RBC Cardinal Health DENVER

JULY 9-12, 2025

NCPA®
NATIONAL COMMUNITY
PHARMACISTS ASSOCIATION

CHC: Best Practices for Meeting 340B Audit and Compliance Requirements

Daniel Neal

340B Product & Service Leader

NCPA
NATIONAL COMMUNITY PHARMACISTS ASSOCIATION

RBC Cardinal Health DENVER JULY 9-12, 2025

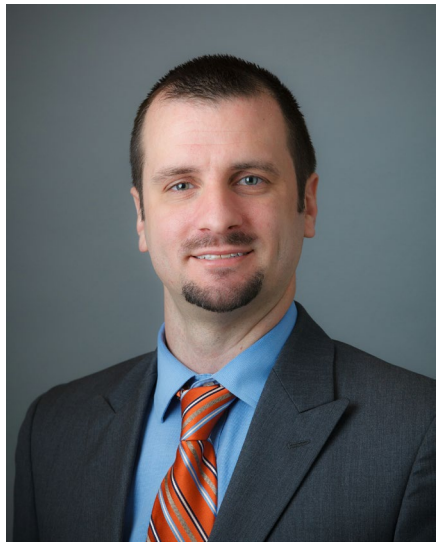
Disclosure Statement

Daniel Neal has a financial interest with Cardinal Health and the relationship has been mitigated through peer review of this presentation. There are no relevant financial relationships with ACPE defined commercial interests for anyone else in control of the content of the activity.

Pharmacist and Technician Learning Objectives

1. Review the legislative, regulatory, and subregulatory history and framework around 340B compliance.
2. Summarize how audit and other compliance ‘tools’ are used, along with trends in audit findings.
3. Discuss strategies for navigating an evolving 340B landscape, including federal, state, and industry-driven changes, as well as ideas for ‘reform’.

Speaker



Daniel Neal

340B Product & Service Leader

Cardinal Health, Inc.

NCPA
NATIONAL COMMUNITY PHARMACISTS ASSOCIATION

340B program

A federal drug pricing program in place since the 1992

- Section 340B of the Public Health Service Act, created under Section 602 of the Veterans Health Care Act; modified via 2010 Patient Protection & Affordable Care Act
- Entitles ‘covered entities’ (CEs) to access covered outpatient drugs (COD) at or below a statutorily-defined ceiling price (340B price)
- Manufacturers must sign a Pharmaceutical Pricing Agreement (PPA) with HHS to have COD products covered by Medicaid and Medicare Part B; creates 340B pricing obligation
- CE and manufacturer each have obligations and oversight per statute

340B program

Administration of 340B stable, but changes coming?

- Current administration falls to the Office of Pharmacy Affairs (OPA), part of Health Resources & Services Administration
  - For now…administration suggests potential administrative change to CMS
- Apexus – private non-profit that holds federal contract to administer the 340B Prime Vendor Program (PVP)
  - Engaged by OPA to provide information, including compliance information, to stakeholders
  - Operates call center, online support, '340B University', and web FAQ database
  - Background on 340B 'Prime Vendor'
- Other agencies have nexus with 340B, such as CMS, FDA, DEA, etc.

340B program

340B regulatory framework

- 340B historically managed via sub-regulatory framework, including Policy Releases, Program Updates, FAQs, webpage notices, stakeholder letters, etc.
- This continues, but in last decade HRSA attempted formal regulation with mixed results:
  - Failed orphan drug rule – defeated in federal court
  - Abandoned ‘mega reg’ / ‘mega guidance’
  - Ceiling Price and Civil Monetary Penalties rule (success)
  - Administrative Dispute Resolution rule (success but long history including withdrawal and reissue)
- HRSA’s rulemaking and enforcement authority remains contentious topic in 2025
- CMS increasingly pushed for guidance and regulation as nexus between 340B and Medicare/Medicaid programs grows

340B program

340B patient definition central to compliance and size of program

- HRSA's 1996 patient definition remains the controlling patient definition despite aborted attempts to issue revised definitions
  - Revised definitions generally more restrictive
- 1996 definition issued via FRN:
  - https://www.hrsa.gov/sites/default/files/hrsa/opa/patient-entity-eligibility-10-24-96.pdf
- Patient definition criticized as being overly broad or overly narrow depending on stakeholder perspective
- Future called into doubt by Genesis Health Care ruling in November, 2023

