Diving into 340B Data

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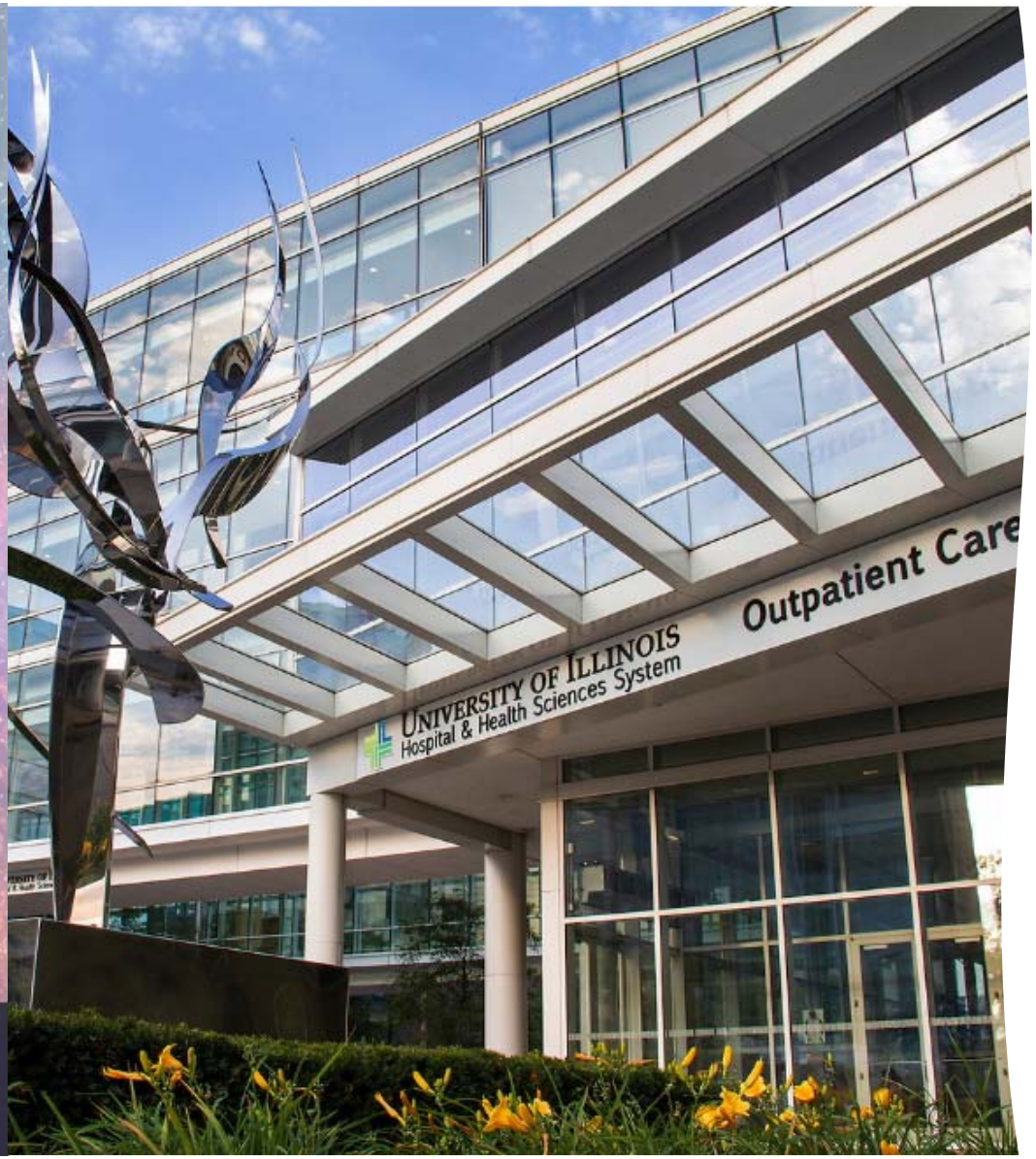
Disclosure Statement

- Christina M. Carrizales Cortez has no relevant financial relationships with ACCME-defined commercial interests for anyone who was in control of the content of the activity.



