Passing Inspection: 340B Audits

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340B Program

- How many here have had a HRSA audit?
- How many have engaged an independent external auditor?
- Participating for how long?
  - 1 to 4 years
  - 5 to 10 years
  - 11+ years

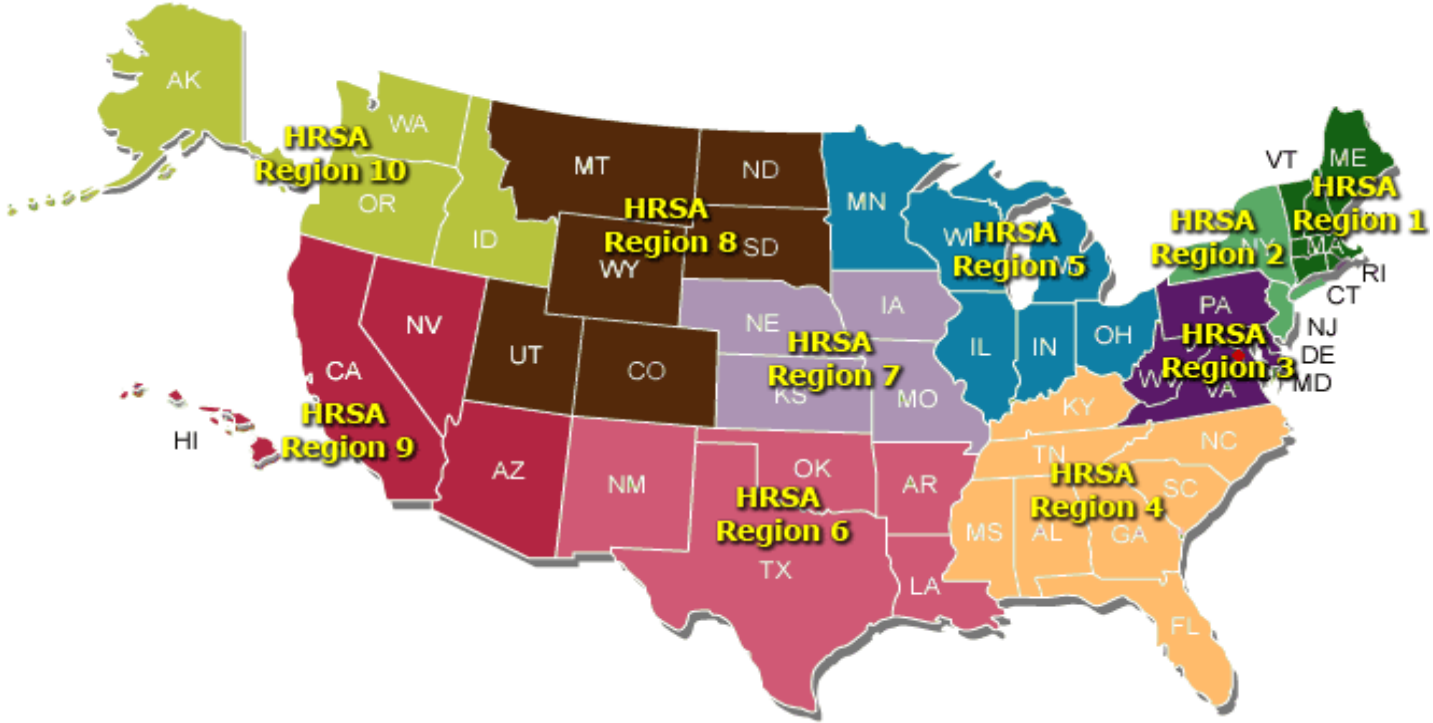
Todays Agenda

- Overview of current audit environment
- On-site portion of HRSA audit
- Self auditing
- Selecting an external independent auditor

340B Program Audits

- HRSA states covered entities are subject to audit by manufacturers as well as the state and federal government.
  - HRSA
  - Manufacturer
  - State Medicaid and Managed Care Organizations

HRSA Regions



Audit Results

FY	TOTAL	GRANTEES	%	WITH FINDINGS	%
2012	51	18	35	13	72
2013	94	44	47	32	72
2014	98	20	20.4	15	75
2015	172	42	24	29	69
2016	8	6	75	1	17
TOTAL	423	130	31	90	69