340B program

340B patient definition from 1996

- The covered entity has established a relationship with the individual, such that the covered entity maintains records of the individual's health care; and

340B program

340B patient definition from 1996

- The covered entity has established a relationship with the individual, such that the covered entity maintains records of the individual's health care; and
- The individual receives health care services from a health care professional who is either employed by the covered entity or provides health care under contractual or other arrangements (e.g., referral for consultation) such that responsibility for the care provided remains with the covered entity; and

340B program

340B patient definition from 1996

- The individual receives a health care service or range of services from the covered entity which is consistent with the service or range of services for which grant funding or Federally-qualified health center look-alike status has been provided to the entity. Disproportionate share hospitals are exempt from this requirement.

340B program

340B patient definition from 1996

- An individual will not be considered a patient of the covered entity if the only health care service received by the individual from the covered entity is the dispensing of a drug or drugs for subsequent self-administration or administration in the home setting.
    - Exception: Individuals registered in a State-operated or funded AIDS Drug Assistance Program (ADAP) that receives Federal Ryan White funding ARE considered patients of the participant ADAP if so registered as eligible by the State program.

HRSA 340B Audits

Statutory basis of 340B CE audits

Section 340B directly requires that CE may be subject to audit by HHS and/or manufacturers

> (C) AUDITING.—A covered entity shall permit the Secretary and the manufacturer of a covered outpatient drug that is subject to an agreement under this subsection with the entity (acting in accordance with procedures established by the Secretary relating to the number, duration, and scope of audits) to audit at the Secretary's or the manufacturer's expense the records of the entity that directly pertain to the entity's compliance with the requirements described in subparagraphs (A) or (B) with respect to drugs of the manufacturer.

HSRA 340B Audits

History of 340B audit

- Early days of 340B oversight – audits infrequent, targeted, often extreme cases
- FY12 – beginning of ‘modern’ 340B audit process
  - Started with government employees, shifted to outside federal contractor
  - 51 CE audits for FY12; moved to ~100 for several years; current target 200 CEs per fiscal year
  - Recent FY typically incomplete as audits involve potentially contested findings and/or delayed production of data
- Audits continue today – may be risk-based or targeted; remote or onsite

HRSA 340B Audits

Publication of results

- Some information posted publicly:
  - Entity name; HRSA ID; state
  - List of findings, if any
  - Outcome of findings, if any
  - Link to manufacturer letter, if any
  - Audit closure date
- Note – public information can vary; recent year saw no public letters, but some entries with contact information added

Borrego Community Health Foundation	CH099010	CA	Diversion – 340B drug dispensed at contract pharmacy, not supported by a medical record; 340B drugs dispensed for prescriptions written by ineligible providers. Duplicate Discounts – Entity was billing Medicaid contrary to information included in the Medicaid Exclusion File.	Repayment to manufacturers	Public letter to manufacturers Audit closure date: March 18, 2016

HRSA 340B Audits

HRSA audit process

- Audit process generally predictable:
  - Notice followed by initial call with auditor
  - Data Request List (DRL) sent by auditor and fulfilled by CE
  - Audit phase (remote or onsite)
  - Report produced by auditor and sent to CE
  - Post-audit phase; potential responses by CE to OPA
- Note that while mostly predictable, HRSA has sometimes changed details, such as specific data or document requested and introduction of expanded remote audit option during pandemic

HRSA 340B Audits

Pre-audit elements

- Audit notice via email
- Virtual meeting with auditor staff
- DRL provided and ‘audit period’ confirmed
- Timelines for audit established – can seek extension based on CE circumstances, but no assurance it will be granted

HRSA 340B Audits

The DRL elements

- 340B P&P manual
- 340B eligibility documentation
- 340B ‘universe’ – dispensation/administration records from audit period for all settings
- Eligible provider list for audit period
- 340B purchase history for audit period
- Purchasing documentation – includes invoice samples, description of purchasing account numbers, and 340B purchase history for audit period
- Contract Pharmacy (CP) documentation – contracts, activity notes, oversight confirmation, etc.
- Non-CP pharmacy documentation
- Self-disclosure details
- Medicaid Fee For Service (FFS) documentation – MPN/NPI, sample claims, multi-state billing information

