



HFMA/NEHIA

2024 Compliance & Internal Audit Conference

Wednesday, December 4 – Friday, December 6, 2024
Mystic Marriott Hotel, Groton, CT

Presenters

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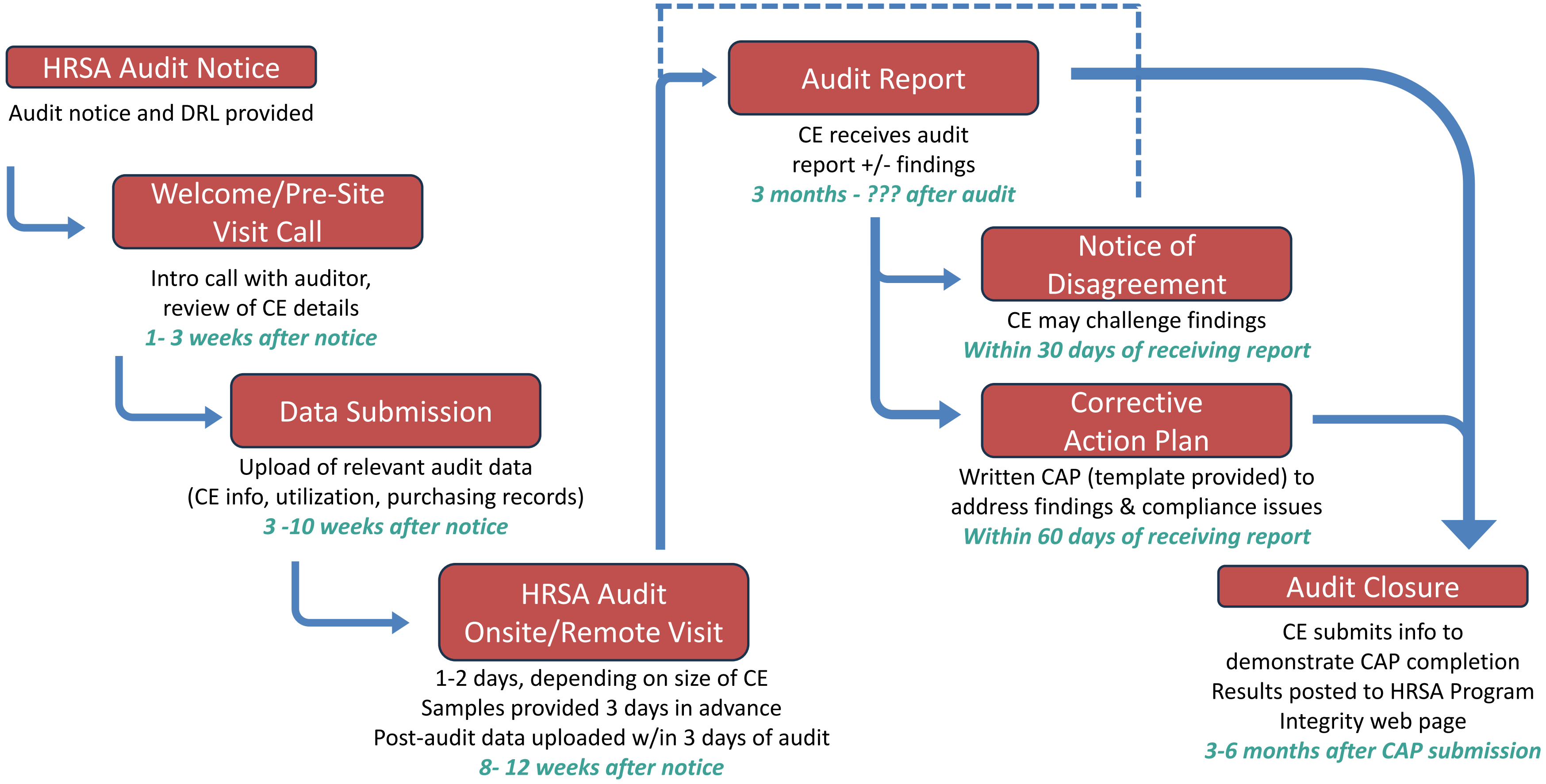


Objectives

- Review typical HRSA audit timeline
- Discuss operational tactics to help survive a HRSA audit
- Identify recent trends in HRSA audit findings