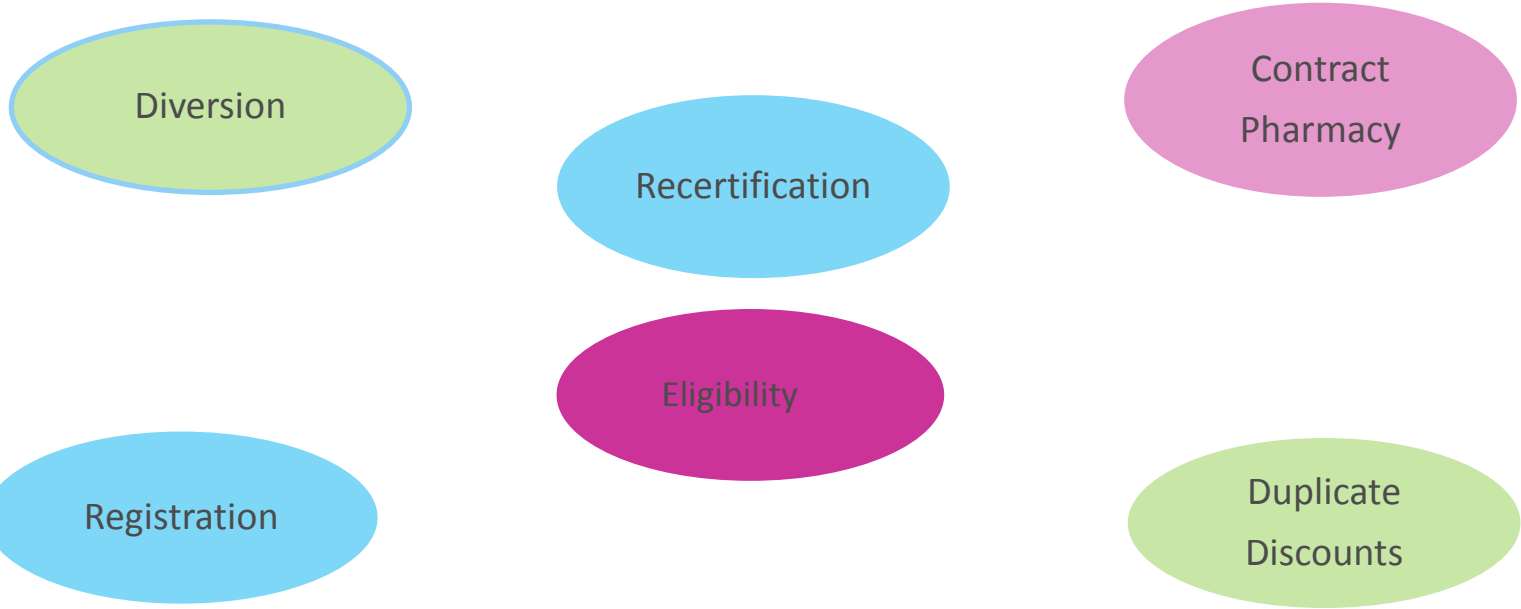
*www.hrsa.gov/opa/programintegrity/auditresults (Accessed 2/7/16)
HRSA last updated 02/05/16

Common Findings

- Database Inaccuracies
  - Incorrect entity contact
  - Contract pharmacy and/or child site not registered
- Diversion
  - Ineligible location
  - Ineligible provider
  - Ineligible patient
- Duplicate Discounting
  - Medicaid
  - Managed Care Organizations (MCO's)

HRSA Focused on 340B Program Compliance

- Key Compliance Areas



HRSA On-Site and Beyond

HRSA says you must:

Keep 340B database information accurate and up to date.

Register new outpatient facilities and **contract pharmacies** as they are added.

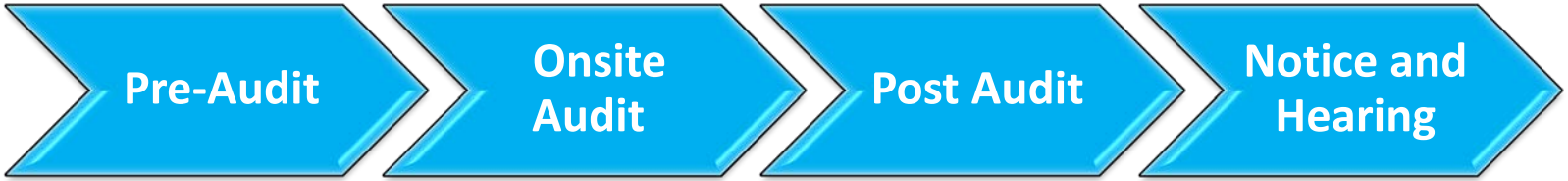
Recertify eligibility every year.

Prevent duplicate discounts. Manufacturers are prohibited from providing a discounted 340B price and a Medicaid drug rebate for the same drug. Covered entities must accurately report how they bill Medicaid drugs on the Medicaid Exclusion File.

Prevent diversion to ineligible patients. Covered entities must not resell or otherwise transfer 340B drugs to ineligible patients.

