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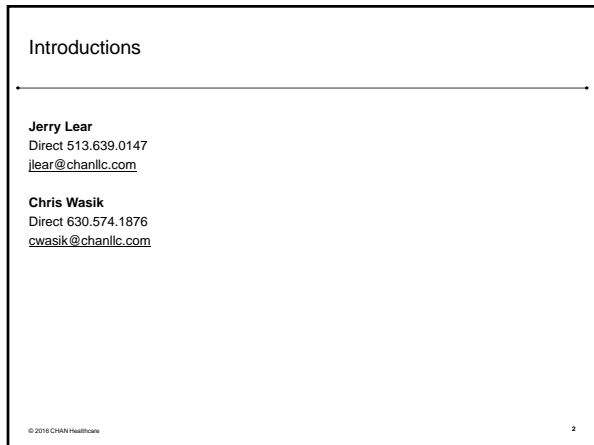
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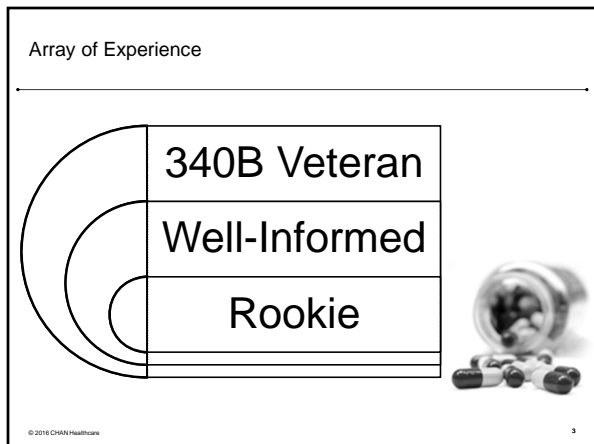
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Course Objectives

- 1 Identify areas to consider as part of your 340B compliance monitoring program, including suggested audit procedures that will provide a full picture of your current program and areas for potential optimization.
- 2 Discuss the HRSA and Manufacturer audit process while also identifying best practice strategies to adequately prepare.
- 3 Present the most frequently identified audit issues, root causes and potential action plans to mitigate the risks moving forward.

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Be Prepared (not just for HRSA audits)



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Agenda

- Part 1
- 340B Drug Discount Program Introduction
    - What is it and why is it important
  - Mega-Guidance
    - What's next
  - HRSA and Manufacturer Audit Process
    - What to expect
    - How has the process evolved
  - Internal Monitoring Program
    - Where to start
    - What areas to focus

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Agenda

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Part 2

- **Most Common Audit Issues**
  - CHAN Healthcare audits
  - HRSA audits
- **Corrective Action Plans**
  - Examples for common risk categories

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340B Program Introduction

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340B Basics

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**The WHAT?**

- Drug discount program created in 1992 by the U.S. federal government that requires drug manufacturers to provide outpatient drugs to eligible health care organizations or covered entities (CEs) at significantly reduced prices

**The WHY?**

- The 340B Program enables CEs to stretch scarce Federal resources as far as possible, reaching more eligible patients and providing more comprehensive care

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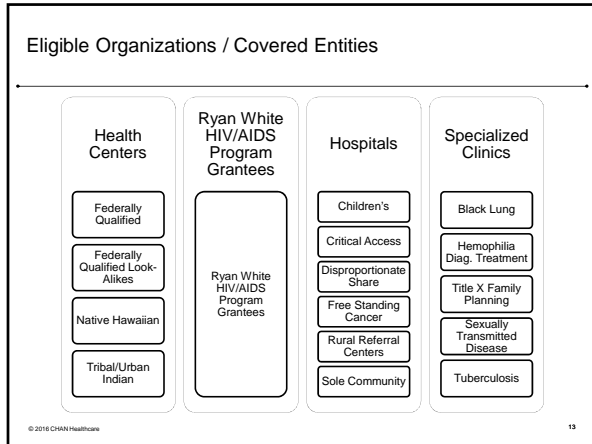
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HRSA Requirements

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Proposed Mega-Guidance Summary

- If the proposed guidance was accepted as final rule, the majority of 340B Programs could have been forced to deal with:
  - Significant software configuration and process changes
  - Overall reduction in savings
  - Increased internal and external monitoring efforts (time and money)

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### Mega-Guidance Status

"On January 30, 2017, the White House Office of Management and Budget (OMB) **withdrew the so-called 340B "mega-guidance"** (RIN:0906-AB08) that was proposed by the Department of Health and Human Services, Health Resources and Services Administration (HRSA), on August 27, 2015.