Introduction – UI Health Background

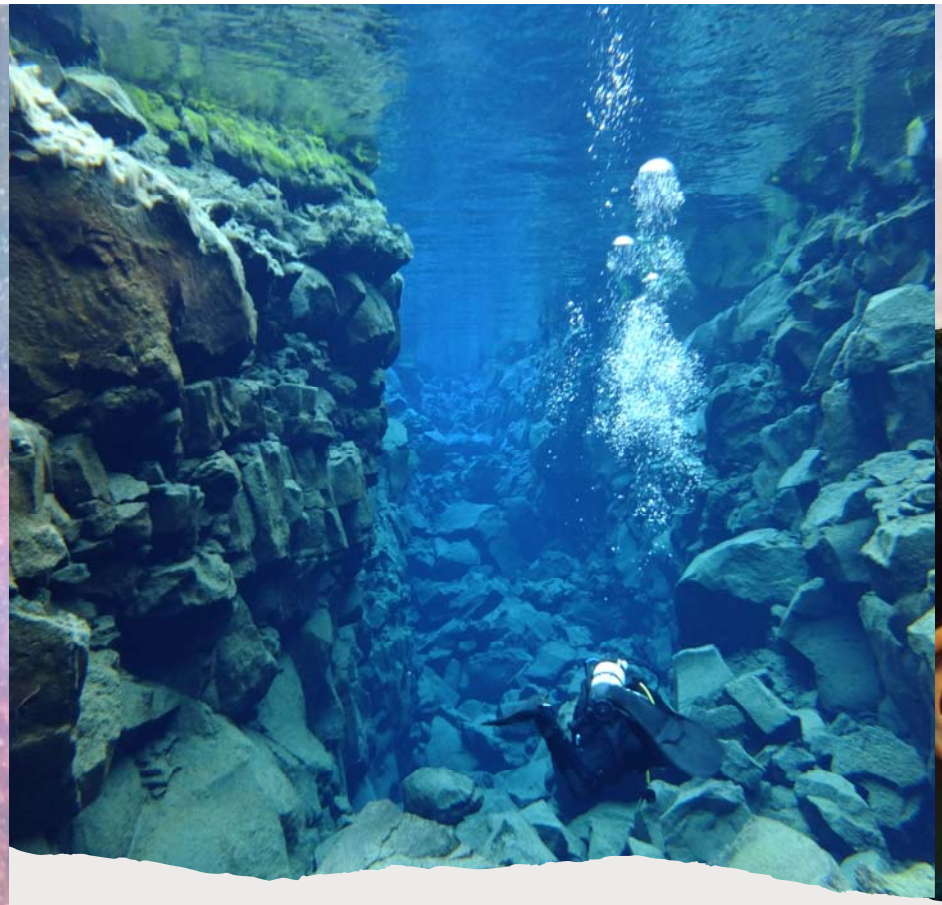
- University of Illinois Hospital and Health Sciences System (UI Health)
  - UI Health 340B participation:
    - Disproportionate Share Hospital (DSH)
    - Federally Qualified Health Center (FQHC)
    - Ryan White Center (RWC)
  - 445-bed state academic hospital
  - 30 Outpatient Clinics with over 500K visits
  - Over 11K outpatient surgeries
  - 7 outpatient pharmacies

Learning Objectives

Define the three 340B compliance pillars.

Explain reporting capabilities within the 340B management system software and the electronic medical record (EMR).

Review examples of report requests to internal business intelligence team to identify gaps in 340B compliance.



Which data analyst describes you?

Intent of the 340B Program

The 340B Program enables covered entities to stretch scarce Federal resources as far as possible, ***reaching more underserved patients and providing more comprehensive services.***

What is 340B?