HRSA AUDIT TIMELINE



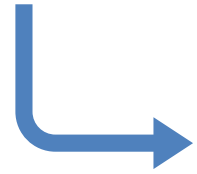


Receipt of Audit Notice & Pre-Audit Call



HRSA Audit Notice

Audit notice and DRL provided



Welcome/Pre-Site Visit Call

Intro call with auditor,
review of CE details

1- 3 weeks after notice



Receipt of Notice & Pre-Audit Call

When you receive the notice you should reach out to individuals and groups who will need to participate right away including:

- Consultant/External Auditor
- Senior Leadership
- Internal/External Counsel
- Compliance Team
- 340B Team
- Purchasing Team
- Credentialing Team
- EMR Team
- Accounting/Finance Team
- Your TPA
- Your Contract Pharmacies
- Your wholesaler(s)

Receipt of Notice & Pre-Audit Call

- 35 Minutes after receiving our audit notice we received a second email from Bizzell Group copied to our onsite auditor with 3 attachments
 - Information Request Form
 - Checklist of Items to prepare for onsite audit and a request to confirm date
 - Must provide names/titles of all staff who will attend welcome call
 - PII Redaction Instructions
 - Data Request List (DRL)
- Calendar link to schedule your welcome call (due within 3 days)
- Due Date for DRL (ours was 52 days after audit notice received)
- Planned date for onsite visit (ours was 73 days after audit notice received)

Receipt of Notice & Pre-Audit Call

- Welcome Call
 - Introductions
 - make sure attendees match what you submitted
 - Data Upload Instructions
 - Including what to do if you make a mistake
 - Walk through of each item on DRL to confirm your understanding
 - Overview of logistics for onsite audit
 - Sampling, Tours, Credentialing Discussion, Purchasing Discussion

Data Submission

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HRSA Audit Notice

Audit notice and DRL provided

Welcome/Pre-Site Visit Call

Intro call with auditor,
review of CE details

1-3 weeks after notice

Data Submission

Upload of relevant audit data
(CE info, utilization, purchasing records)

3-10 weeks after notice

HRSA Data Request List

1) Policies & Procedures

2) CE Eligibility Documentation

3) 340B Universe Information

4) Provider List

5) Purchasing Documentation

6) Contract Pharmacy Information

7) Entity-Owned Pharmacy Information

8) Self-Disclosure Documentation

9) Medicaid Billing Information

Data Submission

Divided into 10 categories

- Policies
- Eligibility
- 340B Universe
- Provider List
- Purchasing Documentation
- Contract Pharmacy
- Pharmacies not registered as contract pharmacy dispensing 340B drugs
- Self-Disclosure Documentation
- Medicaid FFS Billing
- CAPA from Previous Audit

Data Submission

- Helpful to create a spreadsheet that maps your P&P to the requirements
 - Periodically perform a gap analysis against Apexus model policy
 - If you are currently revising any policies, let them know
- Audit Period is the preceding 6 months
 - Will look at ALL 340B dispensing and purchasing for that time period
 - They will select samples for testing and you get the list in advance

HRSA Onsite/Remote Site Visit



HRSA Audit Notice

Audit notice and DRL provided



Welcome/Pre-Site Visit Call

Intro call with auditor,
review of CE details

1- 3 weeks after notice



Data Submission

Upload of relevant audit data
(CE info, utilization, purchasing records)

3 -10 weeks after notice



HRSA Audit Onsite/Remote Visit

1-2 days, depending on size of CE
Samples provided 3 days in advance
Post-audit data uploaded w/in 3 days of audit

