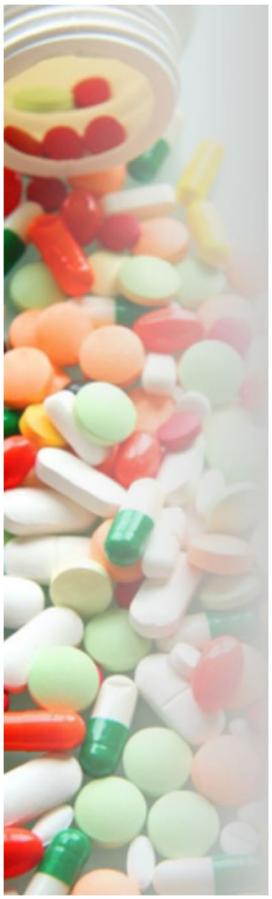
340B Program Audits: Do More with Data

Authors: Michelle L. Beard, CPA, Partner, Crowe
Susan E. Brankin, B.S. Pharm, R.Ph., ACE, Crowe
Lisa M. Robbins, CIA, Crowe

Contents:

A more targeted 340B audit approach



The 340B Drug Pricing Program has faced increased scrutiny by the U.S. Health Resources and Services Administration (HRSA) over the years as well as public challenges by drug manufacturers to limit or change the 340B Drug Pricing Program's contract pharmacy operations, point-of-purchase 340B discounts, and "good faith" inquiries in recent months. This environment makes having insight into risk areas associated with the program even more crucial for today's healthcare internal auditors. Using data analytics (DA) to address compliance concerns can help auditors enhance insights and execute a more efficient, targeted audit approach to a covered entity's 340B Program.

This article provides background on the 340B Program, a review of data analytics and its abilities, and strategies for use in key risk areas, including diversion, duplicate discounts, and purchasing practices. It also includes sample audit findings to illustrate data analytics' capabilities in illuminating 340B compliance issues.

Background: What is 340B?

Created by the U.S. federal government in 1992, the 340B Program requires drug manufacturers that participate in Medicaid to provide outpatient drugs to eligible healthcare organizations and covered entities at significantly reduced prices. The program is intended to help covered entities stretch scarce federal resources, allowing them to reach more eligible patients and provide more comprehensive healthcare services.

HRSA's Office of Pharmacy Affairs (OPA) administers the 340B Program and interprets and implements 340B Program statutes. HRSA is responsible for issuing guidance related to the 340B Program and has the authority to audit covered entities to assess compliance with program requirements. In 2017, HRSA contracted with the Bizzell Group, which now performs the audits on HRSA's behalf. The Bizzell Group hires

pharmacists and experienced experts in the 340B Program to conduct audits, which has improved the quality and depth of HRSA audits.

Currently, six types of hospitals are eligible to participate in the 340B Program:

- Children's hospitals (PED)
- Critical access hospitals (CAH)
- Disproportionate share hospitals (DSH)
- Freestanding cancer hospitals (CAN)
- Rural referral centers (RRC)
- Sole community hospitals (SCH)

In addition, these nonhospital covered entities are eligible for the 340B Program:

- Federally qualified health centers (FQHCs)
- FQHC look-alikes (community-based healthcare providers that meet the requirements of the HRSA Health Center Program but do not receive program funding)
- Native Hawaiian health centers
- Tribal and urban Indian health centers
- Ryan White HIV/AIDS Program grantees
- Black lung clinics
- Comprehensive hemophilia diagnostic treatment centers
- Title X family planning clinics
- Sexually transmitted disease clinics
- Tuberculosis clinics

To participate in the 340B Program, covered entities must register with HRSA and comply with all program requirements,[1] which include:

- Meeting eligibility requirements and recertifying every year

- Keeping OPA Information System (340B OPAIS) information up to date and accurate
- Preventing duplicate discounts
- Preventing drug diversion to ineligible patients
- Preparing for program audits, including maintaining auditable records documenting compliance with 340B Program requirements

Data analytics in healthcare

Data analytics (DA) is the process of analyzing large data sets to draw insights into and conclusions about the information within the data sets. DA is aided by software and emerging technologies that analyze the data sets to produce meaningful takeaways.

The healthcare industry has become increasingly data reliant as a result of the wide adoption and use of electronic medical records (EMRs), patient financial reporting, and inventory management systems across all sectors. Data analytics technologies enable healthcare organizations to make more informed decisions in areas such as clinical effectiveness, compliance, performance improvement, and finance.