The new administration under President Donald Trump ordered a freeze on pending regulatory changes on January 20, 2017, whereupon **federal agencies cannot issue new regulations or guidance currently under review by the Office of the Federal Register.** The OMB withdrawal of the 340B mega-guidance means that there will be no formal changes to the 340B program issues covered in the proposed mega-guidance, at least for the time being."

- American Health Lawyers Association (AHLA) – Derick Blakely

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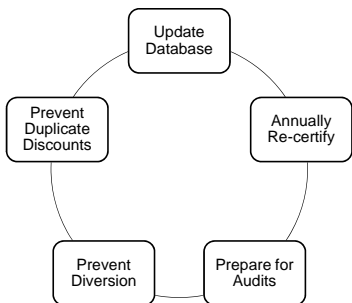
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### HRSA Requirements



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**So what should a CE do now to maintain program integrity and prepare for a potential audit?**



1. Understand what the audit process entails and specific focus areas.
2. Validate your CE has a robust compliance monitoring program.

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### Audits

There are two types of 340B audits that CEs should understand and be prepared for:

1. HRSA audits
2. Manufacturer audits



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### 2017 – HRSA Audit Advancements

- Beginning with the Q1 2017 audits, HRSA will utilize The Bizzell Group to conduct CE audits. Important details include:
  - Audit approach similar to prior years
  - Pre-audit research and analytics are now leveraged
  - Further depth to audit procedures
  - Enhanced auditor training, which should lead to a more consistent approach
  - Higher sophistication with many auditors having Pharmacy backgrounds

**HRSA audit advancements should provide even more reason for CEs to enhance their internal monitoring processes.**

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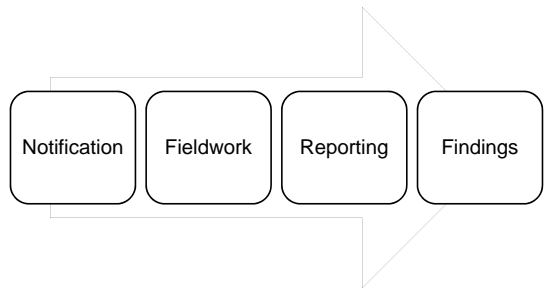
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### HRSA Audit Process



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**HRSA Audit Process**

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- Audit notification
  - CE receives engagement letter informing them of the audit, including scope and what auditors will need onsite
  - HRSA will contact via phone and then set a longer meeting to discuss specific data requests
  - Timing from initial notification to auditors onsite varies, but can be as short as four weeks
    - We've heard that this turn-around will be reduced with the new audit team

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**HRSA Audit Process**

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- Audit fieldwork
  - Typically onsite 3-4 days
  - Procedures normally include:
    1. Confirming CE has a 340B policy/procedures and ongoing monitoring program in place
    2. Confirming CE information within the OPA database is accurate
    3. Testing a sample of 340B dispenses to validate:
      - Eligible patient
      - Eligible provider
      - Eligible location
      - Absence of duplicate discounts

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**HRSA Audit Process**

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- Exit conference
  - While onsite, HRSA typically conducts an exit meeting and shares potential findings
    - We've heard this may be eliminated with the new audit team
- Audit reporting
  - HRSA confirmation of findings and report issuance (can take weeks or months for this to be completed)
  - CE should closely review the report and respectfully challenge if there is disagreement with any findings (within 30 days of receiving the report)
  - Corrective action plan submission for each finding (within 60 days of preliminary report)



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**HRSA Audit Findings**

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- Issues identified are published on the OPA website
  - CE name, audit issue, and related sanctions
- Most common issues identified during 2016 audits surround:
  - Diversion
  - Incorrect database records
    - Child site registration (or lack thereof)
    - Inaccurate CE or contract pharmacy information
  - Duplicate Discounts
    - Dispensing
    - Billing

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**Manufacturer Audits**

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- HRSA Audits are most common, but Manufacturers also have the right to audit CE's
  - However, the audit selection process follows a different path:
    - Manufacturer notifies CE
    - CE inadequately responds to inquiry
    - Manufacturer communicates an audit request to HRSA
    - HRSA reviews and responds
    - If approved, CE is notified of the audit
  - It is anticipated that the increase in 340B savings/revenue will bring about more Manufacturer audits

**KEEP THIS IN MIND – If a Manufacturer asks questions about your 340B Program, respond in a timely fashion.**

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**Every CE's goal is an audit with no findings, how can you achieve this?**