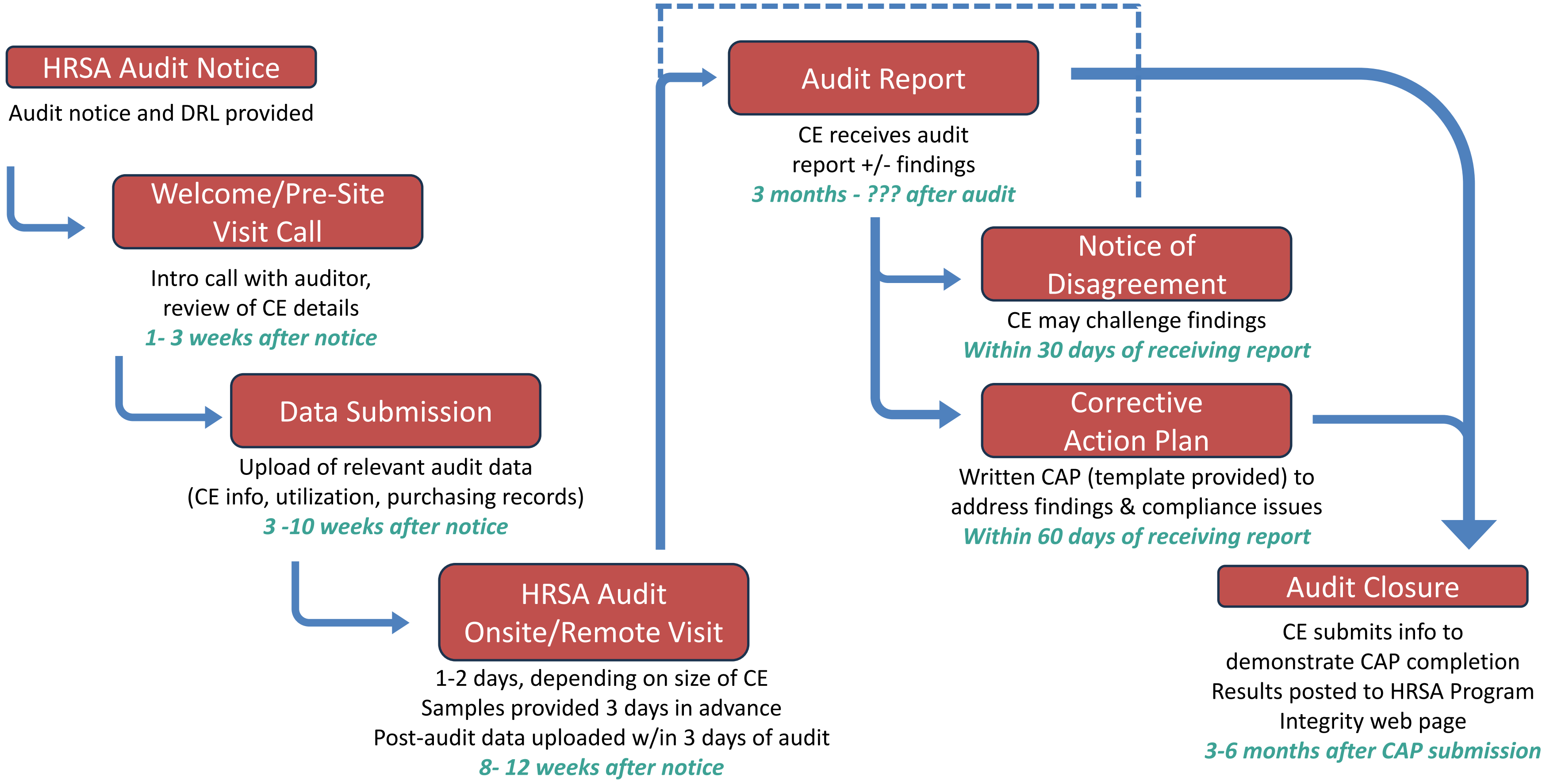
8- 12 weeks after notice

HRSA Onsite/Remote Site Visit

- Although 2 days are scheduled it may be possible to complete the visit in one day
- Because you submit the data ahead of time, and get a list of samples ahead of time, a lot of the work is already done by the time of the audit
- Includes interviews with credentialing staff and purchasing staff
- Tours which may or may not require driving to another site
- If you provide food for the meeting the auditor is permitted to eat it too
- If there are any issues with any samples the auditor will choose a new sample while onsite

