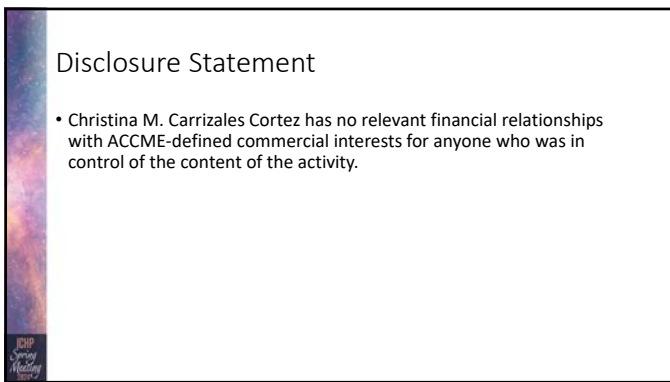




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3

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.


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Which data analyst describes you?

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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.*

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What is 340B?

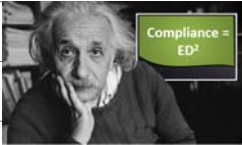
- Enacted in 1992
- Requires certain drug manufacturers to provide covered outpatient drugs to covered entities (CE) at significantly reduced prices
- Administered by Health Resources & Services Administration (HRSA)
- To participate, entities must meet eligibility criteria and comply with program requirements

<https://www.hrsa.gov/opa>

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3 Key Compliance Pillars

1. Eligibility
2. Diversion
3. Duplicate Discount



Noncompliance may result in removal from 340B program participation





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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

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Compliance – Diversion

-  Covered entities must not resell or otherwise transfer 340B drugs to ineligible patients
-  **Outpatient** drug program
-  Federal Register defining patient eligibility <https://www.hrsa.gov/sites/default/files/hrsa/opa/patient-eligibility-10-24-22.pdf>
-  Considerations: Does the health system have clinics that are NOT 340B eligible? P&P to address procedures in place to avoid diversion

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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.

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Importance of Oversight and Auditing



HRSA and Manufacturers may perform audits on CEs



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

Look for eligibility, diversion, and duplicate discounts
Important to have auditable records

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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

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340B Management System & EMR


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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 Systems – 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

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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

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340B Management System Reports

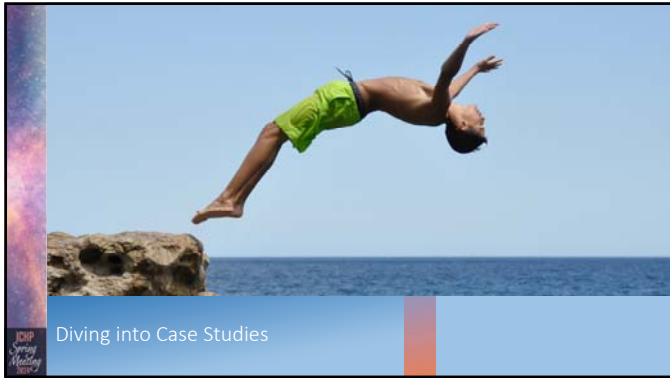
- _____
Duplicate Claims
- _____
Duplicate Invoices
- _____
Self – prescriber Rx claims
- _____
Random Sample
- _____
Missing Providers and/or Term Date is not updated

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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

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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.

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Case Study 1- Inventory

Assessment/Recommendation

- 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

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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?

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Case Study 2 – EMR Requirements

Assessment/Recommendation


- 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

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Case Study 3 – Erroneous Accumulations

Situation/Background

- 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.



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Case Study 3 – Erroneous Accumulations

Assessment/Recommendation

- 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.



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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?

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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.

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Case Study 5 – Provider File Maintenance

Situation/Background

- Provider files are in dynamic state.

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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

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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.

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Case 6 – Missing Data

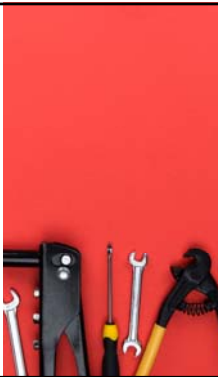
Assessment/Recommendation

- 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

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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

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Questions and Contact Information



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