- Enacted in 1992
- Requires certain drug manufacturers to provide covered outpatient drugs to covered entities (CE) at significantly reduced prices
- Administered by Health Resources & Services Administration (HRSA)
- To participate, entities must meet eligibility criteria and comply with program requirements

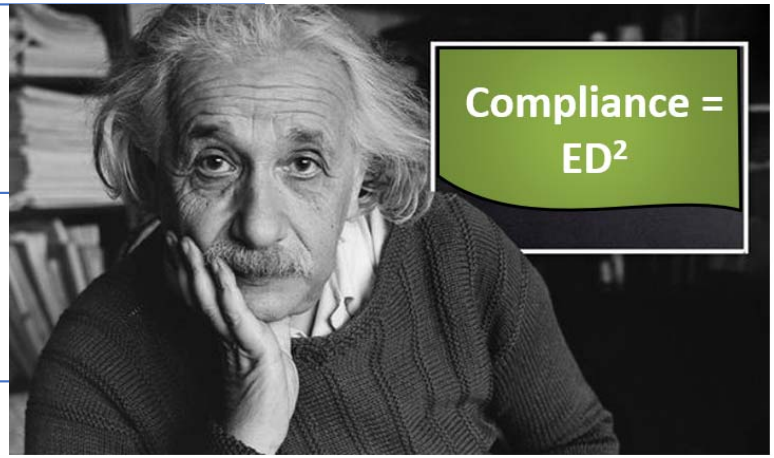
https://www.hrsa.gov/opa

3 Key Compliance Pillars

1. Eligibility

2. Diversion

3. Duplicate Discount



Noncompliance may result in removal from 340B program participation

Compliance – Eligibility

- Eligibility
  - Covered Entity
    - Registration
      - Note registration can occur only during the first two weeks of the start of each quarter (January, April, July, and October)
      - https://www.hrsa.gov/opa/eligibility-and-registration
    - Annual Recertification
    - Keep OPAIS database updated – examples include but not limited to:
      - Authorizing Official
      - Primary Contact
      - Medicaid Exclusion Files
      - New Child Sites
      - Contract Pharmacies

Compliance – Diversion

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

<u>Outpatient</u> drug program

Federal Register defining patient eligibility

https://www.hrsa.gov/sites/default/files/hrsa/opa/patient-entity-eligibility-10-24-96.pdf

Considerations:

Does the health system have clinics that are NOT 340B eligible?

P&P to address procedures in place to avoid diversion

Compliance – Duplicate Discount

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 fee-for-service drugs on the Medicaid Exclusion File, as mandated by 42 USC 256b(a)(5)(A)(i).

- https://www.hrsa.gov/opa/program-requirements/medicaid-exclusion

A drug claim billed to Medicaid can ***either*** receive the Medicaid Drug Rebate ***OR*** the 340B Drug Discount but ***not*** *both*. If both programs are applied on the drug claim, this is considered a Duplicate Discount.

The potential for duplicate discount occurs when:

- The payer is Medicaid (special requirements for billing)
- Medicaid then requests rebates from the manufacturer
- The manufacturer pays the Medicaid rebate
  - Rebate = duplicate discount

Covered entities must accurately report how they bill 340B purchased drugs to *Medicaid payors.*

Importance of Oversight and Auditing

HRSA and Manufacturers may perform audits on CEs

Look for eligibility, diversion, and duplicate discounts

Important to have auditable records

Routine self audits can monitor compliance, establish integrity and prepare for third-party audits

Highly recommended to conduct an annual external audit as part of the CE oversight

Importance of Oversight and Auditing (cont.)

- Best practice to identify how 340B savings are utilized by the covered entity
- Routine 340B Oversight Committee meetings: legal counsel, pharmacy, finance, IS, credentialing team, etc.
- CEs can face penalties for noncompliance including removal from the 340B Program
- Program under scrutiny by drug manufacturers and current administration

340B Management System & EMR

Understanding Data Feeds to Create Targeted Reports

Electronic Medical Record (EMR)	Admit and Discharge Patient Status
Primary Wholesaler	Frequency of Drug Catalog updates to EMR/TPA Will primary Drug catalog override secondary drug catalog
Secondary purchasing accounts	Electronic Data Interface availability
340B Management System – Third Party Administrator	Crosswalk maintenance Qualification Rules & Filters Rx claims: Adjudicated vs. Dispensed
Provider Lists	Medical Staff vs. Graduate Medical Education Frequency of provider updates and integration to EMR & TPA

340B Management System & EMR

Ensure data feeds align to the covered entity's Policies & Procedures

In the event of a HRSA audit, covered entities will be audited regarding internal policies

340B Management System Reports

- Duplicate Claims
- Duplicate Invoices
- Self – prescriber Rx claims
- Random Sample
- Missing Providers and/or Term Date is not updated

