

340B Audit Experiences from
2015: What We Learned
From Over 50 Audits

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Statement of Conflicts of Interest

Rob Nahoopii Rich Bucher have the following conflicts of interest in relation to this presentation:

- ▶ Turnkey Pharmacy Solutions provides 340B independent audits and consulting, which are related to the topic of this presentation.



Learning Objectives

- ▶ List 3 key compliance issues seen on HRSA and independent 340B audits.
- ▶ Recite at least 2 best practices for a compliant 340B program.
- ▶ Name the key contract pharmacy 340B prescription qualification factor looked for by HRSA auditors for compliance.



Goals of this Presentation

- ▶ Describe top five best practices for 340B compliance.
- ▶ Share experience from over 50 annual independent audits (Update: 75 annual independent audits).
- ▶ Share experience from being on-site with 10 HRSA 340B audits (Update: 13 on-site HRSA audits).



CE Question

Which of the following are considered 340B program best practices?

- A. Monthly self-auditing of 340B qualified prescriptions or administered drugs
- B. Annual independent audit
- C. Formal 340B leadership team
- D. All of the above



HRSA Audits

If you have seen one HRSA audit, you have seen one HRSA audit.

- ▶ Inter-auditor variability.
 - Standards not always completely objective.
 - Sometimes finding determinations are subjective.
 - Auditor's onsite findings are not final.
 - Auditors often willing to let HRSA ultimately decide based on covered entity's written response.
- ▶ Improving and fine tuning over time (learning and adapting).
 - Auditors may not have significant relevant healthcare or drug experience or training; ongoing audits provide this experience/training.



HRSA Audits

Recent HRSA audit changes/improvements:

- ▶ Specific policy and procedure elements.
 - Materiality.
 - Definition of accumulation qualification.
 - Patient Status of inpatient (DSH, PED, CAN).
 - Retrospective changes in patient status.



HRSA Audits

Recent HRSA audit changes/improvements:

- ▶ Duplicate Discount Compliance for out-of-state Medicaid.
- ▶ Accumulator file (hospitals).
- ▶ More detailed narrative on how covered entity's process prevents diversion and duplicate discounts.
- ▶ Requesting access to covered entity's internal self-audits and independent audits.
 - Or at least proof of them.



HRSA Audits

Recent HRSA audit changes/improvements:

- ▶ Contract pharmacy and in-house retail pharmacy qualification.
 - The location of where the prescription is written/created is critical for showing responsibility of care (with a few exceptions).



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Contract Pharmacy Compliance

- ▶ Qualification window too large for listed providers.
- ▶ Too many non-exclusive providers.
 - Eligibility criteria for exclusive providers may not be suitable for and non-exclusive providers (e.g., qualification windows).
- ▶ Matching to patient encounters that do not generate visits, clinical care, and/or prescriptions.



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Duplicate Discounts:

- ▶ UD Modifiers and NCPDP 420DK and 423DN modifiers.
- ▶ Correct cost charging (not necessarily a 340B risk).
- ▶ Significant variability among states in their 340B-specific policies and requirements.
 - Some states lack clear 340B-specific policies.
 - The new AMP rule requires states to have 340B-specific reimbursement policies.
- ▶ Managed care organization (MCO) Medicaid.
 - Can be tricky in some states (e.g., MSHO plans in Minnesota, California).
 - The new AMP rule clarifies state responsibilities for preventing duplicate discounts from MCO claims.
- ▶ Out-of-state Medicaid (as discussed in HRSA audit section).
- ▶ Retrospective Medicaid eligibility determination.



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The Accumulator

- ▶ Too many high accumulations and negative accumulations.
- ▶ Lack of accumulator maintenance and self-auditing.
 - Maintaining CDM-NDC crosslinks and conversion factors requires constant attention and close scrutiny.
- ▶ Too much reliance on the vendor.
 - Don't assume the vendor is taking care of it!



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Infusion Services – Non-Contracted Provider Orders

- ▶ External providers with no relationship to the hospital have orders processing as 340B in infusion centers (see patient definition).
 - Reliance on being able to show a referral relationship is risky because it depends on the available evidence and is very subjective.
- ▶ MOU?



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GPO Prohibition (DSH, CAN, PED)

- ▶ One vendor has a terminating GPO account.
- ▶ Direct orders being placed on GPO account only.
- ▶ Purchasing by other departments/locations (e.g., materials management, wound care, imaging).
 - Materials Management purchasing drugs on GPO that are not on the non-covered outpatient drug list.
- ▶ Strategies to mitigate exposure to wholesale acquisition cost (WAC).
 - Non-covered outpatient drugs list.
 - GPO only location.
- ▶ CII orders being placed on GPO account due to lack of vendor ability.



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Independent audits – a comprehensive approach:

- ▶ Requires a comprehensive 340B program assessment in addition to mock HRSA audit.
- ▶ Requires actual healthcare and drug management experience and expertise: there is no substitute.
- ▶ Allows for an interactive process, providing learning opportunities.
- ▶ Allows for a full 340B program analysis and identification of previously unrecognized risk areas.
 - This analysis facilitates enhanced targeted sampling based on these risk areas.
- ▶ Allows for more effective root cause analysis during the audit: why did this sample fail?
- ▶ Allows for practical site-specific recommended corrective actions rather than generic and often impractical recommendations.



Best Practices

Hospital Covered Entity Types:

- ▶ Accumulator maintenance.
- ▶ Non-covered outpatient drug list. (DSH, PED, CAN)
- ▶ Monthly self-auditing of accumulations.



Best Practices

All Covered Entity Types:

- ▶ Know Medicaid rules for your state and out-of-state.
- ▶ Monthly self-auditing of 340B retail prescriptions.
- ▶ 340B Leadership Team with quarterly meetings (minimum).



Best Practices

All Covered Entity Types:

- ▶ Dedicated 340B staff resources.
- ▶ Key 340B staff attend an annual 340B meeting.
- ▶ Annual independent audit of entire 340B program.



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Additional Questions?

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