**Evaluation**

- OUTSTANDING
- Excellent
- Very Good
- Average
- Below Average

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### Activity #1 – Monitoring Programs

- Break into small groups (4-5 people)
- Discuss and list attributes of a successful internal monitoring program
  - Include anything you deem important for compliance – some suggestions:
    - Oversight
    - Testing Procedures
    - Meeting Frequency
    - Department Participation
    - Mixed-use vs Contract pharmacy
- We'll re-convene in about 15-20 minutes and ask each group to present

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### 340B Monitoring Program

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### Creating a Monitoring Program

- CE's must be proactive in identifying where potential issues may be occurring within their 340B Program
- How do we set up a robust monitoring program?
- What procedures should be included?



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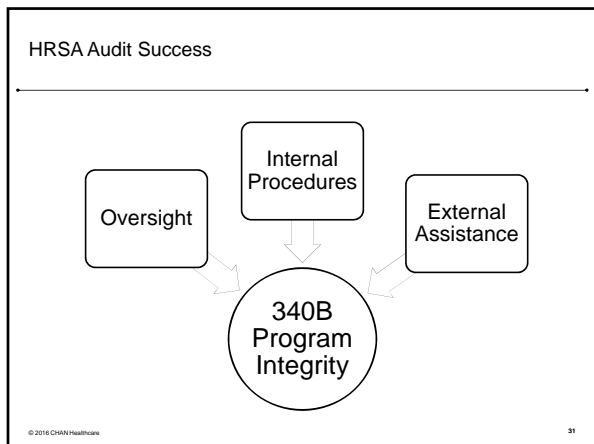
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### Developing Your Self-Monitoring Strategy

#### Who has responsibility for and oversight of your 340B Program?

- Leading practice monitoring programs typically include the following attributes:
  1. **340B Committee** comprised of representatives from **various departments**
  2. A complex federal program coupled with the current healthcare landscape can lead to frequent change, so **program adaptability** is paramount
  3. Ongoing compliance is a time-consuming task, so make sure the **mechanisms used to track progress and measure results** are defined
    - Consider trending results over time
    - Document procedures in policy to show HRSA your dedication to Program compliance

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### Procedures to Validate Compliance

- 5 suggested work steps:
  1. Database Review
  2. Internal Document Review
  3. Internal Auditing/Testing
  4. Independent Audits
  5. Mock HRSA Audits

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1) Database Review

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- OPA Registration Details
- Validate the information included in the OPA database is accurate and up-to-date. This includes:
  - CE information (address, authorizing official)
  - Child site completeness
  - Contract pharmacy information (address, contract in place)
  - Medicaid treatment accuracy

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2) Internal Document Review

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- 340B policy
- Confirm an entity-specific 340B policy exists
- Compare to Apexus policy example and identify areas of enhancement, such as:
  - Entity's reason for participating
  - Enrollment and recertification procedures
  - Purchasing and accumulation processes
  - Eligibility definitions
  - Internal monitoring procedures
  - CE-specific 'material breach' definition

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2) Internal Document Review

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- Other documents requiring review
- Validate your entity has a process for periodically updating the following:
  - Carve-out drug list
  - Eligible provider list
  - CDM-to-NDC crosswalk
- If utilizing a software splitter, also confirm your process includes submitting these documents to the software liaison and configuring into the software

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### 3) Internal Auditing/Testing

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- Typically performed on a sample basis
  - However, the more dispenses tested, the better chance your internal testing will identify issues that HRSA may find during an audit



- Do you want to leave it to chance?

- What if you could review all dispenses, no more 'rolling the dice' that HRSA chooses the 'right' transactions to test?

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### 3) Internal Auditing/Testing

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Utilizing data analytics can be a way to increase your sample size while bringing efficiency to the testing process



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### 3) Internal Auditing/Testing

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- Consider testing the following areas, as these are where HRSA appears to be focusing much of its audit work:
  - **Diversion** – CE providing drugs purchased utilizing 340B pricing to patients not eligible for the Program.
    - Testing procedures should include:
      - Validating the 340B qualifying drug was:
        - Related to an outpatient or an inpatient discharge script;
        - Administered at an eligible location; and
        - Prescribed by an eligible provider.
  - **Duplicate Discounts** – Manufacturers provide both a 340B discount on a drug AND pay a Medicaid rebate to the State on the same drug.
    - Testing procedures should include:
      - **Medicaid Carve-out Entities** – Validate the 340B dispense as NOT to a patient with a Medicaid payor.
      - **Medicaid Carve-in Entities** – If dispense was to a patient with a Medicaid payor, validate it meets all State requirements.
        - State requirements can include inclusion of a specific modifier or billing at the actual acquisition cost.

