GCA

340B

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

A GCA340B EDUCATIONAL WEBINAR

HRSA 340B Audits

What Covered Entities Need to Know Before, During, and After an Audit

Executive briefing on audit readiness, governance discipline, accountability, and 340B program integrity.

Virtue 340B®
Expertise - Commitment - Integrity

GCA 340B

PRESENTERS

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Compliance

Audit Readiness

Oversight

Risk Mitigation

Program Integrity

340B AUDIT PURPOSE

Why HRSA Audits Matter

An audit evaluates the effectiveness of the covered entity’s governance, controls, and operational practices.

How Covered Entities Are Selected for HRSA Audits

Selection can come through routine risk monitoring or specific triggers that warrant deeper review.

Risk-Based Audits

- All covered entity types eligible
- Higher operational complexity
- Multiple outpatient locations
- Contract pharmacy arrangements
- Higher transaction volume
- Enhanced compliance risk

VS.

Targeted Audits

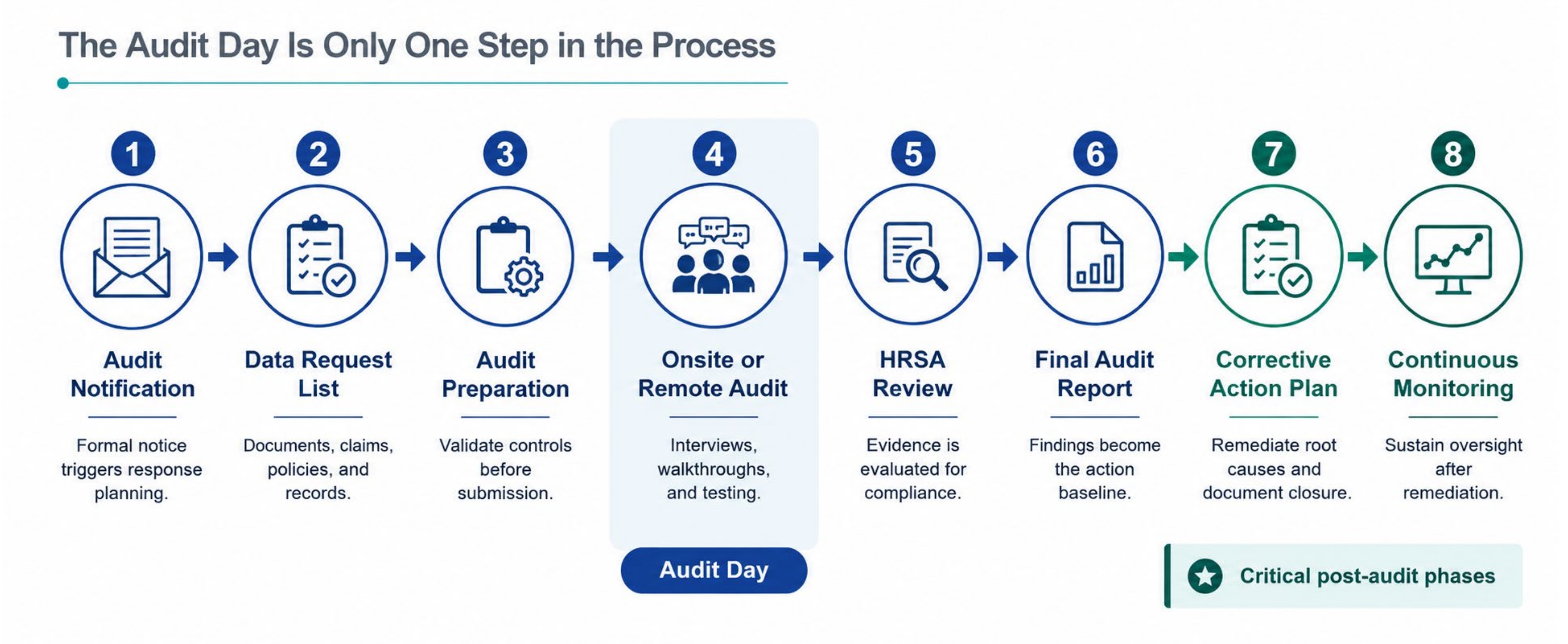
- Specific allegations
- Manufacturer concerns
- Whistleblower complaints
- Follow-up on prior findings
- Corrective action validation

Every covered entity should assume audit readiness is a continuous responsibility.