Receiving a HRSA Audit Report





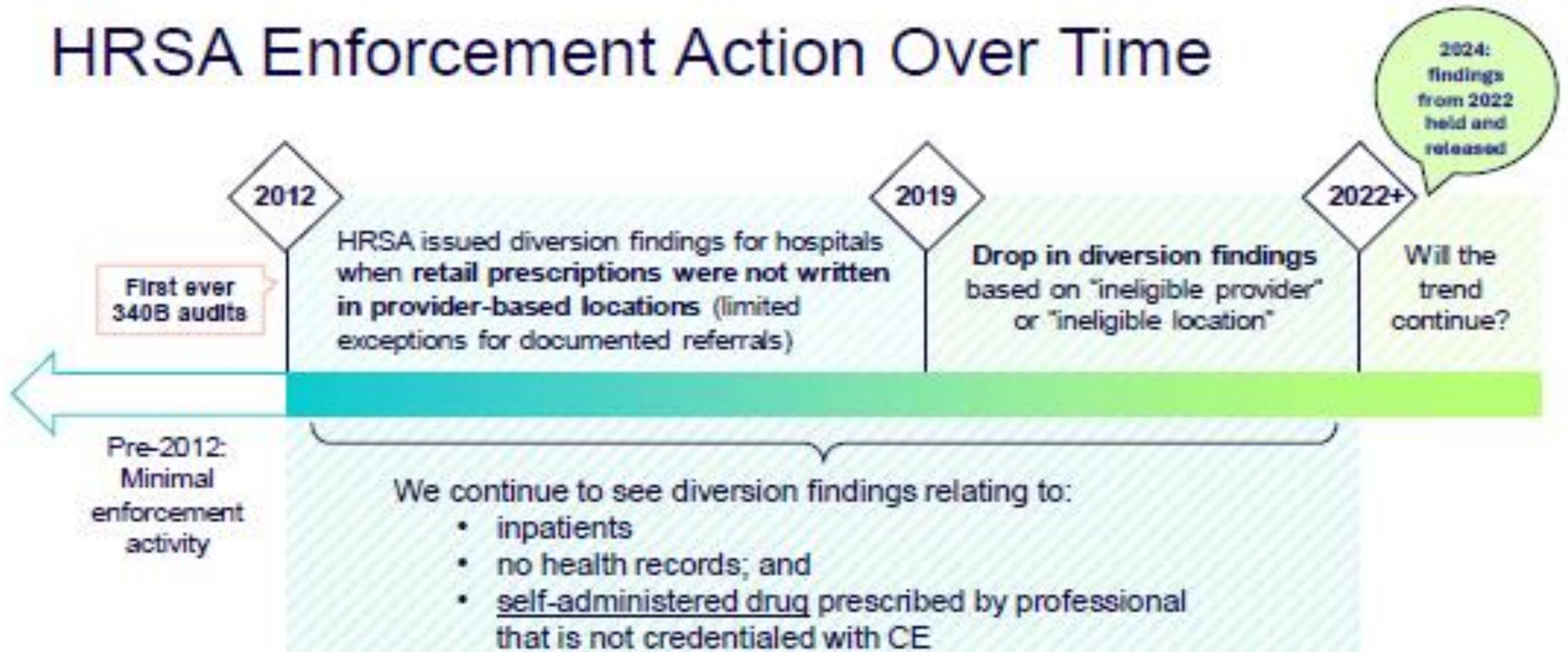
Receiving a HRSA Audit Report

- We are still waiting on the report from our most recent audit
- It may take well over a year to receive your results
- For any findings, you will need to dispute them or submit a Corrective Action Plan
- If you dispute a finding and HRSA upholds it, you need to go to court to appeal it further
- If serious concerns are found, they may audit back further than 6 months
- May require repaying any 340B discounts attributed to noncompliance due to diversion or duplicate discount