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### 3) Internal Auditing/Testing

- **GPO Prohibition** – purchasing covered outpatient drugs from a GPO and is prohibited at DSH, Children's hospitals and free-standing cancer centers.
- Testing procedures should include:
  - If drug was purchased through a GPO, validate the drug was dispensed to an inpatient.
  - If drug was purchased for the first time, validate it was purchased at WAC price and not 340B or GPO.
- **Policy Adherence** – HRSA also performs testing to validate your entity's 340B dispenses are in compliance with your definitions and processes detailed within your 340B policy.
- Testing procedures should include:
  - Confirm your entity's most recent carve-out list, eligible location list and eligible provider list match the lists utilized by your splitter software.
  - Validate the drugs you carve-out are not accumulating in the 340B bucket.

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### 3) Internal Auditing/Testing

- Other testing areas for consideration:
  - NDC match between dispense data and purchasing data
  - Failed data transmission identification
  - Duplicate dispense identification
  - Vaccine exclusion validation

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### 4) Independent Audits

*"...HRSA agrees that independent audits can play an important role in ensuring Program integrity. The guidelines have been revised to state that the covered entity must have sufficient information to meet its obligation of ensuring ongoing compliance and the recognition of any problem. Furthermore, the guidelines have been revised to indicate that it is the expectation of HRSA that covered entities will fulfill their ongoing obligation by the utilization of independent audits."*

- Notice Regarding 340B Drug Pricing Program – Contract Pharmacy Services, March 2010

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#### 4) Independent Audits

"HHS believes that covered entities that do not regularly review and audit contract pharmacy operations are at an increased risk for compliance issues. An **annual audit of each contract pharmacy location** will provide covered entities a regular opportunity to review and reconcile pertinent 340B patient eligibility information at the contract pharmacy and prevent diversion. Conducting these audits **using an independent auditor will ensure the pharmacy is following all 340B Program requirements**. Additionally, as a separate compliance mechanism, the covered entity should compare its 340B prescribing records with the contract pharmacy's 340B dispensing records at least quarterly to ensure that neither diversion nor duplicate discounts have occurred."

- 340B Drug Pricing Omnibus Guidance, "Mega-Guidance," August 2015

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#### 4) Independent Audits

- Typically performed by third party audit or consulting firms.
- It is important to keep the following in mind, through each phase of the audit:
  - Firm Selection
    - Do they have previous experience with:
      - Your CE type?
      - Your splitter software?
      - Your patient financial system?
    - Have they performed work for clients who have subsequently undergone HRSA audits?
      - If so, did HRSA have additional findings?
  - Audit Methodology
    - What risks do they test? Do they include all of the HRSA focus areas?
    - How large of a sample will they test?
    - What data will be needed for them to perform their testing procedures?

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#### 4) Independent Audits

- Audit Deliverable
  - Does the deliverable include a detailed findings section?
  - Will there be recommended corrective actions for each issue identified?
  - Will the firm provide education related to the issues identified?
- After the Audit
  - Retain the audit report, as HRSA will ask for evidence of prior audits during their audit process
  - Document actions taken based on the findings identified
    - Including dates, responsible parties and additional validation
  - Begin issue resolution process ASAP

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### 5) Mock HRSA Audits

- Internal monitoring and independent audits are necessary, but planning 'dress rehearsals' of HRSA audits is a great next step
- Mock audits should consider the following:
  - Involve all departments that would be needed to completely walk through a dispense
    - Includes pharmacy, billing, IT, legal, compliance, credentialing, and finance
  - Ensure software splitter liaison understands the process and provides the same data sets HRSA would request
  - Identify a 'Mock HRSA Auditor' (this is commonly someone from Internal Audit)
  - Perform testing for a sample of dispenses and retain all supporting documentation
  - If issues are identified, draft corrective actions and follow them through to completion

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### Monitoring Program Summary

- 340B is a complex arrangement in need of near constant attention and ongoing compliance validation
- It is recommended to:
  - Periodically perform a Program review and testing procedures
  - Contract with experts to perform independent assessments and
  - Prepare for the work steps HRSA will perform when your entity is selected for an audit

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### Part 1 Summary

- HRSA has outsourced 340B audits to a third party firm. We expect the audit process to be more sophisticated and consistent than in previous years.
- Covered entities should assess their current monitoring procedures and validate HRSA-focused risks are periodically tested.
- The new administration has put the proposed Mega-Guidance on hold and there is little information as to when updated guidance may be published.