HRSA 340B AUDIT LIFECYCLE

The HRSA Audit Lifecycle

Lifecycle view from notification through sustained monitoring

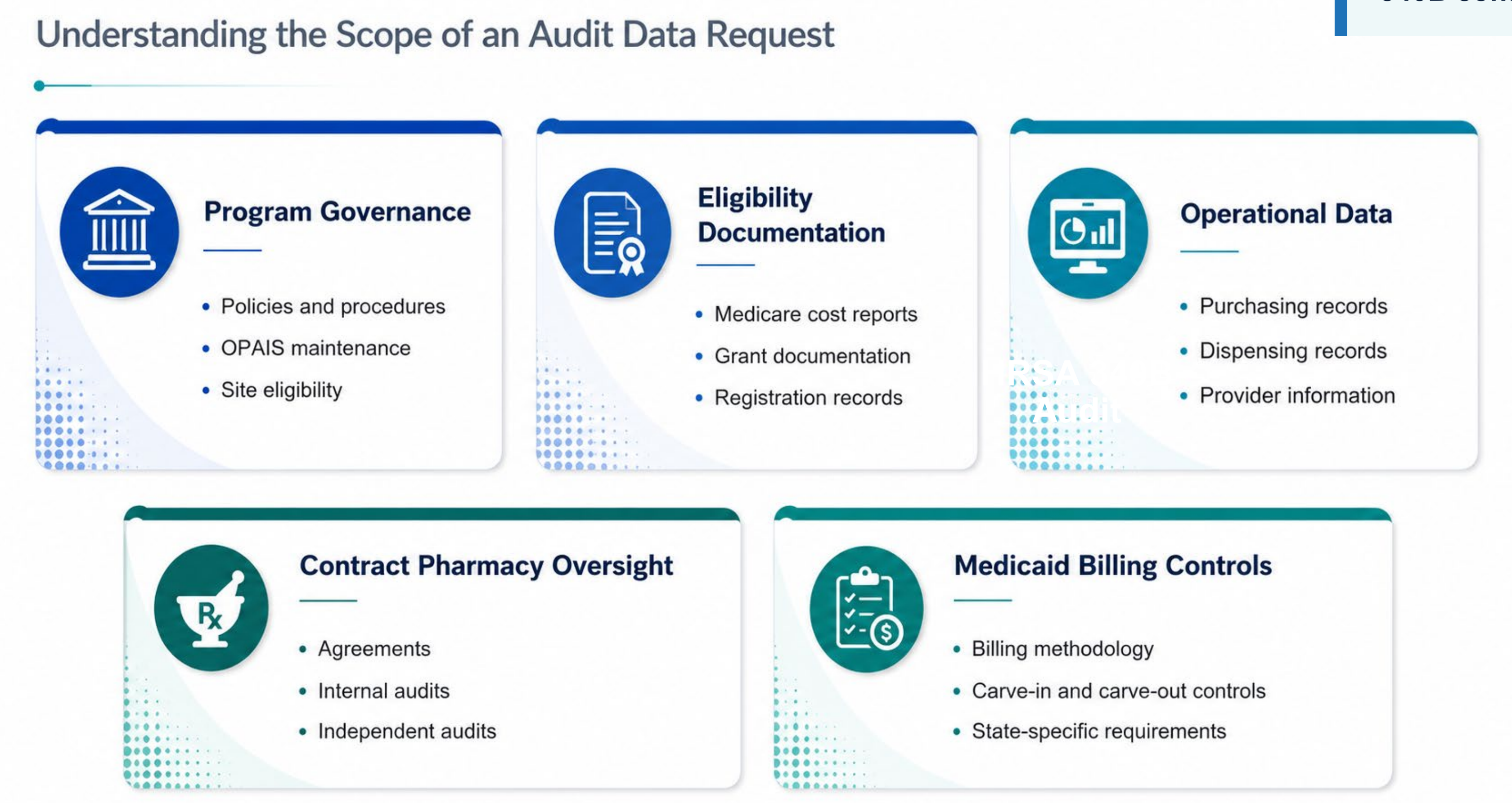


The most significant effort often occurs after the audit concludes.