EMR System Reports

Providers practicing in multiple locations (eligible and ineligible 340B locations)
Discharge reports
Ensuring new departments/locations are added to TPA data feed if applicable
Department/location mapping to Medicare Cost Report (MCR)
Payer audits
Manual reversals
Transactional claim review: eligible patient, eligible location encounter, eligible provider
Inventory management: purchases to utilization

Diving into Case Studies

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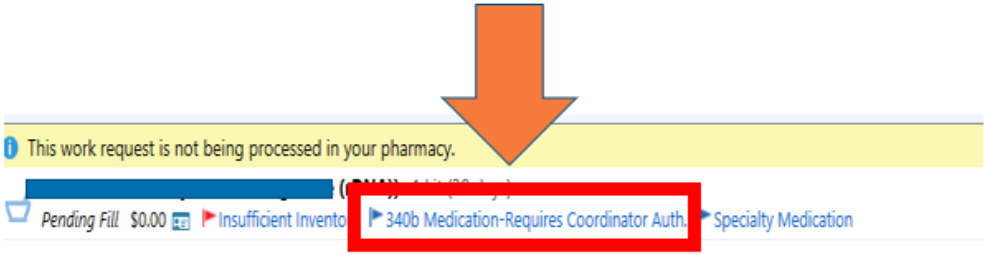
Case Study 1 - Inventory

Situation/Background

- The covered entity manages its 340B inventory through a virtual replenishment model except for 4 identified medications (A, B, C, & D) which are managed as physical inventory. You are tasked with ensuring each 340B purchased drug (A, B, C, & D) is dispensed to a 340B eligible patient. Identify workflow strategies to ensure 340B physical inventory is dispensed to an eligible patient.

Case Study 1- Inventory

<u>Assessment/Recommendation</u>



- Engaged all stakeholders
  - Pharmacy Operations Team
  - IT Analyst
  - Purchasing Officer
  - 340B Pharmacy Team
- Prescription processing system used a hard stop “Flag” for the identified NDCs, and the prescription cannot be sold to a patient unless the 340B hard stop flag is removed by the 340B Team member
- 340B Team maintains auditable and retrievable records of all approved flag removals
- 340B Pharmacy Technician leads the audits, resolves hard stop flags, and reconciles dispenses

Case Study 2 – EMR Requirements

Situation/Background

Prescriptions that require a location per system requirements, consider asking the following:

- What does the location field extract?
  - Rx generating location or location of where patient received care?
- What impact does that have on 340B qualifications?
- Does the TPA support a location field in addition to an encounter feed?
- What are the implications for refill authorizations and refill pools?
- What are the implications for providers that practice at multiple 340B eligible and ineligible locations within the health system?