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Break – 15 Minutes

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Audit Issues Summary

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CHAN Audit Summary

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- Information in this section is based on actual audit issues:
  - Over 110 covered entity audits performed
  - Over 450 audit issues identified

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Audits Under Privilege

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# ACP Vs Non-ACP

Note – Issues identified in ACP audits are not included in this presentation.

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Activity #2 – Most Common Audit Issues

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•Rank the following risks in order of most to least number of audit issues identified:

1. Diversion
2. Duplicate Discounts
3. GPO Prohibition
4. Lost Opportunity
5. Program Management
6. Purchasing/NDC Match

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340B Risk Areas

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•Actual rankings:

- 5. Program Management
- 1. Diversion
- 4. Lost Opportunity
- 6. Purchasing/NDC Match
- 2. Duplicate Discounts
- 3. GPO Prohibition

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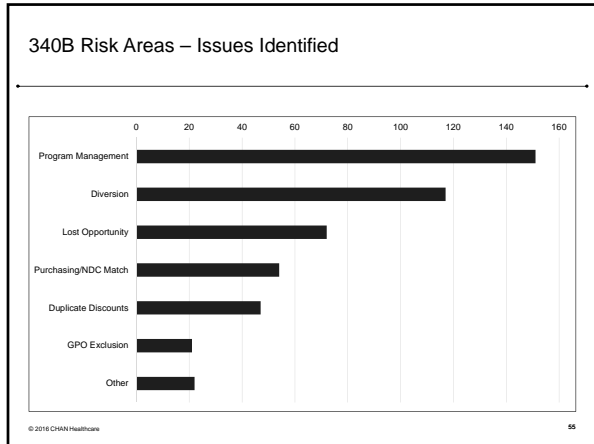
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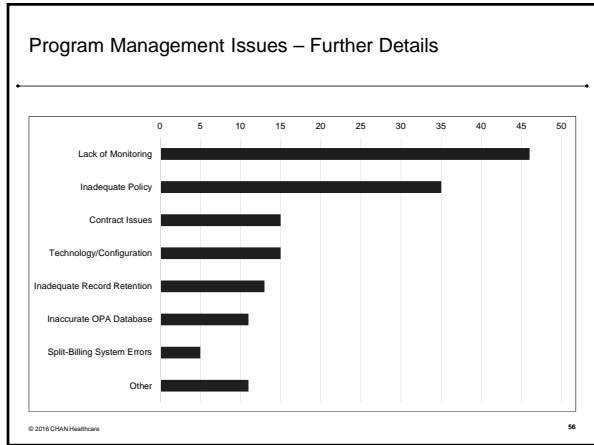
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- ### Program Management – Root Causes
- Areas with the most room for improvement:
    - Program ownership
      - Pharmacy-only focus
      - No compliance/legal presence
    - Program education
      - Initial and ongoing
      - In advance of registering
    - Splitter education
      - Configuration options
      - Qualification process
      - Reporting offerings
      - Push the vendors
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### Activity #3 – Diversion Root Causes

- Break into the same small groups (4-5 people)
- Discuss and list potential root causes of diversion – the goal is to be as detailed as possible:
  - For example, ineligible providers were found to be included in 340B dispenses/accumulation because the provider list maintenance process did not include eliminating terminated providers in a timely manner.
- We'll re-convene in about 10 minutes and ask each group to present

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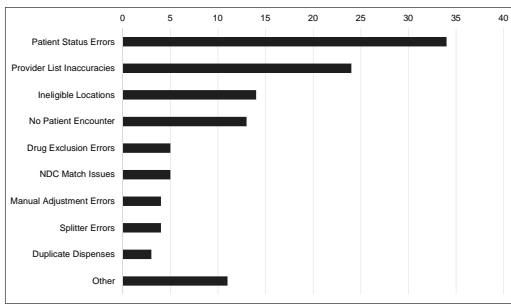
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### Diversion Issues – Further Details



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### Duplicate Discounts – Further Details

- Medicaid carve-in entities
  - Billing expectations not met
    - UD modifier
    - Actual Acquisition Cost (AAC)
- Medicaid carve-out entities
  - Medicaid payors (primary, secondary, tertiary) included in 340B

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Lost Opportunity – Further Details

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- Majority of missed opportunities relate to:

## Software Configuration

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Activity #4 – Split-billing Software Brainstorming

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- Break into groups with individuals utilizing the same split-billing vendor/system.
- Discuss current concerns, if anyone has run into similar issues previously, and how they were able to mitigate risks moving forward.
- We'll re-convene in about 10 minutes and debrief on the most common issues and related implementation strategies to reduce future risk.

