

# Understanding the 340B Drug Pricing Program Audit Process

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U.S. Department of Health and Human Services



# Agenda

- Audit background
- Staffing investments
- Audit process and recent changes



# Audit Background

- Audit intent
- Covered entities are subject to audit by manufacturers or the federal government
- Any covered entity that fails to comply with 340B Drug Pricing Program (340B Program) requirements may be liable to manufacturers for refunds of the discounts obtained or removed from the 340B Program.
- Covered entities will be audited for all 340B Program requirements
- 236 audits of covered entities over the past three fiscal years to date
  - 2,475 outpatient facilities/subgrantees
  - Over 6,600 contract pharmacy sites



**Slide 3**

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**SP1**

add additional consequence.

DFI Reviewer , 8/13/2014

# HRSA Conducted Audits

- All covered entity types considered for risk-based audit
- Risk-based factors include:
  - Number of outpatient facilities
  - Number of contract pharmacies
  - Complexity of the 340B Program
  - Volume of 340B purchases
- Parent sites in the program for less than 1 year and 1 quarter are not subject to audit selection through risk-based factor.
- Target audits focus on specific violations or allegations regarding noncompliance



# Staffing Investments

- Additional \$6 million in FY 14 to improve the program integrity and oversight of the 340B Program.
- Enhancing existing two branches
  - Operations Branch
    - Additional technical assistance and education
    - Revamping FAQs, currently on the Prime Vendor website (PVP)
  - Information Systems Branch
    - Hiring additional specialized assistance in data areas
    - Increasing needs to understand the data around covered entities and manufacturers, their purchasing and pricing



# Staffing Investments Continued

- New branch created with the funds, called Program Performance and Quality
  - Oversees the program integrity initiatives for covered entities and manufacturers



# Program Performance and Quality Branch

- Branch Responsibilities:
  - Recertification
  - Develops covered entity audit reports and posts summaries on HRSA's website
  - Works with HRSA program integrity analysts to ensure accurate assessment of covered entities
  - Reviews allegations and self-disclosures by covered entities
  - Works with covered entities to develop corrective action plans (CAP)
  - Collaborates with internal and external HRSA partners on covered entity compliance



# Improvements in Audit Process

- Seeking to streamline the audit protocol and reporting. New improvements in overseeing covered entity compliance
- Goal is to double the number of audits and make improvements
- Notification to the covered entity and audit processes remain relatively unchanged
- Hired additional program integrity analysts to conduct audits of covered entities, as well as partner with OIG to conduct audits of manufacturers



# Pre-Audit

- Engagement letter from HRSA
- Auditor will schedule a pre-site visit conference call
  - Audit objectives, logistics, scheduling, space needs, and initial data requests
- Data request includes:
  - Policies and procedures related to 340B
  - Most recently filed Medicare cost report
  - 340B drug orders or prescriptions
  - List of providers authorized to write prescriptions for drugs deemed 340B eligible
  - Current 340B drug inventory
  - Listing of contracts pharmacies utilized, and all current contracts
  - A schedule of 340B drug purchase orders



# Onsite Audit

- Opening Meeting
- HRSA program integrity analysts obtain and review 340B Program data and internal controls
- Audit procedures include, but not limited to:
  - Review of relevant policies and procedures and how they are operationalized
  - Verification of eligibility, including GPO and outpatient clinic eligibility
  - Review of 340B Program compliance at covered entity, outpatient or associated facilities, and contract pharmacies
  - Verification of internal controls to prevent diversion and duplicate discounts
  - Testing of 340B drug transaction records on a sample basis



# Post Audit

- HRSA program integrity analysts provide a preliminary report to OPA for review
- OPA reviews the preliminary findings, documents and addresses concerns
- OPA drafts a Final Report and issues the report to the covered entity, with a request for a CAP, if applicable



# Post Audit: Notice and Hearing

- Final Report
  - Agree – if covered entity agrees with the Final Report, a covered entity must submit a CAP to HRSA within 60 calendar days
  - Disagree – if covered entity disagrees with the Final Report, they must notify HRSA in writing within 30 calendar days with appropriate supporting documentation of disagreement
  - OPA reviews covered entity's response and, if appropriate, may reissue the Final Report



# Post Audit: Corrective Action Plan

- If a covered entity fails to submit a CAP, it could be removed from the 340B Program
- The CAP is to ensure future compliance
- Although there is no requirement at this time regarding implementation timeline, HRSA does want entities to establish a framework with a definite end in mind.



# Post Audit

- Once HRSA reviews and approves the submitted CAP, CE's with diversion or duplicate discount findings are required to provide HRSA a public letter which will be posted on OPA's website
- Intent of letter
- HRSA closes out the audit
- Covered entities whose findings involve repayment will be subject to an audit the following year
- Once an audit report is finalized by OPA, the findings and any associated corrective action will be summarized on the OPA website
- Results used to create tools and resources for covered entities