Case Study 2 – EMR Requirements

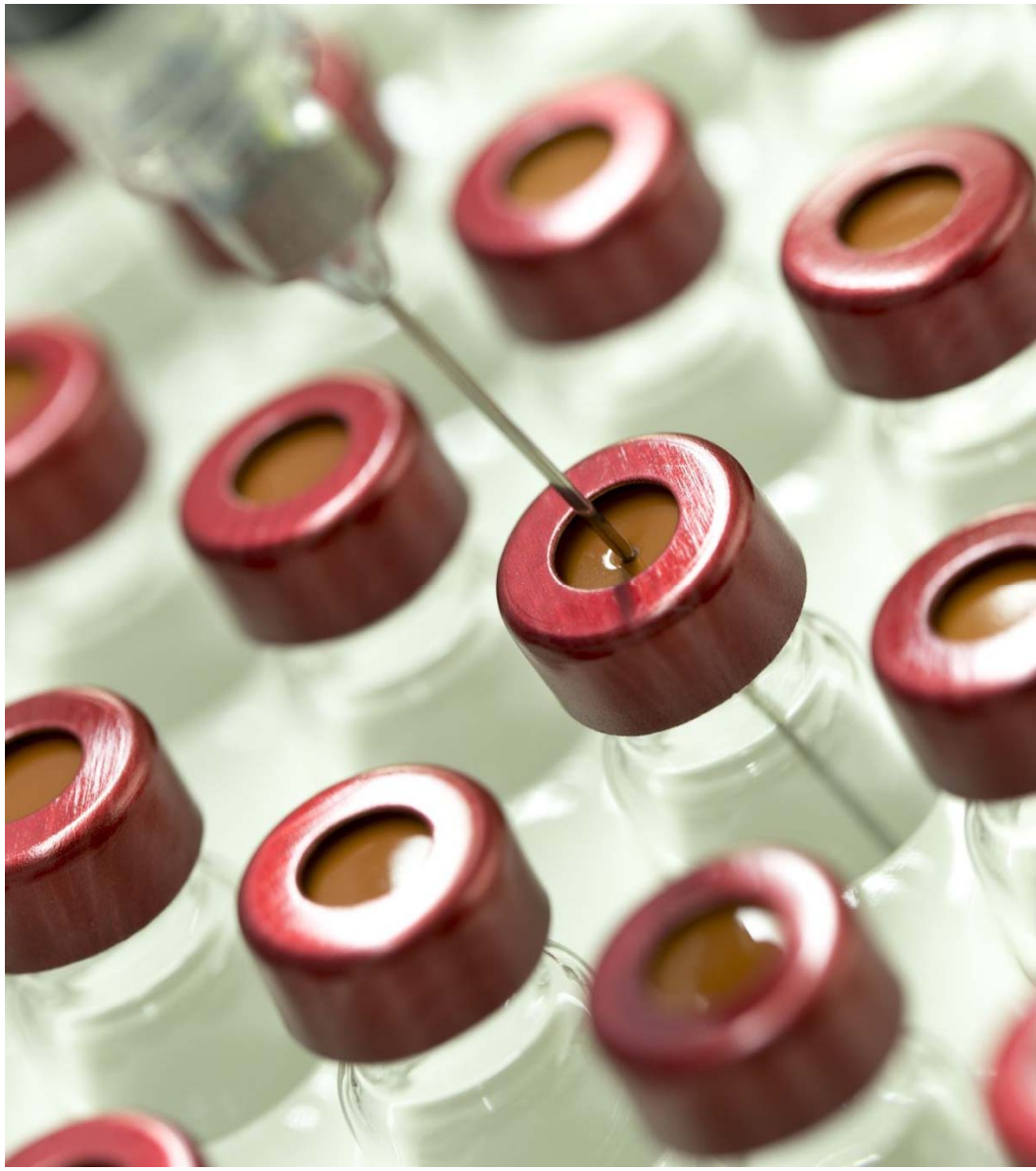
<u>Assessment/Recommendation</u>

- Reporting options/updates
  - Request a new location field generated from a matched provider (NPI) to patient (MRN) with a department of patient care location being the new source data
  - Identify mismatches of Rx generated location to department of patient care
- Next steps:
  - Align it to your organization's 340B eligible location list to determine eligibility or targeted audit

Case Study 3 – Erroneous Accumulations

<u>Situation/Background</u>

- A covered entity that used a 340B virtual replenishment model noticed 500 accumulated 340B packages for a ceftriaxone vial. The utilization history did not support 500 packages as eligible 340B accumulations.



Case Study 3 – Erroneous Accumulations

<u>Assessment/Recommendation</u>

- Data transmitted to the TPA included the dispensed unit and not the NDC package unit which can create missed opportunity or a compliance risk.
- Created a dispensing unit audit to identify claims with erroneous accumulations.

Case Study 4 – Wholesaler Exceptions

Situation/Background

- Your pharmacy buyer notifies you that drug X is not available through your primary wholesaler. Drug X is also supplied by a vendor that does not support an EDI feed to your TPA or your inventory management system. What are some concerns and who should be notified of this new purchase?

Case Study 4 – Wholesaler Exceptions

Assessment/Recommendation

- There is a 340B compliance concern. If drug X will be purchased on a 340B account, then those invoices will require manual uploading to the TPA.
- Since the vendor does not support electronic orders, streamline a process for inventory management.
- Auditing – creating inventory reports to monitor adjustments to invoices received.

Case Study 5 – Provider File Maintenance

<u>Situation/Background</u>

- Provider files are in dynamic state.