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HRSA Audit Findings

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- Most common findings are similar to CHAN audit results
  - Diversion
    - Many related to ineligible sites
  - Duplicate Discounts
  - OPA Database Inaccuracies
- Interesting findings
  - Numerous issues noting lack of contract pharmacy oversight
    - Penalties include termination of contract pharmacy arrangement and termination of the entire contract pharmacy setting
  - Ineligible site qualifying 340B scripts
    - Penalties include termination of the child site from 340B
  - GPO purchasing issue, but the period extends back nine months (more than the six we typically see)
  - Contract pharmacy timing issues – registering (not qualifying scripts as 340B) prior to a contract being in place
  - Using third party audit reports to identify issues

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# Corrective Action Plans

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CHAN Audit Process

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- The following slides relate to action plans implemented based on CHAN audits, not HRSA audits. However, you'll see many could be leveraged (or at least assist) when developing HRSA corrective account plans.

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Program Monitoring and Oversight

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Compliance Risk	Example Action Plan
Program Integrity (Oversight/Monitoring)	Management will develop a 340B steering committee that includes a representative from each department with responsibility for maintaining 340B compliance. The committee will meet on a monthly basis, with meeting minutes compiled and sent to the group within two business days of the meeting taking place. Committee details will be recorded in the policy document.
Program Management (Auditing)	Management will develop a monthly audit process for each contract pharmacy arrangement and a quarterly audit process for the mixed-use setting that includes selecting a sample of 340B dispenses and validating each meets all attributes of eligibility. The internal audit process will be recorded in the policy document.
Program Management (Policy)	Management will update the 340B policy to include all items included in the Apexus example policy and will review the policy at least every two years.

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### Diversion

Compliance Risk	Example Action Plan
<b>Diversion (Provider Issues)</b>	Management will work with the physician credentialing and IT departments to create an initial eligible provider listing that agrees to the definition as stated in the 340B policy. This list will be updated monthly to account for new and terminated physicians and will be sent to each contract pharmacy. This provider maintenance process will be recorded in the policy document.
<b>Diversion (Eligible Encounter, Drug)</b>	Management will work with the IT department to review the current data extract file that is being uploaded into the splitter software and verify that it accurately excludes those departments and locations that do not currently qualify for the program, as stated in the OPA database. In addition, management should review the logic that is excluding certain drugs from the program to confirm that the logic is accurate given the program setup. Any modifications to the extract logic should be updated as necessary within the policy document.

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### Purchasing

Compliance Risk	Example Action Plan
<b>Purchasing (NDC-to-NDC Match)</b>	The pharmacy management department will review purchasing procedures and determine if there is a way to automate all aspects of the process in order to eliminate the ability to manually adjust the bucket in which the drug is to be purchased, as provided by the splitter. Any changes will be recorded within the policy document.
<b>Purchasing (Accumulation)</b>	The pharmacy management department will review the conversion factors currently included in the splitter software and compare them to their internal factors by NDC. Any discrepancies will be communicated to the splitter software. If discrepancies are identified, management will determine the impact on prior accumulation and 340B purchases. Management will implement a process to review periodically all changed conversion factors so that the covered entity and splitter agree.

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### Part 2 Summary

- While Compliance risks make up the majority of audit issues, Program Management and Monitoring are often found to be lacking.
  - HRSA is now taking a hard stance if oversight is not in place
- Diversion is widespread and can take on many forms – sites, providers, duplicate dispenses.
- The root cause of many audit issues is the configuration/setup within the split-billing system, which reinforces the need to fully understand the software during the implementation process.
- Corrective action plans should be detailed and many times include enhancing the policy document.

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**Additional 340B Information**

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**HRSA Guidance**  
<http://www.hrsa.gov/opa/index.html>

**OPA CE Database**  
<https://opanel.hrsa.gov/340B/Views/CoveredEntity/SearchDirectory>

**HRSA Audit Results**  
<http://www.hrsa.gov/opa/programintegrity/auditresults/results.html>

**Apexus Tools and Sample Documents**  
<https://www.apexus.com/solutions/education/340b-tools>

**Apexus 340B University**  
<https://www.apexus.com/solutions/education/340b-university>

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