COMPREHENSIVE PHARMACY SERVICES
How Hospital Pharmacy Leaders Drive Transformation

Incorporate Elements of a 340B HRSA Audit into your 340B Program

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Comprehensive Pharmacy Services

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Conflicts of Interest

I have no conflicts of interest to declare
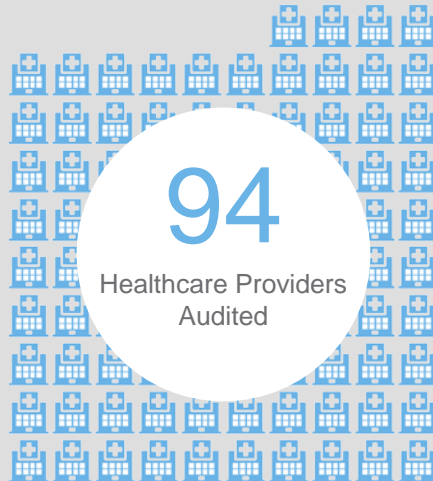
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Objectives:

At the conclusion of the program the participants will:

1. Understand the current HRSA audit process.
2. Realize the risks based on current HRSA results.
3. Implement internal audit process to minimize the risks.
4. Realize the political climate of the 340B Program.

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What department is responsible for 340B program compliance?

A. Pharmacy

B. Compliance

C. Finance

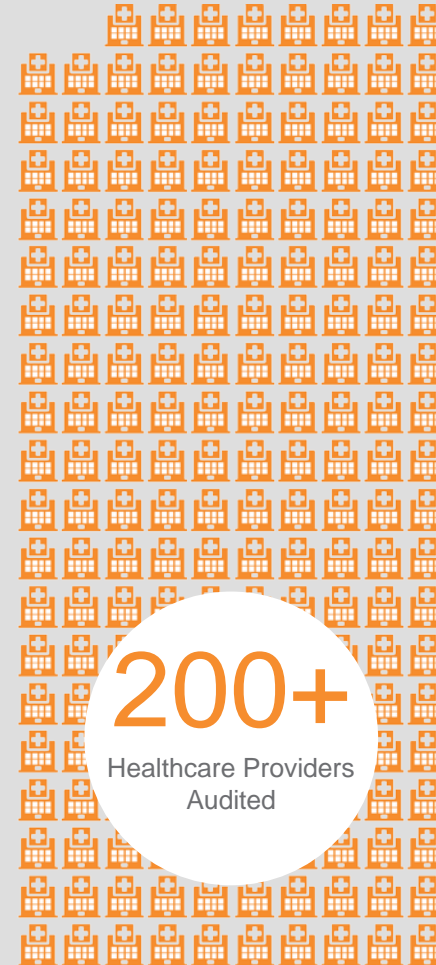D. Information Services

E. Administration

F. All of the above

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HRSA 340B Program Audits

94 Healthcare Providers Audited — **FY 2013**

99 Healthcare Providers Audited — **FY 2014**

200+ Healthcare Providers Audited — **FY 2015, 2016, 2017, 2018**

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HRSA Audits

✓ New Audit firm 10/1/2016 Bizzell Group

- All have Pharmacy background

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HRSA Audits – Kickoff

- ✓ Email notification of pending audit
- ✓ Introductory call with auditor and hospital team
- ✓ Data collection

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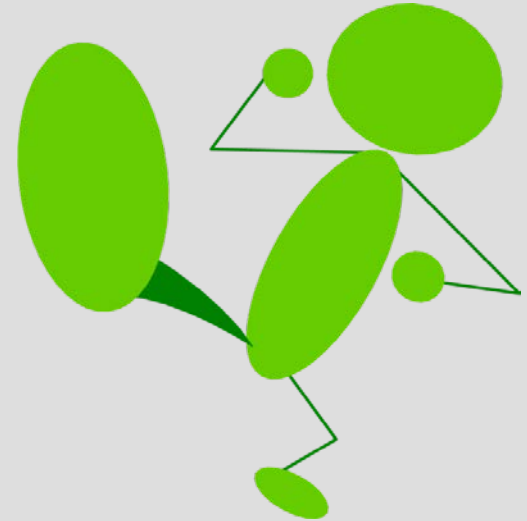
HRSA Audits – Site Prep