Case Study 5 – Provider File Maintenance

Assessment/Recommendation

- Identified active providers in EMR and validated to credentialing list to identify gaps in Rx renewals
- Identified inactive providers within TPA that should contain active dates
- Monthly provider audits to ensure TPA and EMR match credentialing records

Case 6 – Missing Data

Situation/Background

- The pharmacy received a reversal rejection for an Rx claim, the pharmacy called the insurance company to reverse the claim and subsequently called the pharmacy help desk to reverse a claim. The claim qualified as a 340B eligible claim in your TPA.

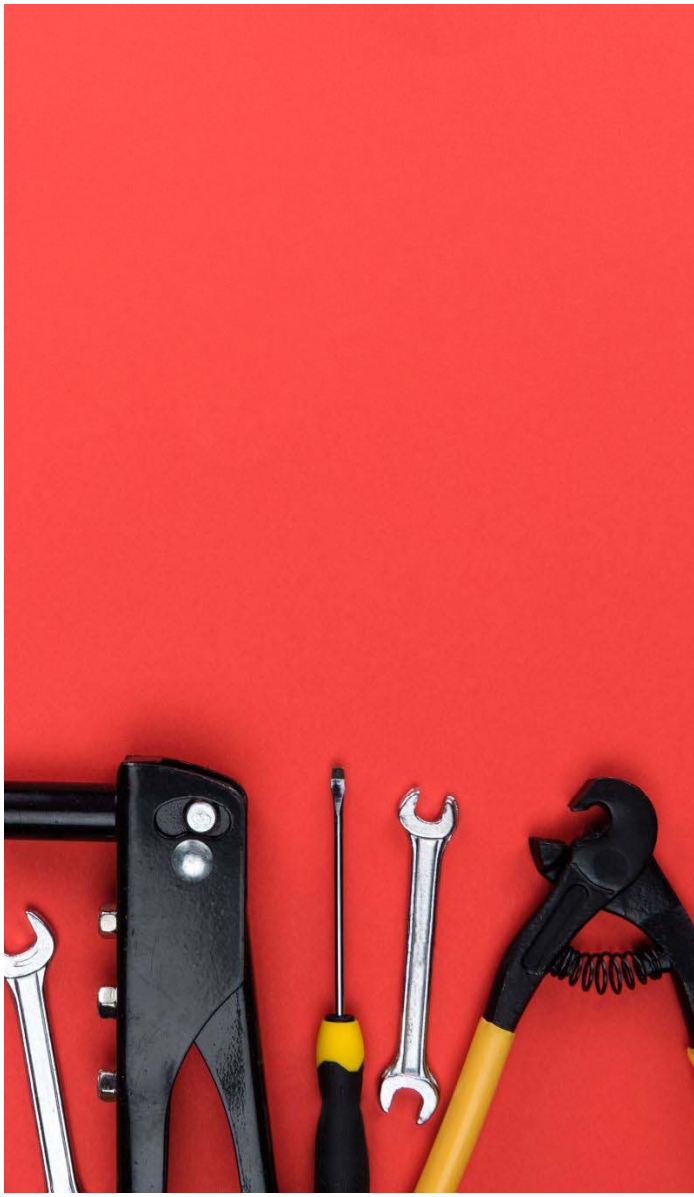
Case 6 – Missing Data

<u>Assessment/Recommendation</u>

- Missing EDI feed to TPA with a reversal match to the manually reversed claim
- Created a report to identify manually reversed claims that occurred within a month
- Monthly change the status of the claims from 340B to non-340B status

340B Toolkit

- HRSA website: https://www.hrsa.gov/opa
- OPAIS: https://340bopais.hrsa.gov/
- Apexus: https://www.apexus.com/340b-certificate-program/resources
- Webinars
- Podcasts
- Follow State and Federal Legislation
- Publications
- Excel Certificate Training
- Internal and External Stakeholders



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Summary

The 3 compliance pillars of the 340B program are: Eligibility, Duplicate Discount, and Diversion

Understanding the complexity of data feeds can help create targeted reports/audits to identify compliance gaps

Leverage your multidisciplinary teams both internal and external to create reporting tools to identify gaps in 340B compliance

Questions and Contact Information

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