HRSA Audit Findings - Trends



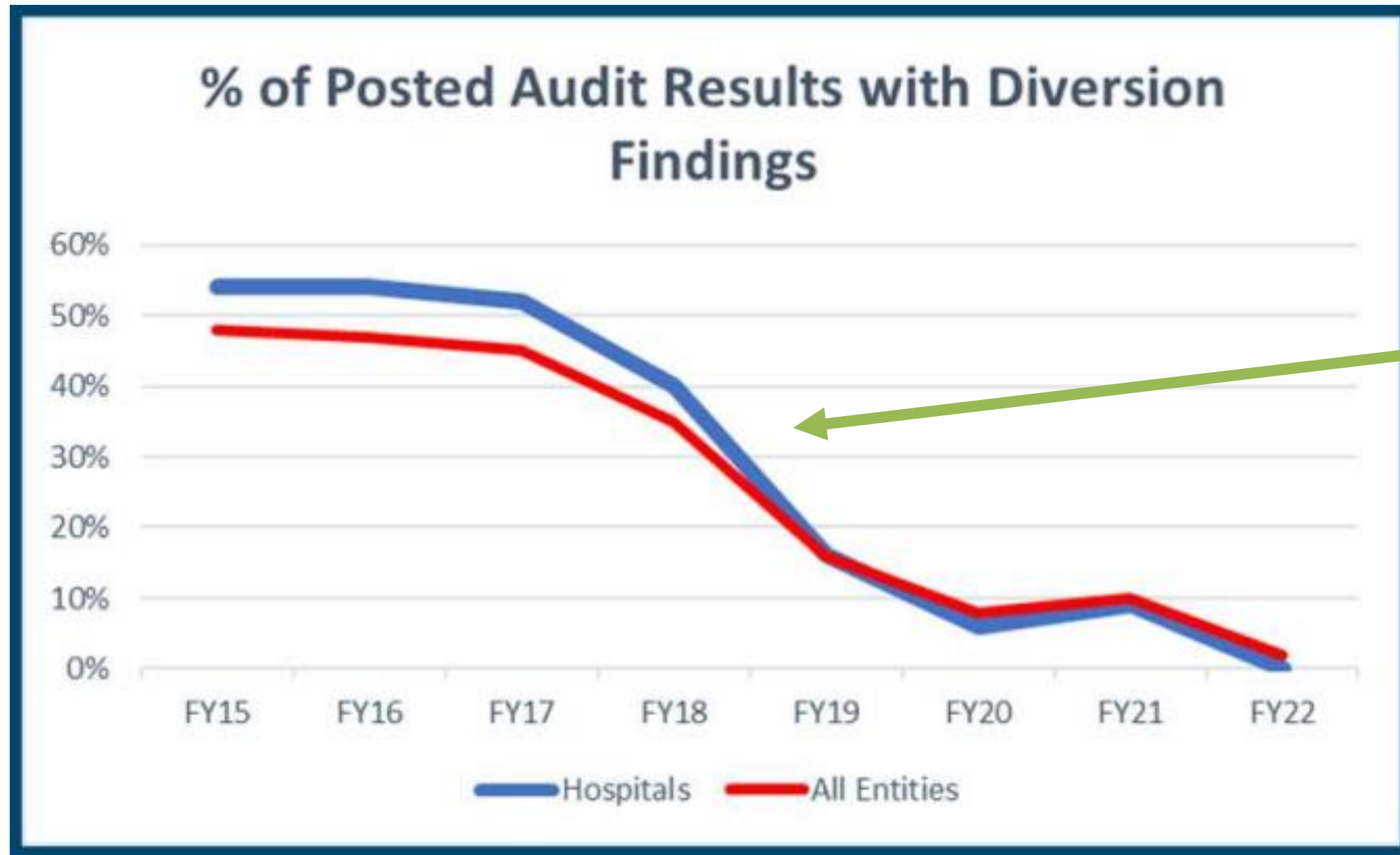
HRSA Enforcement Action Over Time



HRSA Audit Finding Trends - Hospitals

	FY15	FY16	FY17	FY18	FY19	FY20	FY21	FY22	FY23**
Diversion	54%	54%	52%	40%	17%	6%	9%	10%	6%
FFS Duplicate Discount*	18%	20%	18%	21%	18%	11%	9%	11%	18%
Inaccurate Medicaid Exclusion File*	8%	7%	11%	17%	12%	11%	16%	17%	17%
Inaccurate Database	48%	28%	29%	31%	25%	22%	50%	55%	42%
GPO Exclusion	11%	6%	4%	1%	3%	<1%	2%	1%	2%

HRSA Audit Findings – Diversion & Patient Definition



- Genesis Lawsuit
- 2020 GAO Report

Future HRSA Audit Trends

- In June 2024, HRSA communicated via OPA website that a series of outstanding audit reports will be issued to CEs with audit findings
- Several HRSA audit reports have been reviewed with diversion findings attributed to:
 - Ineligible location(s),
 - Ineligible provider(s), and
 - Failure to demonstrate “responsibility of care”

