



Healthcare Systems Bureau

DATE: May 9, 2014

TO: 340B Covered Entities

FROM: CDR Krista Pedley, Director, Office of Pharmacy Affairs

SUBJECT: Audit Results

Dear Colleagues,

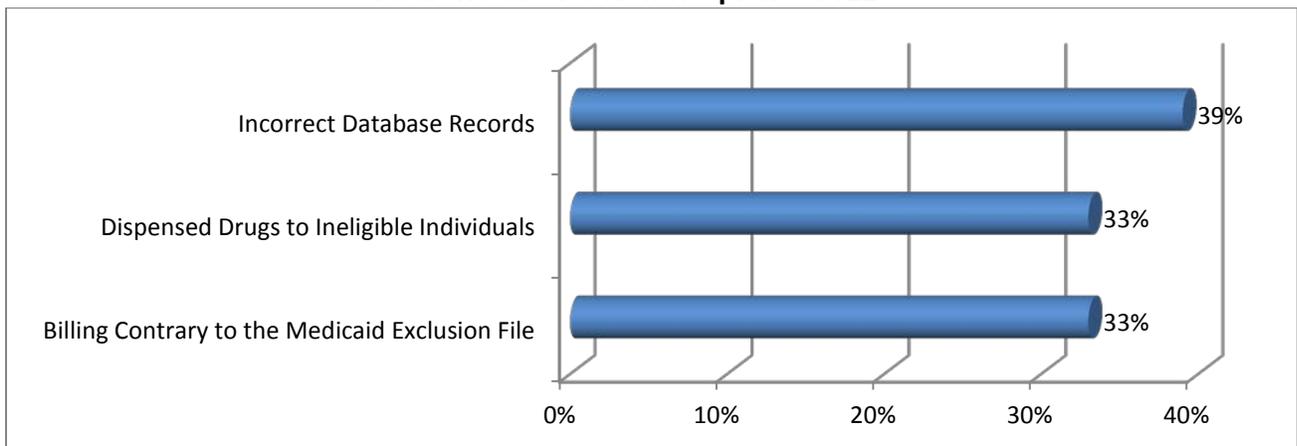
As the 340B stakeholder community is aware, the Health Resources and Services Administration (HRSA) invests significant resources – from staff time to financial contributions – to ensuring that 340B covered entities and manufacturers are in compliance with all program requirements. This month, we wanted to give you a sense of some of the lessons we have learned in the early years of our investments, and how we plan to apply these lessons in our efforts moving forward.

In Fiscal Year 2012 (FY12), HRSA began auditing 340B enrolled covered entities. The “sentinel effect” of these audits has been remarkable – we have seen many more covered entities prioritizing compliance, seeking technical assistance, and taking steps to rectify violations. These audits have allowed HRSA and 340B stakeholders opportunities to improve oversight, monitor for potential violations, prevent and detect diversion and duplicate discounts and, importantly, share information gained to increase compliance across all entities.

In order to better understand the issues covered entities are facing, we conducted an in-depth analysis of the findings from the FY12 audits. HRSA audited 51 covered entities during FY12, encompassing over 410 outpatient facilities/sub-grantees and over 860 contract pharmacy locations.

There are several recurring critical areas of non-compliance for hospitals and non-hospitals. For non-hospitals, the three major non-compliance areas were the covered entity’s inability to maintain accurate database information, billing contrary to the Medicaid Exclusion File which may have resulted in duplicate discounts, and dispensing drugs to ineligible individuals (diversion). Diversion occurred both at the covered entity and contract pharmacies. The main diversion findings involved ineligible prescribers, ineligible outpatient sites, and the lack of records to demonstrate responsibility of care was maintained by the covered entity.