HRSA 340B Audits

The audit phase

The audit phase turns focus on assessing compliance:

- 340B P&P manual – does it exist, is it complete, does it align with practice?
- CE 340B eligibility – includes general eligibility expectations such as maintenance of auditable records and CE-specific requirements (GPO Prohibition, contracts with state/local government, EHB, grant funding, etc.)
- Medicaid elements - MEF, OPAIS elections, MPN/NPI entries
- Database accuracy
- Controls and processes to prevent diversion and duplicate discount
- Possible visits to review procedures at 340B sites/pharmacies
- Testing of samples (typically 60-75 records)

HRSA 340B Audits

Post-audit phase

- After audit, CE will receive the Final Report – report is from OPA, not from the individual auditor or contracted firm
  - There is no firm timeline on how long before report is received
- Report includes summary, narrative, Findings, and Areas for Improvement (AFI)
- Under current standards, only Findings require a Corrective Action Plan (CAP) from CE
- If Findings, CE may respond either with CAP in 60 days or dispute of Findings within 30 days
  - Sometimes an extension of time to respond is requested

HRSA 340B Audits

Responding to Findings

- Findings generally require either dispute or CAP; other audit elements such as AFI currently do not require CAP
  - Dispute if successful will result in no CAP for that finding
  - If unsuccessful, only two real pathways:
- Option 1 - Develop and submit CAP; OPA reviews and accepts or suggests changes
  - Once CAP plan approved, execution expected within 6 calendar months
  - Findings of partial/complete ineligibility, failure to submit CAP, failure to complete CAP, and/or repeated audits with similar Finding of diversion may all lead to temporary removal from the 340B program
- Option 2 - Challenge audit in federal court (see Genesis Health Care)

HRSA 340B Audits

HRSA audit findings have displayed trends

- Early years saw high Diversion findings – sometimes in more than 50% of final reports
- Diversion, GPO Prohibition significantly decreased over time but slight uptick in Diversion recently could reflect renewed confidence in patient definition enforcement
- Inaccurate database most common finding
- Medicaid findings can require interpretation – some cases reflect merely potential duplicate discount where none in fact occurred; others may reflect significant instances of probable duplication

HRSA 340B Audits

The future of HRSA 340B audits

- *No known proposal to reduce frequency or scope of 340B audits*
- Some legislative proposals to increase aspects of HRSA's authority and/or introduce funding mechanism for additional oversight efforts via 'user fee' on 340B drugs
- HRSA leadership several times has asked Congress for clearer, stronger, and broader rulemaking and enforcement authority in Congress
- Changes in Presidential administration have influenced HRSA audit findings
- Would a change for OPA from HRSA -> CMS alter how audits are conducted?
  - For example, would Medicaid Managed Care (MCO) duplicate discount be added to scope?

HRSA 340B Oversight

HRSA has attempted non-audit program integrity efforts

- Self-disclosure process
- Annual recertification
- Administrative Dispute Resolution (ADR)
- Combined Purchasing Models
- Additional documentation requests to verify eligibility

HRSA 340B Oversight

The 340B Prime Vendor Program offers resources to prepare for audit and manage 340B compliance

- Educational and informational resources
  - OnDemand modules
  - Virtual 340B University
  - In-person 340B University
- State Medicaid profiles
- Searchable HRSA-aligned FAQs
- Apexus Answers
- Tools & Templates including:
  - Sample DRL
  - Self-audit
  - HRSA audit overview

Manufacturer Oversight

Manufacturers can conduct formal audits of 340B CEs

- Much rarer than HRSA 340B audits, but more reports of manufacturer audits in recent years
- Manufacturer audits grounded in statute and FRN issued by HRSA in 1996:
  - https://www.hrsa.gov/sites/default/files/hrsa/opa/dispute-resolution-process-12-12-96.pdf
- Manufacturers conduct audits via a work plan submitted to HRSA and reviewed
  - Note – HRSA may object to the work plan, but the work plan does not need explicit 'approval' to move forward
- Manufacturer should have reasonable cause
- Audit scope includes potential diversion and duplicate discount only; reports of manufacturers being allowed to audit Medicaid MCO claims, typically out of scope for HRSA audit
- Entities have 30 days to respond to findings in a manufacturer audit