Prepare for program audits Maintain auditable records documenting compliance with 340B Program requirements.

HRSA On-Site and Beyond



http://www.hrsa.gov/opa/programintegrity/index.html

HRSA On-Site and Beyond

- Notification
  - Initial email from HRSA 340B Audit [340baudit@hrsa.gov]
    - Requesting the following items be available to HRSA auditors while they are on site:
      - An enclosed, lockable working space for up to three staff
      - Internet access for three computers
      - Access to a telephone, fax machine, and photo copier
      - Parking for up to two vehicles
      - Access to all financial, transactional documents and patient information related to the 340B Program.
    - Should also have available personnel with operational knowledge of your EHR, clinic, and 340B vendor software as well someone dedicated to the auditor during the auditors time on-site

HRSA On-Site and Beyond

- Notification cont.
  - Email from HRSA auditor conducting your audit
    - Pre audit data request attached (usually due within 4 weeks)
    - Suggested on-site date
- On-site visit to follow within 8 weeks of initial notification
- Upon notification of your HRSA audit you should inform your 340B software vendor and the auditor that conducted your external independent audit for support

HRSA On-Site and Beyond

- While on-site auditors will obtain and review select 340B program data and internal controls
  - Audit procedures include, at a minimum:
    - Review of relevant policies and procedures and how they are operationalized
      - http://www.hrsa.gov/opa/updates/2016/january.html 2/12/16
    - Verification of eligibility, including GPO and outpatient clinic eligibility
    - Verification of internal controls to prevent diversion and duplicate discounts, including how the covered entity defines whether a patient is considered inpatient or outpatient, HRSA Medicaid Exclusion File designations, and accuracy of covered entity's 340B database record

HRSA On-Site and Beyond

- Audit procedures continued:
  - Review of 340B Program compliance at covered entity, outpatient or associated facilities, and contract pharmacies
  - Testing of 340B drug transaction records on a sample basis

- HRSA Statement:
  - Regional auditors collect the facts throughout the audit but are not authorized to summarize any findings to the entity
  - Their report to OPA ***will contain the facts as they understand it*** and must undergo OPA review
  - Additionally, any auditor statements made during the audit are not considered final and are subject to change

HRSA On-Site and Beyond

- Notice and comment
  - 30 calendar days to review findings and HRSA's request for a CAP
  - 60 days to submit a CAP for HRSA's approval if an entity agrees with the Final Report
  - If a covered entity disagrees, it has 30 calendar days to provide appropriate supporting documentation of the covered entity's disagreement
  - If an entity fails to submit a CAP, it may be removed from the 340B Program

  http://www.hrsa.gov/opa/programintegrity/index.html

Self-Auditing

- Why some entities or grantees do not perform self-audits

Chances of an audit are slim

Don’t have the time

My vendor audits and manages my program

Don’t know how

Don’t have the resources

Self-Auditing

- Why you need to self-audit
  - Ultimate program responsibility lies with the entity or grantee
  - Validate initial data extracts and current data feeds
  - Continued maintenance needed for providers, locations and contract pharmacies
  - Protect your savings

Self-Auditing

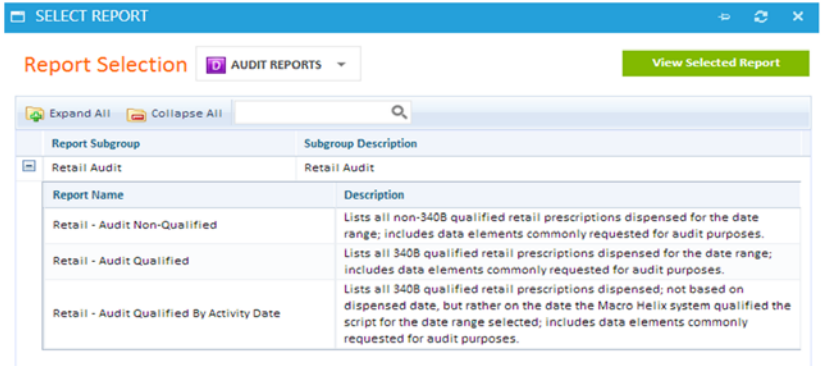
- Recommendations
  - Map self-audit guide and procedure

Monthly Auditing Guide Procedure

1. Tracking System: Contract Pharmacy Accumulation Audit

1.1 Click the drop down arrow in Current Pharmacy window

a. Change pharmacy
b. From list select desired pharmacy
c. Click on view selected
d. Click on reporting tab
e. Select standard reports
f. Next to select report field click on binoculars
g. In the report selection field click on the drop down arrow and select audit reports



h. Expand retail audit report sub groups by clicking the + sign
i. Select "retail audit qualified"