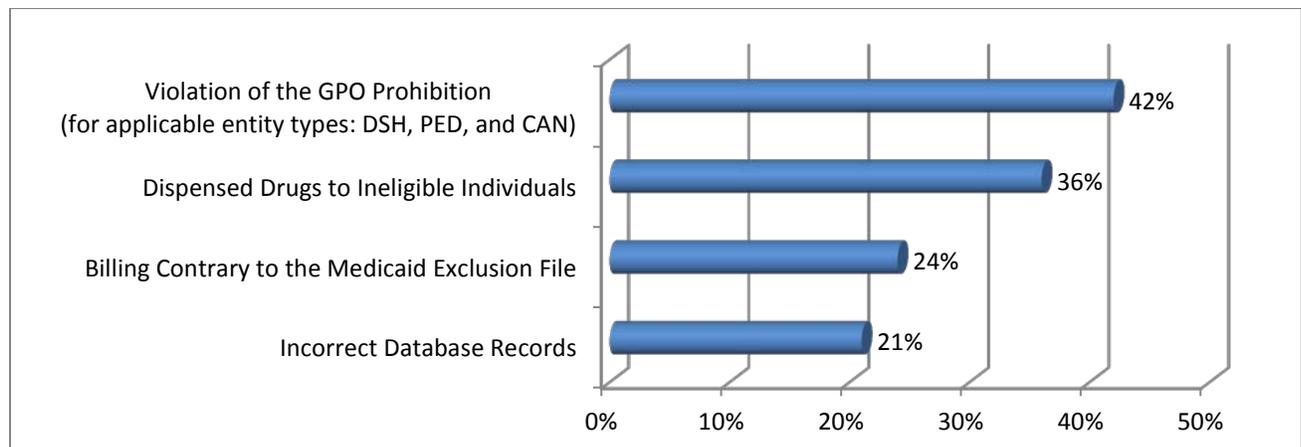
Audit Results for Non-Hospitals - FY12



The major area of non-compliance for hospitals was obtaining covered outpatient drugs through a Group Purchasing Organization (GPO). The GPO prohibition is a statutory requirement that applies to disproportionate share hospitals (DSH), children's hospitals (PED), and free-standing cancer hospitals (CAN). Upon registration for the 340B Program, these covered entity types must acknowledge that they understand the restriction with using a GPO for covered outpatient drugs, and during the 340B annual recertification process, they must attest to compliance with the GPO prohibition.

In 2013, HRSA issued a policy release regarding GPO and replenishment models, which are commonly used in the hospital setting. That release set a deadline for compliance with the policy of August 7, 2013. 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 August 7, 2013. All violations of the GPO Prohibition that were found in the FY 12 audits occurred before the August 7 deadline for compliance. The 42% percent below is reflective of the total number of hospitals in violation of the GPO prohibition versus the number of hospitals audited subject to the prohibition.

Audit Results for Hospitals - FY12



340B participants must remember that compliance is the responsibility of the covered entity. It is therefore essential to exercise constant oversight over a well-designed and well-managed compliant program.

There are best practices that we have gleaned from the audits that should assist every covered entity with minimizing the risks of non-compliance and negative audit findings. These practices include, but are not limited to:

- Development and documentation of comprehensive 340B Program policies and procedures.
- Development of concrete methodologies for routine self-auditing.
- Routine processes for internal corrective action.
- Verification that contract pharmacy arrangements comply with the 340B requirements and are properly listed in the OPA database.

- Strong partnerships with State Medicaid agencies to meet state-specific requirements and to ensure prevention of duplicate discounts.

There are many tools and resources available to 340B stakeholders to ensure compliance with 340B Program requirements. The following table outlines some of those resources to assist covered entities in running a compliant program.

Resources

Resource	Description
HRSA OPA	HRSA Office of Pharmacy Affairs homepage http://www.hrsa.gov/opa/index.html
About 340B Program Audits of Covered Entity	HRSA Program Integrity Page http://www.hrsa.gov/opa/programintegrity/auditscopeandprocess.html
Policy Releases	HRSA Policy releases regarding the 340B Drug Pricing Program http://www.hrsa.gov/opa/programrequirements/policyreleases/index.html
OPA FAQs	HRSA Office of Pharmacy Affairs Frequently Asked Questions (FAQs) http://www.hrsa.gov/opa/faqs/index.html
HRSA 340B Peer-to-Peer Webinars	Register for upcoming 340B Peer-to-Peer Webinars and listen to past webinars http://www.hrsa.gov/opa/peertopeer/webinars.html
340B University	340B University slides and notes along with other available tools https://www.340bpvp.com/340b-university/tools-and-resources/
340B Prime Vendor Program Call Center	Phone: 1-888-340-2787 ApexusAnswers@340bpvp.com Web: www.340bpvp.com
340B Prime Vendor Program FAQs	Prime Vendor Program Frequently Asked Questions (FAQs) https://www.340bpvp.com/resource-center/faqs/