AUDIT DATA REQUEST SCOPE

What HRSA Actually Requests

Requested evidence should prove both the design and execution of 340B controls.



HRSA evaluates both documented policies and actual operational practices.

AUDIT COORDINATION

Building the Right Audit Team

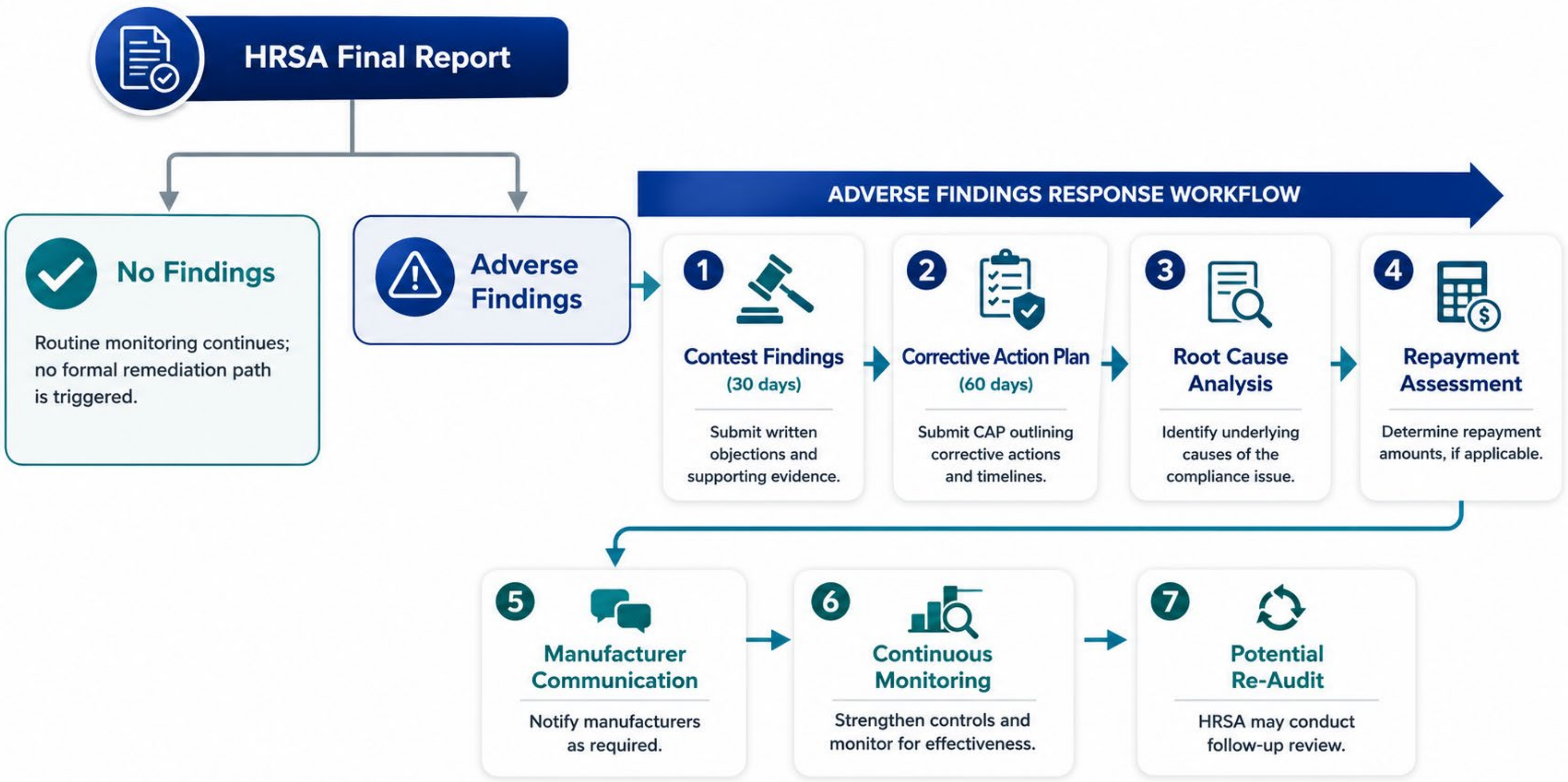
EXECUTIVE TAKEAWAY

Audit readiness is cross-functional.