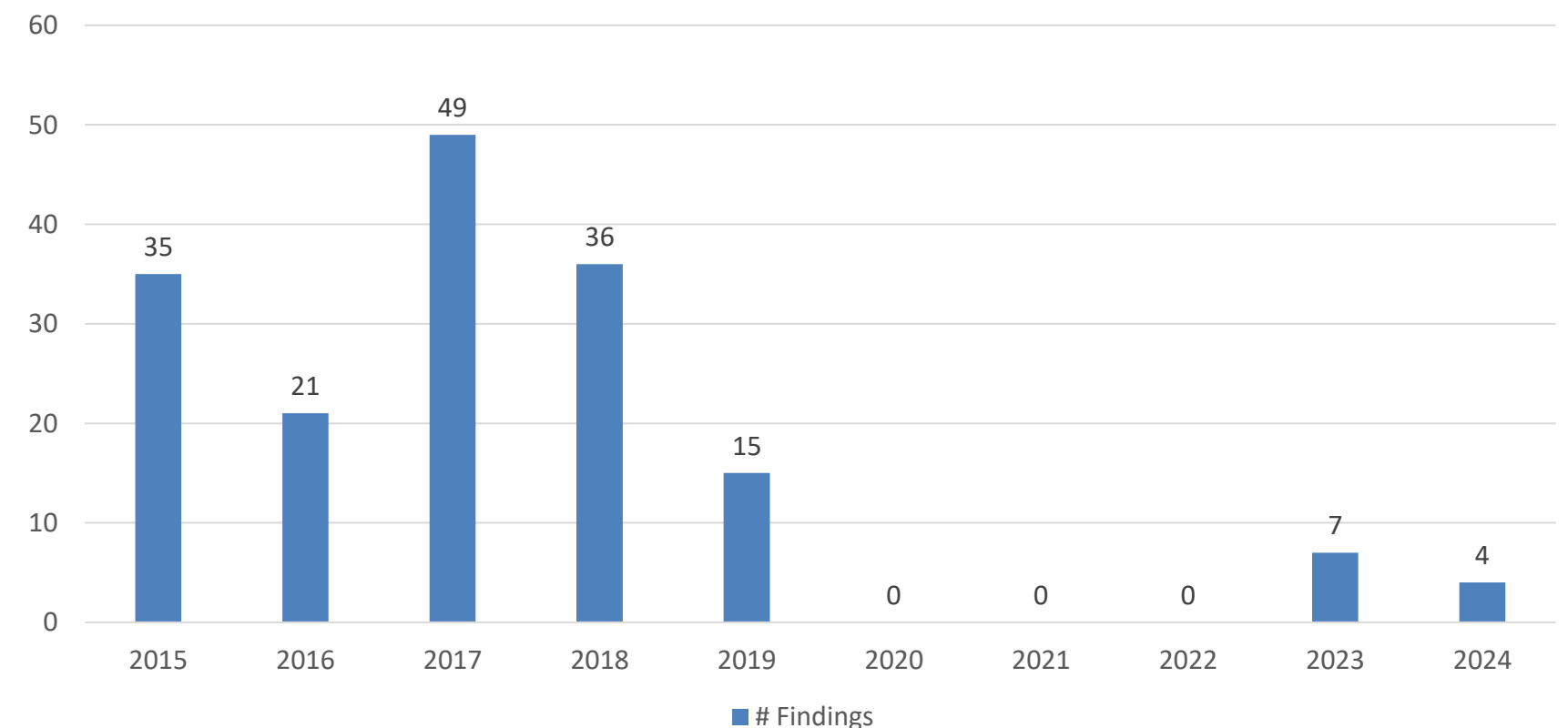
Diversion:

Dispensing of 340B drugs to ineligible individuals, as prohibited by section 340B (a)(5)(B) of the PHSA

A covered entity may be part of a health care system; however, the inclusion of a covered entity within a larger organization does not make the entire organization eligible for the 340B Program.² Therefore, only sites able to be registered as part of the covered entity qualify for the 340B Program as a critical access hospital under Section 340B(a)(4)(N) of the PHSA.

An individual is not considered a patient of a covered entity when the healthcare service was provided to the individual outside of an employment, contractual, or other arrangement (e.g., referral for consultation) with the covered entity.⁴ The provision of health care services to the individuals at other points in time unrelated to the 14 sampled 340B prescriptions and sharing of medical records with providers at sites not able to be registered in the 340B Program, is not sufficient to demonstrate that the responsibility for care provided remained with the covered entity.

Diversion Findings:
RX Written From Location



Responding to HRSA Audit Findings

- For our last audit in 2016 we had finding related to our Medicaid Exclusion File. This was related to out-of-state Medicaid Plans that we do not routinely accept. There was a possibility claims for these plans could have been carved-in and a duplicate discount paid since they were not listed on our MEF.
- Resulted in our needing to send letters to multiple drug companies alerting them and offering to repay duplicate discounts
- Ultimately we repayed about \$100 but the cost of labor to resolve the issue far exceeded that

QUESTIONS

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