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"You are never wrong, if you do the right thing."

**GCA340B Education Series:
Internal Audits
for
Covered Entities**

09/30/2026

Overview of Today's Discussion

- ✓ What is Internal Auditing?
- ✓ Why is Internal Auditing Important?
- ✓ Key Areas for Internal Auditing
- ✓ Internal Audit Process
- ✓ Mixed-Use Auditing
- ✓ Contract Pharmacy Auditing
- ✓ Key Takeaways
- ✓ Questions

What is Internal Auditing?

“Internal Auditing” is a proactive, organization-led review of a Covered Entity’s (CE) 340B Drug Pricing Program to verify compliance, identify risks, and correct issues *before* external HRSA or manufacturer audit occurs.

Why is Internal Auditing Important?

Internal auditing is a *critical* control mechanism for organizations participating in the 340B Drug Pricing Program because it ensures compliance, integrity, and risk mitigation before external scrutiny.

- ✓ Ensures Compliance with 340B Rules
- ✓ Detects and Prevents Compliance Issues
- ✓ Supports Program Integrity and Accountability
- ✓ Reduces Financial and Reputational Risk
- ✓ Improves Operational Efficiency

Key Areas for Internal Auditing

SITE ELIGIBILITY AND REGISTRATION

- Verify OPAIS Registration Accuracy
- Outpatient / Child Site Registration

PATIENT ELIGIBILITY VERIFICATION

- Verify Against Patient Definition Policy
- Ensure No Dispensing to Ineligible Patients (“diversion”)

CONTRACT PHARMACY COMPLIANCE

- Pharmacy Services Agreement (PSA)
- Oversight Processes

DUPLICATE DISCOUNT PREVENTION

- Medicaid Carve In / Carve Out Adherence
- Accurate TPA Mapping

DIVERSION PREVENTION

- Develop Systems for Dispensation / Administration to Qualified Patients ONLY

INVENTORY AND PURCHASE TRACKING

- Review Purchase / Dispensing Records to Ensure Accurate Accumulations

Internal Audit Process

Define Scope



- Identify Dispensations / Administrations

Select Samples



- Target Samples
- Random Samples

Verify Eligibility



- Location
- Patient
- Provider
- *Grant Scope (Grantee CEs only)*

Review Claims



- Ensure Correct Coding

Document Findings



- Material Breach Threshold Met?
- Maintain **All** Audit Records (*Electronically if Possible*)

Report and Remediate



- Share Results with Leadership
- Track Corrective Actions
- Update Policies (*as applicable*)

Mixed-Use Internal Auditing

- ✓ Patient of the CE
- ✓ Date of Dispensation/Administration
- ✓ Patient Status Type
- ✓ Location
- ✓ Prescriber
- ✓ NDC
- ✓ Quantity
- ✓ Insurance

Patient in EMR	Date of Administration	Patient Status / Type	Patient Location	Prescriber	NDC	Quantity	Insurance	Notes

Contract Pharmacy Internal Auditing

- ✓ Patient of the CE
- ✓ Verify ePrescription in EMR
- ✓ Date of Encounter
- ✓ Written Location Where Prescription was Generated
- ✓ Prescriber
- ✓ Diagnosis/Notes within EMR Specific to Prescription
- ✓ Insurance

Locate the Patient in the EMR	Verified the ePrescription in the EMR	Date of Encounter (Referencing the actual drug / prescription)	Written Location of Prescription (covered 340B location registered in OPAIS)	Prescriber	Diagnosis / Notes within EMR Specific to Prescription	Insurance	Audit Notes

Key Takeaways

- ✓ Internal Auditing is an **Expectation by HRSA** for 340B Program Oversight
- ✓ Build an Audit Checklist
- ✓ Implement Self-Monitoring
- ✓ Assign Roles and Responsibilities
- ✓ Review, Report, and Correct

We're Here to Help!

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