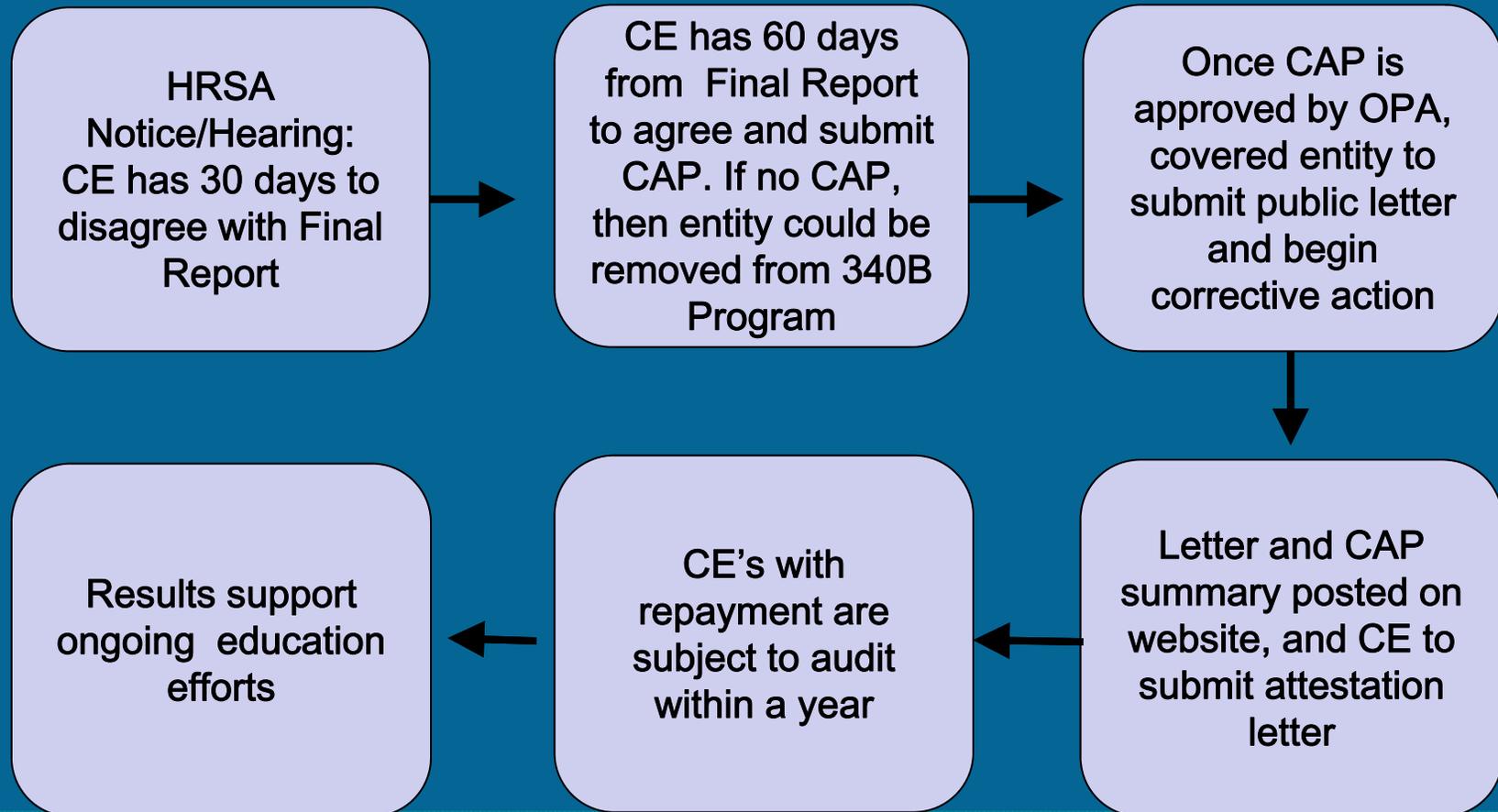


# Changes to the Audit Process

- HRSA no longer issues preliminary reports to the audited covered entities.
- HRSA notifies audited covered entities of the audit findings in the HRSA Final Report.
- The entity's opportunity for Notice and Hearing (to provide written disagreement) is after the Final Report.
- Formal exit interviews during the on-site audit will no longer be conducted.



# Recap of the Post-Audit Process



# Next Steps

- Finalizing the FY 13 and FY 14 audits – some of the FY 13 audits have already been finalized and posted
- Plan to conduct twice as many audits in FY 15 and improve efficiencies in our process.
- Currently select entities for audits using a risk stratification model
- Continuing to assess the risk factors that are used



# Best Practices

- Development and documentation of written comprehensive 340B Program policies and procedures
- Development of concrete methodologies for routine self-auditing
- Routine processes for internal corrective action.



# Best Practices Specific to Duplicate Discounts and Diversion

- Plan for continuous monitoring, to include regular sampling of 340B dispensed drugs
  - Periodic assessment of controls for provider eligibility, site eligibility, medical records and responsibility of care
- Audit software regularly
  - Be involved in building the logic
- Verification that contract pharmacy arrangements comply with the 340B Program requirements and are properly listed in the OPA 340B database



# Best Practices Specific to Duplicate Discounts and Diversion Continued

- Have a clear understanding of how each contract pharmacy deals with carve-out
- Strong partnerships with State Medicaid agencies to meet state-specific requirements and to ensure prevention of duplicate discounts
- Regular assessment of each site's Medicaid billing information in the 340B database



# Questions?

If you have any questions, please contact:

[ApexusAnswers@340bpvp.com](mailto:ApexusAnswers@340bpvp.com)

Phone: 1-888-340-2787

Hours: 9 am – 6 am ET M-F



# Resources

- [Office of Pharmacy Affairs](#)
- [About 340B Program Audits of Covered Entities](#)
- [Policy Releases](#)
- [Office of Pharmacy Affairs Frequently Asked Questions](#)
- [340B Peer-to-Peer Webinars](#)
- [340B University](#) with slides, notes and other tools



# Contact Information

Office of Pharmacy Affairs (OPA)  
Main Office Phone Line: 301-443-4353  
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