Notifications

- ✓ Contract Pharmacies
- ✓ Wholesaler
- ✓ Software Vendor

Logistics

- ✓ Work space
- ✓ Computers
- ✓ Supplies
- ✓ Refreshments

Practice Run

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HRSA Audits – Onsite

✓ Introduction and opening remarks

✓ Dissemination of records to audit

✓ Review of records

   ✓ Facility

   ✓ Contract Pharmacies

✓ Facility tour(s)

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HRSA Audits – Onsite

- ✓ Accumulator review
- ✓ Provider Validation
- ✓ Outstanding items
- ✓ Closing remarks
- ✓ Wait….

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What are the Risks?

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Findings

Audits

Grantees 23.3%
Hospitals 76.7%

California has the most audits= 106 (12%)

26.4% Are Grantees

Entity Type	# of Audits	%	CA	%	Type
CH	128	12.6%	22	20.8%	G
CHC	9	1.6%			G
FP	26	3.1%			G
FQHC	3	0.1%	3	2.8%	G
HM	7	0.6%	1	0.9%	G
HV	8	1.1%	1	0.9%	G
RWI	13	1.3%	1	0.9%	G
STD	17	2.1%			G
TB	5	0.6%			G
CAH	151	57.5%	7	6.6%	H
CAN	2	57.5%	1	0.9%	H
DSH	492	57.5%	64	60.4%	H
PED	23	2.3%	5	4.7%	H
RRC	11	1.3%			H
SCH	33	3.4%	1	0.9%	H
Grand Total	928	100%	106	100%	

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Findings

Type of issue	%
Incorrect 340B database	36.50%
No adverse findings	28.40%
Diversion	20.60%
Duplicate Discount	5.30%
* GPO Prohibition	5.30%
Database Medicaid Exclusion File	1.10%
No Oversight- Cont. Pharmacy or program	1.10%
Database	0.60%
* Auditable Records	0.30%
Incorrect Child Sites	0.30%
Orphan Drug prohibition	0.30%
Eligibility	0.10%
Grand Total	100.00%

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MUST
BE
AUDIT
READY

- The data requirements for a routine HRSA 340B audit may require up to 80 hours.
  - ✓ Multiple departments are involved
    - Pharmacy
    - IT
    - Finance
    - Business office
    - Local Compliance Officer
    - Your Software vendor(s)
    - Contract Pharmacy Managers

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✓ *What is needed to be Audit Ready?*

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Audit Ready

- ## Policy and Procedures
  - ✓ 9 specific criteria
    - Purchasing and Inventory management
    - Material Breach
    - Exclusions to covered outpatient drugs
    - Registration/recertification
    - Contract Pharmacy Oversight
    - GPO prohibition
    - Orphan drug exclusion
    - Prevent diversion
    - Prevent duplicate discounts

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Audit Ready

- OPA Database
  - ✓ Contacts
  - ✓ Addresses
  - ✓ Eligible areas
  - ✓ Contract Pharmacies
  - ✓ Medicaid Carve-In/Out

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Audit Ready

- Medicaid Billing
  - ✓ Actual copies of Medicaid Bills
  - ✓ Match OPA database
- Grants

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Audit Ready

- Auditable Records
  - ✓ Internal Audits
    - Each universe of data
    - Target problem areas
    - Accumulation verification
    - Copies of Contract Pharmacy prescriptions

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Audit Ready

- Provider Lists
  - ✓ Infusion Centers
- Contract Pharmacy Agreements
- Resources to manage the program

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Audit Ready

Practice !

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If you have a finding, How do you Close an Audit

- Audit is closed when CE certifies that the CAP has been implemented and settlements finalized with manufacturers, including repayment

- Not all manufacturers respond to CE Notices, however CE should make more than one attempt.

- Potential re-audit after CAP is closed.

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Why is Congress so concerned about 340B

Follow the Money

Both State and Federal governments

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Questions

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