Manufacturer Oversight

Manufacturers can engage through less formal process

- Increasingly common ‘letter of inquiry’ (LOI) used by manufacturers to investigate perceived concerns
- Not a full audit; typically, a set of transactions such as purchases and/or dispensation/claims records
- LOI in some cases may cover a longer period and require more effort to resolve than an audit due to complexity of request and need to research data from aged periods
- Reports that in some cases LOI not resolved to manufacturer satisfaction could lead to further action, even ‘reasonable cause’ basis for audit

Manufacturer Oversight

Manufacturers have other ways to address perceived 340B compliance issues

- Retroactive chargeback (CB) denials based on eligibility dating on OPAIS or other perceived eligibility issues
  - CB – transactions between wholesaler that facilitate 340B contract pricing; if reversed can lead to 'billback' event
- Since 2020, CP policies issued and revised; often include manufacturer-specified conditions such as minimum timeframe between dispense and 340B replenishment orders
  - Such policies were challenged by HHS but ultimately survived several court battles
- Some manufacturers have proposed 340B 'rebate' models; such models could include manufacturer-determined rules on 340B price access
  - Such policies are subject of multiple court battles; court so far supports HRSA review and approval process but does not consider such models inherently unlawful; final fate remains to be seen

State Oversight

States have long had interest in 340B compliance

- Medicaid a state/federal partnership program that includes Medicaid Drug Rebate Program (MDRP)
- Nexus with 340B dates to 1992; expanded in 2010
- Fee-For-Service (FFS) Medicaid claims must not create ‘duplicate discount’
  - Occurs when same drug is both acquired at 340B price and subject to Medicaid rebate request to manufacturer
- FFS managed via MEF and OPAIS data; states may also require specific claims modifiers and/or attestation forms
- 2010 PPACA added Medicaid Managed Care Organization (MCO) claims to potential rebate eligibility; created duplicate discount risk

State Oversight

States issues Medicaid/340B policies and may pursue recoupment of funds

- Each state may have their own approach to Medicaid and 340B, often broken out along lines including:
  - Pharmacy vs. Medical
  - Entity-owned vs. Contract Pharmacy
  - FFS vs. MCO
- States may audit CEs for potential duplicate discount situations
- States may attempt to claw back payments if they believe duplicate discount occurred and/or state-specific requirements (i.e., claims modifiers, AAC billing, etc.) were not followed
- Recommended to continually monitor for potential changes to state Medicaid/340B policies

State Oversight

Recent years see states considering additional 340B obligations for CEs

- As of May 2025, five states have enacted laws that require some form of CE 340B reporting requirements
  - Maine, Idaho, Minnesota, Indiana, and Washington state
- Minnesota first to publish a report, focused on ‘net revenue’ for 340B CEs
  - https://www.health.state.mn.us/data/340b/docs/2024report.pdf
- Several state laws focus on hospital reporting; others require non-hospital CEs
- Many states considering reporting laws; some even evaluating required use of savings, mandatory claims modifiers, pass-through pricing, and other restrictions

Managing 340B compliance

HRSA expects CEs to proactively manage 340B compliance – good practice to be prepared for any audits or inquiries!

- Evaluate diversion risk factors, including data feed issues, provider file challenges (inc. providers that may work for multiple organizations), ineligible sites, dating issues with CPs, and potential interpretation challenges such as referral without documentation and labs as basis for patient status
- Evaluate duplicate discount risks, including out-of-state plans, secondary/tertiary position, retroactive enrollment/billing, MEF and OPAIS accuracy, consistency of operations with carve-in/carve-out election, and use of state-required modifiers
- At least annually confirm accuracy of all OPAIS data elements, including CP listings
- Establish oversight program with strong leadership support, including steering committee, internal audits, external review, and formal staff training plans (inc. periodic updates)

Questions?

Daniel Neal
340B Product & Service Leader
Cardinal Health, Inc.
daniel.neal@cardinalhealth.com

NCPA
NATIONAL COMMUNITY PHARMACISTS ASSOCIATION