



340B Compliance

LIFE AFTER A HRSA AUDIT
AND IMPLEMENTING A CORRECTIVE ACTION PLAN

HCCA Compliance Institute

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Overview

- 340B Program Background
- Athens Regional Medical Center's ("ARMC") Experience
- Corrective Action Plan
- Independent Assessment
- Industry Best Practices and Areas of Caution

340B Program Background



Why Is 340B Important?

The 340B Program was created in 1992 by President Bush, and requires drug manufacturers to provide covered **outpatient** drugs to eligible Covered Entities ("CEs") at significantly reduced prices. The CEs benefit from the difference between the drug's reduced cost and the full reimbursement received from payers.

"The 340B Program enables Covered Entities to stretch scarce federal resources as far as possible, reaching more eligible patients and providing more comprehensive services."
- Health Resources and Services Administration ("HRSA")

Many CEs use these funds towards providing additional community benefit programs to patients who are poor, uninsured, or underinsured. Currently, the 340B Program does not restrict the use of the 340B savings for certain purposes; however, it is important that CEs document and demonstrate their use of savings annually.

340B Impact

\$3.8 Billion

Estimated annual savings attributed to 340B in 2013

32,071

Total Registered Sites participating in the 340B Program as of October 1, 2015

HRSA's Increased Focus on Compliance

+ \$7M

in additional budgetary funding for **FY 2017**



Goal: 100

Additional
Onsite CE HRSA Audits in FY 2017

Source: HRSA Fiscal Year 2017 Budget Justification Document.

Who is Eligible to Participate?

- Safety-net healthcare organizations serving vulnerable patient populations, which are classified into two main categories:



Hospitals

- Children's Hospital
- Critical Access Hospital ("CAH")
- Disproportionate Share Hospital ("DSH")
- Free Standing Cancer Center
- Rural Referral Center ("RRC")
- Sole Community Hospital ("SCH")



Federal Designees/Grantees

- Community Health Centers ("CHC")
- Federally Qualified Health Centers ("FQHCs")
- FQHC Look-Alikes
- Tribal/Urban Indian Health Centers
- Ryan White HIV/AIDS Program Grantees
- Sexually Transmitted Disease Clinics
- Family Planning Clinics
- Tuberculosis Clinics
- Hemophilia Treatment Centers
- Black Lung Clinics

ARMC's Experience



Background

- Athens Regional Medical Center ("ARMC") has participated in the 340B Program since 2005 and qualifies as a DSH (ID DSH110074).
- HRSA conducted an audit in August 2013:
 - Audit period was January 1, 2013 through June 30, 2013.
 - The auditor was on site for four days.
- HRSA audit report of findings was provided on July 14, 2014.
- The report's findings required ARMC to develop a corrective action plan.



Background (cont'd)

- At the time of the audit, ARMC had the following locations listed on the OPA database as participating in the 340B Program:
 - Hospital
 - Home Infusion



HRSA Audit: Key Findings

- 1. Diversion: 340B drugs were dispensed to ineligible individuals.
 - The dispensation sample included 13 (340B eligible) prescriptions at the home infusion location.
 - All patients of home infusion were treated as eligible by ARMC, regardless of where patient received healthcare services.
 - Prescriptions were written by ineligible providers at ineligible sites.
 - Prescriber must be employed by or under a contractual or other arrangement with the CE.
 - ✓ Ineligible sites include those hospitals and/or private physician offices not reimbursable on ARMC's Medicare cost report without an arrangement demonstrating that the responsibility for care remained with the entity.

HRSA Audit: Key Findings (cont'd)

- 2. Diversion: 340B drugs were not properly accumulated. Adequate controls to prevent diversion of 340B drugs were not in place.
 - The hospital pharmacy replenished 340B drugs with substitutes (different NDC numbers and manufacturers).
 - The replenishment system could not ensure proper accumulation (exact match – NDC and manufacturer).
 - ✓ Auditable records demonstrating proper accumulation in a replenishment model are required.



HRSA Audit: Key Findings (cont'd)

- 3. Duplicate Discounts: Adequate controls were not in place to prevent duplicate discounts.
 - A drug purchase cannot be subject to both a 340B discount and a Medicaid rebate.
 - ARMC had "carve-in" status to include billing Medicaid for drugs purchased at 340B prices.
 - Incorrect Medicaid numbers were listed in the Medicaid Exclusion File for both the parent and home infusion (child) sites.



HRSA Audit: Areas for Improvement*

1. ARMC obtained covered outpatient drugs through a GPO.
 - GPO Prohibition: DSH CEs may not "obtain covered outpatient drugs through a GPO or other group purchasing arrangement".¹
 - Audit discovered that ARMC was replenishing using a GPO.
 - "ARMC should immediately stop using this replenishment model or be found in violation of GPO prohibition." - HRSA Audit Report
 - ARMC was not in compliance with GPO prohibition prior to July 9, 2013.
 - ARMC was taking proactive steps to become compliant.