Healthcare internal audit and compliance departments rely on data analytics to improve auditing, monitoring, and compliance, which provides auditors with an enhanced understanding of risks and opportunities. Use of data analytics is particularly valuable in the healthcare field, given its complex regulatory and reporting landscape.

Data analytics and 340B auditing

One of data analytics' greatest benefits for 340B Program internal auditors is its ability to assist auditors in testing 100% of the entity's qualified dispensations and program data. Having complete insight into program data – versus relying on small sample size audits – can aid auditors in uncovering problem areas more quickly while providing additional comfort in overall program compliance.

First, auditors must understand a covered entity's 340B definitions and eligibility criteria when using data analytics. This knowledge can allow them to test 100% of drug administrations in the mixed-use setting (a hospital area serving both outpatients and inpatients) and prescriptions in the owned retail (retail pharmacy owned by the covered entity) or contract pharmacy (an outside pharmacy with which the covered entity contracts to provide pharmacy services using medications purchased through the 340B Program) setting with meaningful results.

Additionally, it is critical to understand a covered entity's specific patient definition when testing for compliance issues, as patient definitions vary widely from covered entity to covered entity. For example, the eligible patient definition should include how eligible transactions are qualified (at the time of drug dispensing, drug administration, or drug billing) and whether eligibility is determined in real time or is batched.

Typically, to aid in 340B compliance, 340B Program covered entities use software solutions for patient eligibility identification, inventory management, dispensing and replenishment, and reporting. These software solutions commonly are referred to as "split-billing software" because they split replenishment orders for eligible medications into various purchasing accounts based on the covered entity's eligible patient definition criteria. Software solutions might use a covered entity's charge data, administration data, or a combination of both to determine eligible 340B transactions.

Last, internal auditors need to determine the source of truth for eligibility data when using data analytics. Doing so helps auditors confirm they are comparing the appropriate data elements representing the covered entity's patient definition used by HRSA auditors. Auditors also need to confirm which systems supply the data used to determine eligibility (for example, patient financial system, EMR, pharmacy system, physician credentialing, or pharmacy wholesaler inventory management system).

Following is a closer look at how healthcare internal auditors can use DA to take a more targeted audit approach in the top 340B Program risk areas of diversion, duplicate

discount, and purchasing compliance.

Diversion prevention

Per Section 340B(a)(5)(B) of the *Public Health Service Act*, covered entities are prohibited from reselling or otherwise transferring a drug to a person who is not a patient of the entity.[2] Diversion occurs when a 340B drug is:

- Provided to an individual who is not an eligible outpatient of the entity
- Dispensed either through administration or prescription in an area of a facility or location that is not eligible
- Administered or prescribed to a patient who receives healthcare services from a healthcare professional who neither is employed by the covered entity nor provides healthcare under contractual or other arrangements or is not supported by documentation in the medical record as being provided to an eligible patient

Auditors can use diversion prevention analytics to confirm the provider writing the prescription or administering the medication is an eligible provider as defined by the covered entity, that the location where the medication is ordered or administered is an eligible location, and that the patient encounter is eligible as defined by HRSA's 340B Program guidance. By reviewing these key data elements, auditors can uncover potential diversion issues prior to the medication being purchased on 340B.

Examples of ways in which healthcare internal auditors could use DA in the area of drug diversion prevention include:

- **Mixed-use setting:** Match 340B accumulation data by National Drug Code (NDC) to drug administration data. By comparing drug administration data from the EMR to 340B accumulation data from the split-billing software, auditors might discover drugs that are billed on dispense and accumulated as 340B but never charted as administered, which is key to eligibility testing for HRSA.

- **Owned retail or contract pharmacy services:** Match 340B and prescription data to the covered entity's defined eligible provider list and eligible location list.
- **Clean-use service (hospital offsite clinic, department, or service that serves only outpatients):** Match purchasing records and expired medication documentation to drug administration and waste capture data from the EMR to confirm all medications purchased through the 340B Program were administered, wasted, or expired.

Duplicate discount prevention

Drug manufacturers are not required to provide a discounted 340B price to a covered entity and a Medicaid drug rebate to the state for the same drug. This stipulation is known as a "duplicate discount." As part of the 340B Program, covered entities must have mechanisms in place to prevent duplicate discounts.

