



FACT or FICTION: HRSA's Policy Release 2013-1 on Group Purchasing Organization Prohibition for the 340B Drug Pricing Program

With the Health Resources and Services Administration's (HRSA) recent release of the Statutory Prohibition on Group Purchasing Organization (GPO) Participation we, at Ponaman Healthcare Consulting (PHC), appreciate that questions or concerns may arise with respect to potential implications for your 340B covered entity. Since the policy release, PHC has interviewed representatives from HRSA's Office of Pharmacy Affairs (OPA) and Safety Net Hospitals for Pharmaceutical Access (SNHPA) in an effort to provide our clients with credible, reliable information and recommendations.

1. The Statutory Prohibition on GPO Participation only applies to hospitals registered within the 340B Program as:

- **Disproportionate share hospitals (DSH)**
- **Children's hospitals**
- **Free-standing cancer hospitals**

2. All covered outpatient drugs should be purchased at 340B pricing and cannot be purchased through a GPO.

HRSA Recommendations: 340B covered entities that are unable to purchase covered outpatient drugs at the 340B price should take immediate action by submitting written notification to the OPA, detailing the affected covered outpatient drug(s), the manufacturer and the process by which the entity was notified that the purchase could not be made.

PHC Recommendations and How we Can Help: At the outset, while there is no OPA fixed definition for covered outpatient drugs, PHC recommends a conservative approach and suggests to reference the Centers for Medicare and Medicaid Services' definition of a covered outpatient drug. In addition to HRSA's OPA notification recommendation, PHC recommends written notification to the drug manufacturer, stressing that it is prohibited to deny 340B pricing on specific covered outpatient drugs. As a partner of SNHPA, PHC has obtained notification templates to assist you in this process. Throughout the next several weeks, PHC will undertake a notification mailing campaign to HRSA and manufacturers. Any organization requiring assistance with the notification process is encouraged to contact us with a list of denied covered outpatient drugs currently purchased through a GPO. We can then partner with you to develop and submit the notifications.

3. GPO Purchasing Should Cease Completely. HRSA does not authorize GPO replenishment models and requires that all 340B covered entities and their covered outpatient clinic sites cease purchasing through a GPO account.

HRSA Recommendations: 340B covered entities using a replenishment model are urged to purchase through a non-GPO account and only replenish with 340B drugs, once 340B patient eligibility is confirmed and can be documented through auditable records. Additionally, covered entities using replenishment models must have the ability to demonstrate compliance through auditable records.

PHC Recommendations and How we Can Help: PHC recommends that you immediately contact your drug wholesaler to identify the most favorable approach for meeting HRSA's purchasing account expectations (e.g., set up a Wholesalers Acquisition Cost (WAC) account). Without access to a GPO, the set-up of a WAC account will provide your covered entity with a reliable back-up plan. In addition, we urge you to contact your split-billing vendor to determine its ability to assist you in managing this new requirement. Contact us should you need guidance or assistance with this process.

4. There is a 60-day Compliance Deadline. PHC and SNHPA recognize that this timeframe is aggressive. Without the proper software developments, many modifications will need to be put in place within the hospital pharmacy's purchasing systems. Additionally, wholesalers will be greatly affected by this prohibition, with the need for a high volume of notifications and adjustments. SNHPA is currently working with HRSA to voice your concerns and to request additional time to ensure all affected 340B covered entities and their wholesalers can make the necessary adjustments to meet compliance.

PHC Recommendations and How we Can Help: The PHC team believes that an essential component of a quick resolution is to coordinate your split-billing system and your wholesaler services. With our extensive experience and understanding of this field, PHC can guide you through this process.