agencies). Savings achieved by covered entities through drug discounts are intended to expand access to services for uninsured and low-income patients.

Disproportionate share hospitals (DSH), children’s hospitals, and free-standing cancer hospitals that are registered on the Office of Pharmacy Affairs (OPA) database as participating in the Program, are subject to a Group Purchasing Organization (GPO) prohibition and cannot purchase any **outpatient** 340B covered drugs through a GPO or a group purchasing arrangement.

A hospital subject to the GPO prohibition may not purchase outpatient 340B covered drugs through a GPO for any of its clinics or departments within the four walls of the hospital (same physical address) under any circumstance. In addition, certain off-site outpatient facilities of the hospital (known as “child sites”) may not use a GPO for purchasing covered outpatient drugs if **one** of the following conditions exists:

1. The off-site outpatient facility has the same physical address as the parent;
2. The off-site outpatient facility is registered on the OPA 340B database as a participating site;
3. The off-site outpatient facility purchases drugs using the same pharmacy wholesaler account as the 340B participating parent; or
4. There is not sufficient recordkeeping performed by the hospital to track usage of GPO drugs in 340B registered off-site locations.

This prohibition has been part of the Program since 1994; however, it was not strictly enforced. In February 2013, the Health Resources and Services Administration (HRSA) issued *Program Notice 2013-1 – Statutory Prohibition on Group Purchasing Organization Participation*. This notice contained the following sanction related to violations of the GPO prohibition.

“Since the GPO prohibition is an eligibility requirement, covered entities found in violation will be considered ineligible and immediately removed from the 340B Program. Covered entities may also be subject to repayment to manufacturers for the time period for which the violation occurred. Covered entities removed from the 340B Program for GPO prohibition violations must demonstrate the ability to comply with the GPO prohibition to be considered eligible to reenter the 340B Program during the next regular enrollment period.”
On May 9, 2014, in a release by the Healthcare Systems Bureau, HRSA again addressed the prohibition and resulting sanction.

“Therefore, during an audit, if a hospital is found to have violated the GPO prohibition and that violation occurred before August 7, 2013, that non-compliance will be identified as an area for improvement for the covered entity. Violation of the GPO prohibition will be deemed as a finding and be grounds for removal from the 340B Program if the sample period of the audit is after Aug. 7, 2013.”

How easily can a GPO prohibition violation occur? Some violations are obvious, such as not tracking GPO utilization or purchasing GPO drugs for use in an employee pharmacy located within the four walls of the hospital. However, other violations are not that apparent.

Many hospitals utilize 340B split billing software to accumulate inpatient and outpatient drug dispense information. The type of accumulation (inpatient or outpatient) is often based upon the patient status at the time the drugs are dispensed. Drugs dispensed while patients are in an inpatient status are routed to the GPO accumulator. Drugs dispensed while patients are in an outpatient status are routed to the 340B accumulator. Consider the following scenarios:

- The patient is registered as an inpatient; however there is no valid inpatient order by the physician in the medical record. Since the patient is registered as an inpatient, drug transactions will map to the GPO accumulator. Without a written physician inpatient order, the patient status is technically outpatient. Has a GPO violation occurred?
- The physician writes an inpatient order for a patient. The patient is registered as an inpatient. Drugs are administered to the patient and the transactions post to the GPO accumulator. Prior to discharge, the patient status is changed from inpatient to outpatient, in accordance with Medicare guidelines regarding condition code 44. The charges are billed to Medicare as outpatient charges. However, the drug transactions remain in the GPO accumulator. Has a GPO violation occurred?

The following frequently asked question (FAQ ID 2015) on the 340B Prime Vendor Program website offers little insight regarding patient status changes and GPO violations.

Q: Our hospital uses the fact that a patient was admitted as an inpatient at all during the hospital stay, to make ALL of those transactions associated with that patient (whether they were inpatient or outpatient at the time of drug admission) technically INPATIENT. Is it appropriate for us to leave transactions/drugs administered while the patient was in the ER (as an outpatient) in the accumulator for GPO for inpatient?

A: The 340B hospital must have fully auditable records that clearly document how it defines inpatient vs. outpatient, and the policy must be consistently applied. The policy must meet HRSA’s 1996 patient definition guidelines (61 Fed. Reg. 55156 (Oct. 24, 1996)).
Based on the above response, it is critical that hospitals address patient status changes when developing 340B Policies and Procedures. Pharmacy staff, and others responsible for 304B compliance at the hospital, must have a good understanding of registration processes and how patient status changes are handled. Don’t just test these processes once; self-audits should be periodically performed to determine if the medical record supports the patient status used in the accumulators.

Bottom line - HRSA is very serious about compliance with the GPO prohibition and will be focusing audit efforts on this requirement. Violations could result in removal from the 340B Program. It is not safe to assume split-billing software will prevent GPO Prohibition violations. The software can only process the data fed into it. If the data is erroneous, violations can occur. Ongoing monitoring is essential, along with regular staff training, to ensure continued participation in the 340B Program.

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