Covered entities in the 340B Program need to decide whether they will dispense 340B purchased drugs to their Medicaid fee-for-service (FFS) patients – known as "carving in" – or if they will not use 340B purchases for their Medicaid FFS patients, which is known as "carving out." In the contract pharmacy setting, covered entities are required to carve out unless they are contracted with the state to do otherwise.

If covered entities decide to bill Medicaid FFS for drugs purchased under the 340B Program using a Medicaid provider number or National Provider Identifier (NPI), then all drugs billed under that number must be purchased through the 340B Program. The Medicaid provider number or NPI must be listed in the Medicaid Exclusion File (MEF) maintained by HRSA.

Covered entities participating in the 340B Program also must comply with all state Medicaid laws that mandate billing requirements for 340B purchased medications. This might include billing the drug ingredient cost or adding claim modifiers. States also might determine whether the Medicaid billing requirement includes 340B purchased medications billed to Medicaid managed care organizations (MCOs). Covered entities

billing out-of-state Medicaid agencies for 340B purchased medications must comply with each state's billing requirements.

Examples of ways in which healthcare internal auditors could use DA in the area of duplicate discount prevention include:

- **For 340B Medicaid carve-in mixed-use and owned retail:**
  - Based on state-specific FFS Medicaid outpatient billing requirements (MCO included if required by state), internal auditors can review Medicaid outpatient claims data files (837 claims) to assess whether the required billing claim modifier is appended to all unbundled hospital-administered drugs and entity-owned retail pharmacy prescriptions and that the required drug ingredient cost is charged.
- **For 340B Medicaid carve-out mixed-use and owned retail:**
  - Based on state-specific FFS Medicaid outpatient billing requirements (MCO included if required by state), auditors can review Medicaid outpatient claims for a Medicaid payer.
- **For 340B Medicaid carve-out contract pharmacy:**
  - Auditors can review contract pharmacy payer data for a Medicaid FFS payer (MCO included if required by state) by bank identification number (BIN), processor control number (PCN), or group ID. If a BIN, PCN, or group ID is not provided, auditors can test against a hospital payer field to confirm no Medicaid payer exists for the claim.

Purchasing compliance (GPO prohibition)

Per 340B Program rules, DSHs, PEDs, and CANs participating in the 340B Program cannot obtain covered outpatient drugs through a group purchasing organization (GPO) or other group purchasing arrangement. If a covered entity violates GPO prohibition, it would be considered ineligible for the 340B Program for the time period in which it violated the rule. This ineligibility can result in significant financial loss to the covered entity or removal from the 340B Program.

A covered entity can define certain drugs as exclusions to the covered outpatient drug definition. These drugs cannot be purchased through the 340B Program, but they also are not subject to 340B Program requirements such as GPO prohibition and may therefore be purchased on a GPO account. A covered entity's interpretation of exclusions to the covered outpatient drug definition should be defensible, consistently applied in all areas, noted in all 340B Program policies and procedures, and auditable.

An example of a way in which healthcare internal auditors could use DA in the area of GPO prohibition compliance includes:

- Identifying inappropriate GPO purchasing by comparing GPO accumulations by NDC to GPO purchases by NDC

Monitoring 340B Program performance with analytics

Continual monitoring of overall 340B Program performance is essential for covered entities to maximize savings and uphold the highest level of program compliance. By using analytics, auditors can better identify data transfer issues and purchasing practices to identify compliance risks that can weaken program performance and opportunities for additional program savings.

Examples of how internal auditors can use analytics to monitor 340B Program performance include:

- Reviewing gaps in service dates, volume-by-service date, and duplicate records, which can identify unusual variations in quantity of records and detect data transfer issues
- Performing data analytics to maximize financial savings including assessing the covered entity's contract pharmacy program to achieve revenue maximization

Sample audit findings

Examples of audit findings resulting from data analytics testing in the mixed-use and contract pharmacy setting are listed here to aid in identifying risk areas within a 340B Program.

Mixed-use setting

- **Inaccurate inpatient versus outpatient accumulation data:**
    - Hospital programming logic incorrectly identified outpatient versus inpatient transactions.
    - Initial patient status was being entered incorrectly, with the corrected status not being communicated to the 340B vendor software.
- **Medicaid carve-out billing errors:**
    - Medicaid FFS (or MCO if required by state) was a secondary or tertiary payer and billed for 340B medications.
    - Out-of-state Medicaid MCO was billed for 340B medications, and state billing requirements were not followed.
- **Medicaid carve-in billing errors:**
    - All Medicaid billing numbers, including NPIs, the covered entity used were not registered on the OPAIS.
    - Out-of-state Medicaid billing numbers were not registered on the OPAIS.
    - Billing modifiers were not included on the claims data for FFS (or MCO if required by state) for out-of-state Medicaid claims.
- **Duplicate accumulations:**
    - Manual uploads for the same transactions occurred more than once.
- **Data upload omissions or failures:**
    - Uploads to 340B vendor software had missing, partial, or duplicate data.
- **Drug reversal and credits not interfacing correctly to the accumulator:**
    - Data sent to 340B vendor software was based on service date rather than postdate.
    - Negative quantities were not being sent to 340B vendor software.