*Note: An area for improvement does not identify any specific violations of the 340B Program requirements.
¹ Source: 42 U.S.C. 256b(a)(4)(3)(B) <https://www.gpo.gov/fdsys/pkg/USCDOE-2010-09-04/doctype/USCDOE-2010-09-04-chap4-subchap1-partD-subpart1-sec256b.pdf>

HRSA Audit: Areas for Improvement (cont'd)

2. HRSA recommended that ARMC develop written 340B Program policies and procedures to describe appropriate oversight of each contract pharmacy's compliance with ARMC's 340B Program.
 - ARMC **had** written 340B Program policies and procedures for contract pharmacy arrangements.
 - Policies and procedures did not reflect all oversight activities and did not include specific **controls to verify eligibility or prevent diversion** of 340B drugs.
 - ✓ Policies and procedures should describe monitoring procedures, to include effective eligibility **determination** process and **reconciliation** of dispensing and purchasing records.

HRSA Audit: Areas for Improvement (cont'd)

3. HRSA recommended that ARMC remove the 3 contract pharmacies currently registered until the use could be compliant with all 340B Program requirements.
 - **No oversight of contract pharmacies** through independent annual audits had occurred since contract agreements had commenced.
 - ✓ HRSA expects all CEs using contract pharmacies to perform **annual independent audits of all contract pharmacies**.

Post-HRSA Audit Activities

- Corrective Action Plan
- Manufacturer Repayment
- Independent Assessment



Post-Audit Corrective Action Plan ("CAP")

- The report's findings required ARMC to develop a CAP
- Initial CAP provided to HRSA on October 19, 2014
- OPA representative was in frequent contact with ARMC
- Revised CAP issued on January 8, 2015



Post-Audit CAP (cont'd)

1. Diversion: ARMC dispensed 340B drugs to ineligible individuals.
 - ARMC performed a review after receiving the HRSA audit report. Dispensations were re-qualified for 340B based on the patient definition.
 - Pharmacists were educated on the qualification process and criteria (including prescriber and location elements)^{1,2}.
 - A 340B Program compliance training module was also completed.
 - Policy and procedures were developed and internal monitoring was implemented.

Note:

1) Prescriber must be employed by or under a contractual or other arrangement with the CE.

2) Ineligible sites include those hospitals and/or private physician offices not reimbursable on ARMC's Medicare cost report without an arrangement demonstrating that the responsibility for care remained with ARMC.

Post-Audit CAP (cont'd)

2. Diversion: 340B drugs were not properly accumulated. Adequate controls to prevent diversion of 340B drugs were not in place.



- ARMC's pharmacy software vendor assisted with an 11-digit NDC replenishment system.
- A wholesale acquisition cost ("WAC") account was established with the vendor.
- Electronic accumulator software was implemented to apply qualified purchases to the 340B account.

Post-Audit CAP (cont'd)

3. Duplicate Discounts: Adequate controls were not in place to prevent duplicate discounts.

- Director of Pharmacy at Georgia Medicaid confirmed all Medicaid numbers were correct as updated in the OPA database for hospital and home infusion locations.
- ARMC worked closely with Georgia Medicaid to determine if any duplicate discounts were received.
- Internal Audit began to monitor pharmacy records quarterly to assess compliance with Medicaid billing for 340B drugs. Reports were provided to Senior Leadership.

Post-Audit CAP: Areas for Improvement*

1. ARMC obtained covered outpatient drugs through a GPO.
 - ARMC began purchasing all drugs at WAC, and began replenishing after 340B eligibility was confirmed.
 - ARMC's Internal Audit department began conducting random quarterly audits to document compliance with non-GPO account.
 - ARMC selected an external independent firm for its 340B Program assessment.
 - ARMC began conducting staff education based on role/responsibility.



*Note: An area for improvement does not identify any specific violations of the 340B Program requirements

Post-Audit CAP: Areas for Improvement (cont'd)

2. HRSA recommended that ARMC develop written 340B Program policies and procedures to describe appropriate oversight of each contract pharmacy's compliance with ARMC's 340B Program. Additionally, HRSA recommended that ARMC remove the 3 contract pharmacies currently registered until the use could be compliant with all program requirements.
- Contract pharmacies were removed from the 340B Program.
 - Quarterly internal reviews of in-house retail pharmacy patient qualification process with review by ARMC and pharmacy leadership.

Manufacturer Repayment



- After the HRSA audit, ARMC worked with GA Medicaid to confirm no duplicate discounts were received.
- ARMC issued a letter to drug manufacturers:
 - Initial refunds occurred within the first 12 months.
 - ARMC continues to work through the refund process with manufacturers (low dollar amounts).