Self-Auditing

- Recommendations cont.
  - Initially audit every month
  - Make adjustments as needed
  - Transition audits to quarterly
  - Report findings to 340B taskforce
  - Use HRSA pre-audit data as a guide

Pre-Audit Data Request

Example of a Data Request

Data Request – Covered Entity (CE)
1. Policies and procedures A. CE registration/recertification and ensuring that the 340B database is up-to-date B. Description of procurement process (including contract pharmacy, if applicable) C. Prevention of GPO violations (applies only to *DSH, PED & CAN*) D. Definition of covered outpatient drugs, including any exclusions E. CE's process for conducting oversight of its contract pharmacy(ies) F. How the CE accounts for 340B inventory or replenishment/accumulation (including NDC matching), if applicable G. Prevention of diversion at CE and contract pharmacy – Process for confirming the following: site eligibility location, referral/responsibility of care remained with CE, medical/patient health record, patient eligibility (including status change), provider eligibility (relationship), consistent with the scope of grant (if applicable / non-hospital) H. Mechanism to prevent duplicate discounts at CE, off-site outpatient facilities, and contract pharmacies with details explaining carve-in or carve-out status I. When and how CE would self-disclose and CE's definition of non-compliance material breach
2. Most recently filed (and applicable) Medicare cost report and trial balance documentation.
3. 340B Drug Orders or Prescriptions (include in-house and contract pharmacies) A listing of all 340B orders or prescriptions issued during the 6-month sampling period – preferably in Excel format or another electronic format. The following data elements should be included: A. Unique identifying number – this is likely the RX number, but can be any number you assign that will allow tracking through your system to retrieve all information associated with the order B. The drug/product name/NDC C. The acquisition price D. The type of account the drug was purchased through and the associated 340B ID number E. The quantity issued F. The patient id number G. The payer (Medicaid) H. The ordering provider I. The location/site 340B drug was administered/ordered/prescribed J. Whether the drug was dispensed/or used, reversed, or returned to stock

Pre-Audit Data Request

Description of the 340B Universe: The CE should include a narrative describing the methodology, by which the data was gathered, and any limitations or exclusions (e.g. whether reversed transactions were excluded or other 340B orders or dispenses, were direct purchases included or other purchasing mechanisms). A sample of prescriptions will be selected for testing while the audit team is on site. For the selected items, individual records will need to be available in either electronic or paper format. If electronic health records are utilized, please provide an individual with system knowledge to navigate the EHR.
4. CEs should be prepared to show the auditor proof of employment, contract, or credentialing for providers during the audit.
5. A listing of CE's wholesalers and 340B drug purchase orders made between dates of selected time frame,

including price paid. **July 2015- December 2015**
6. A listing of contract pharmacies utilized, and the current contracts individually identifying each contract pharmacy.
7. A copy of any self-disclosures made to the Office of Pharmacy Affairs since the beginning of the audit timeframe.
8. A listing of all accounts used to purchase drugs for the parent and off-site outpatient facilities, which includes locations dispensing or distributing 340B drugs and a description of the applicable pricing (340B, GPO, WAC, CSOS, Other).
9. A listing of all clinics and locations where health care services are provided to individuals for which the CE deems itself responsible for the health care services provided for purposes of meeting 340B eligibility.
10. A listing of all Medicaid billing numbers and NPI numbers utilized to bill Medicaid for 340B drugs.
11. For hospitals - if the hospital has a contract with a State or local government to provide health care services to low income individuals, provide a copy of that contract.
12. For grantees (Ryan Whites, CHCs, FQHCs, FQHCLAs, FPs, STDs, TBs, HTCs)- provide Notice of Grant Award (NGA) or subgrantee documentation.

Self-Auditing

- Entity internal monthly/quarterly report example

See handout

External Independent Auditors

- Use the auditor as a HRSA dry run
  - Validate your audit action plan and amend as needed
  - Try to adhere to the HRSA timelines i.e. providing pre-audit data in timely manner
  - Take notes on where your processes break down and address them
- Choose an auditor that has implementation experience
  - Working knowledge of how data extract files and feeds effect compliance
  - Ability to fix issues and validate that desired outcome is achieved
  - A deep understanding of pharmacy operations

External Independent Auditors

- Obtain multiple quotes from different companies
  - The 340B auditing space has grown tremendously in recent years
  - Cost of audits are all over the board
  - Understand the scope of what each company will provide
  - A traditional “mock” HRSA audit will not be adequate
    - Seek solutions with higher support and value for a reasonable cost
  - Request references and follow through

Executive Summary

- Areas of the 340B Program Discussed
  - Overview of current audit environment
  - On-site portion of HRSA audit
  - Self-auditing
  - Selecting an external independent auditor

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