

Office of Pharmacy Affairs – a Focus on Program Integrity: Current and Future

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Questions to Run On

- What is the mission of OPA and the programs it leads?
- What were the GAO findings and Recommendations
- Overview of ongoing 340B Integrity Measures

Office of Pharmacy Affairs

Mission:

Promote access to clinically
and cost effective pharmacy
services

Intent of 340B

Permit covered entities “to stretch scarce Federal resources as far as possible, reaching more eligible patients and providing more comprehensive services.”

H.R. Rep. No. 102-384(II), at 12 (1992)

Program Administration

- Three Legs of the OPA
 - Federal Team
 - Pharmacy Services Support Center (PSSC/PharmTA)
 - 340B Prime Vendor Program (PVP)



Program Prohibitions

- Diversion - Drug provided to individuals who are not patients
- Duplicate Discounts - Accessing the 340B Discount + Medicaid Rebate on same drug
- * Covered Entities required to maintain Auditable Records Demonstrating Compliance with these Prohibitions

GAO FINDINGS

- The 340B program allows certain providers within the U.S. health care safety net to stretch federal resources to reach more eligible patients and provide more comprehensive services.
- Covered entities interviewed reported using it for these purposes.
- Distribution of drugs at 340B prices generally did not affect providers' access to drugs.
- Oversight of the 340B program is inadequate to provide reasonable assurance that covered entities and drug manufacturers are in compliance with program requirements.
- 340B program has increasingly been used in settings, such as hospitals, where the risk of improper purchase of 340B drugs is greater.

GAO REPORT RECOMMENDATIONS

- 1) *Covered Entity Audits*: Conduct selective audits of 340B covered entities to deter potential diversion;
- 2) *Patient Definition*: Finalize new, more specific guidance on the definition of a 340B patient;
- 3) *Nondiscrimination*: Further specify its 340B nondiscrimination guidance for cases in which distribution of drugs is restricted and require reviews of manufacturers' plans to restrict distribution of drugs at 340B prices; and
- 4) *Hospital eligibility*: Issue guidance to further specify the criteria that hospitals that are not publicly owned or operated must meet to be eligible for the 340B program.

Program Integrity Current Activities

- Determination of eligibility and maintenance of system
- Recertification
- Quarterly calculations of 340B prices
- Posting Medicaid Exclusion File
- Investigations/resolutions of alleged drug diversion and incorrect pricing/inappropriate limits on drug access
- Audits
- Technical Assistance, webinars, FAQs, guidances

ACA Program Integrity Activities

- Manufacturer Integrity (Civil Monetary Penalties)
- Covered Entity Integrity
- Pricing Changes and Transparency (Regulations & on line access in 340B data system)
- Administrative Dispute Resolution

Program Integrity - Enrollment

- Grant eligibility
- Hospital Eligibility
 - Hospital Type
 - DSH percentage
 - Ownership & Eligibility
 - GPO prohibition (DSH, Children's & Cancer)
 - Outpatient facilities
- Ship to addresses

Program Integrity - Recertification

- Current:
 - FQHC grant eligibility quarterly
 - DSH percentage quarterly
 - Ownership status quarterly
- Began phased implementation of annual recertification
 - Ryan White Grantees (completed 10/1/11)
 - STD/TB (started 10/1/11)
 - Continue with other entities as online systems are developed

Program Integrity – Other activities

- Patient Definition
- Non-discrimination policy
- Penny Pricing Policy
- Manufacturer Audits
- OIG Report on Medicaid