- **Medication purchased outside the pharmacy not included in 340B data:**
    - Data for medication dispensed outside the pharmacy was not being sent to the 340B software vendor for proper accumulation and purchases.

Contract pharmacy setting

- **Prescriptions filled for animals:**
    - Prescription qualified on provider eligibility only.
- **Eligible patient encounters from child site locations not considered:**
    - The eligible location list sent by the covered entity to the 340B software vendor was not updated or included in software logic to determine eligibility.
- **Ineligible patient encounter deemed 340B eligible:**
    - The 340B software solution used incorrect logic to match to patient encounters.
    - Ineligible locations were being sent as eligible to the 340B software vendor.
    - The 340B software vendor was not using both location and provider to determine eligibility.
- **Prescribing physician with no contractual relationship to the covered entity:**
    - Provider list used by 340B software vendor was inaccurate or not updated by the covered entity.
    - The 340B software vendor was using incorrect logic to match providers (contractual versus employed).
- **Duplicate prescriptions:**
    - Duplicate data files were sent to the 340B software vendor.
- **Medicaid patients not carved out:**
    - Medicaid BINs, PCNs, and group IDs were not correctly identified and excluded by 340B software vendor.
    - Medicaid MCO (where required by state) was not included in the Medicaid payer exclusion list.

Conclusion: Achieving sustainable 340B Program performance

As the 340B Program faces increased federal scrutiny and challenges from drug manufacturers, it's more important than ever for internal auditors to have thorough insights into a covered entity's 340B Program. Data analytics can help internal auditors achieve a more effective audit, identifying risk areas and helping the covered entity comply with program rules. In addition, by being able to test 100% of certain 340B requirements, covered entities can be better positioned to show the strength of their programs to HRSA and drug manufacturers.

By using data analytics, internal auditors are better able to continually monitor 340B Programs. Monitoring assists covered entities in achieving sustainable performance and, ultimately, frees up valuable time for covered entities to focus on goals such as program expansion that can allow for increased patient access to much-needed medications and healthcare services.

Endnotes:

[1] "Program Requirements," U.S. Health Resources and Services Administration, https://www.hrsa.gov/opa/program-requirements/index.html

[2] Sec. 340B Public Health Service Act, "Limitation on Prices of Drugs Purchased by Covered Entities," U.S. Health Resources and Services Administration, https://www.hrsa.gov/sites/default/files/opa/programrequirements/phsactsection340b.pdf

About AHIA

The Association of Healthcare Internal Auditors (AHIA) is a network of experienced healthcare internal auditing professionals who come together to share tools, knowledge, and insight on how to assess and evaluate risk within a complex and dynamic healthcare environment. AHIA is an advocate for the profession, continuing to elevate and champion the strategic importance of healthcare internal auditors with executive management and the Board. If you have a stake in healthcare governance, risk management and internal controls, AHIA is your one-stop resource. Explore our website for more information. If you are not a member, please join our network, www.ahia.org. AHIA white papers provide healthcare internal audit practitioners with non-mandatory professional guidance on important topics. By providing healthcare specific information and education, white papers can help practitioners evaluate risks, develop priorities, and design audit approaches. It is meant to help readers understand an issue, solve a problem, or decide. AHIA welcomes papers aimed at beginner to expert level practitioners. This includes original content clearly related to healthcare internal auditing that does not promote commercial products or services.

Interested? Contact a member of the AHIA White Paper Subcommittee.

Subcommittee

Alan Henton, White Paper Chair
alan.p.henton@vumc.org

Mark Eddy
mark.eddy@hcahealthcare.com

Linda Greer
tlbmc@cox.net

Debi Weatherford
debi.weatherford@piedmont.org

Laura L. Sak-Castellano
Laura.Sak-Castellano@advocatehealth.com

Deborah Pazourek, AHIA Board Liaison
Deborah.L.Pazourek@medstar.net