Manufacturer Repayment Process – Lessons Learned



Independent 340B Program Assessment



- ARMC engaged PYA to assist with an independent assessment of its 340B Program.
- PYA's review included the hospital (parent), home infusion, and outpatient surgery center (child site) locations.
- ARMC's in-house retail pharmacy was also included in the review.
- PYA's review was conducted in May 2016.

Independent Assessment: Key Findings

- Centralized 340B compliance committee
- Standardized pharmacy processes
- Home infusion and retail pharmacy patient and prescriber eligibility
- Non-covered outpatient drug definitions
- Limitations related to home infusion software and reporting functions



Current State – Piedmont Athens Regional

- ARMC is now Piedmont Athens Regional (effective October 1, 2016):
 - DSH Parent Site
 - Inpatient/Outpatient Surgery Center child site
 - Home Infusion child site **terminated** as of June 2016



Industry Best Practices and Areas of Caution



Infrastructure

Things to Watch For:



- The CE should be able to produce a dispensation report that includes all necessary information to monitor compliance with eligibility criteria.
- Policies & procedures which are not comprehensive, or which do not match the processes in place at all locations.
- Lack of formal and/or regular auditing and monitoring processes.

Entity Eligibility

Things to Watch For:

- Accuracy of child site and contract pharmacy registration on cost report
- Missing child sites which should be registered
- Changes in qualifying DSH percentage
- Non-reimbursable locations on cost report
- Processes for identification and tracking of 340B eligibility – are the child site processes the same as within the parent site, or different?

Prescription Eligibility

Things to Watch For:

- Is eligibility identified within the split-billing software, or through another data source like the Admissions, Discharges, and Transfers ("ADT") feed?
- How often does the hospital ADT feed interface with split-billing software? How are ADT changes applied (e.g., patient status changes from observation to inpatient)?



Prescription Eligibility (cont'd)

Things to Watch For:

- What filters is the CE utilizing to determine prescription eligibility?
 - How does the CE define its eligible prescribers?
 - Are there any date parameters for prescription eligibility?
 - Are there any controls in place related to observation patients?
 - How does the CE treat Medicaid-pending and Medicaid MCO patients?
- Employees are not an exception to the patient definition, they must still meet all requirements to be eligible.
- When reviewing documentation, locate a physician order for the prescription, not just documentation that it was administered.
 - If all filters are not in place, a drug may be incorrectly qualified as eligible.

Contract Pharmacy Arrangements

Things to Watch For:

- Written Contract Pharmacy agreement, which addresses HRSA's 12 Essential Compliance Elements
- Accuracy of OPA Database registration
- Detailed policies and procedures
- Lack of monitoring by CE and/or Contract Pharmacy
- Maintenance of records, and reporting of information to CE

Procurement and Inventory

Things to Watch For:

- Purchasing accounts are appropriate for entities subject to GPO Prohibition
- Internal controls are in place and records are maintained to support accumulations for 340B and GPO accounts
- Is there a process for reversal of inaccurate accumulations?



Determining Prescription Eligibility

As a best practice, CEs should identify 340B eligibility at the prescription level, and take into account each of the following factors:

Prescriber Eligibility:

- CE's definition of eligible prescriber should meet current HRSA guidance.
- All prescriptions purchased under 340B should be ordered by prescriber on CE's eligible listing.

Patient Eligibility:

- Does the CE maintain records for the patient's care?
- Did the patient receive a health care service other than the dispensing of a drug?

Drug Eligibility:

- Is the CE subject to the Orphan Drug Exclusion?
- Confirm that orphan drugs have not been purchased under 340B after October 10, 2015; if prior to this date, CE must have documentation of non-orphan indication for 340B eligibility.

**Note: considerations are based upon current guidance only.*

Determining Prescription Eligibility (cont'd)

As a best practice, CEs should identify 340B eligibility at the prescription level, and take into account each of the following factors (cont'd):

Location of Prescription Origination:

- Was the patient seen within the four walls of the hospital, or at an eligible child site?
- Confirm that the encounter where the drug was prescribed is not related to a visit to the private practice of an eligible prescriber.

Patient Status:

- Was the prescription dispensed while the patient was in outpatient or observation status?
- Confirm that an order to admit to inpatient status was not entered prior to drug dispensation.

Payer Status:

- Medicaid Carve-Out: Confirm that no patients with a Medicaid payer type received 340B dispensations.
- Medicaid Carve-In: Review Medicaid exclusion file for accuracy.

What's Next?

- HRSA made an attempt to impose stricter 340B requirements and clarify some of the historically "gray" areas through proposed Mega Guidance.
- HRSA withdrew its Guidance on January 30, 2017.
- Current guidance still stands.
- CEs should look to HRSA's Frequently Asked Questions, Apexus resources and recent audit findings for assistance with program planning and internal program monitoring.

Protect Your Program, Protect Your Savings

"The 340B Program enables Covered Entities to stretch scarce Federal resources as far as possible, reaching more eligible patients and providing more comprehensive services."

- HRSA

THANK YOU!



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