- Successful audits require coordination across departments.
- HRSA audits evaluate organizational processes, not just pharmacy operations.

Assign evidence ownership before the audit request arrives.

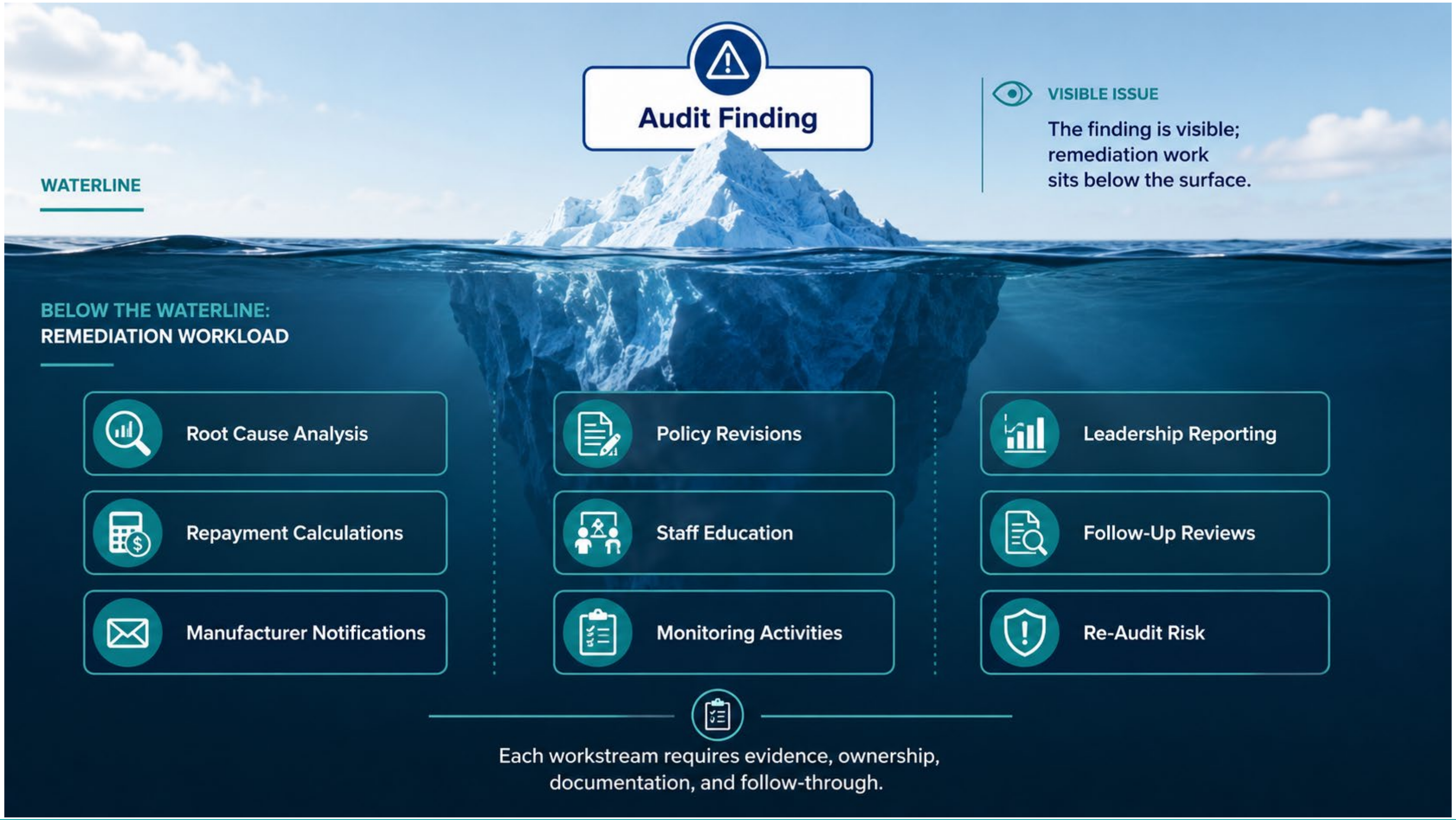
What Happens If Findings Are Identified?



The real work often begins after the audit is completed.

POST-AUDIT REMEDIATION BURDEN

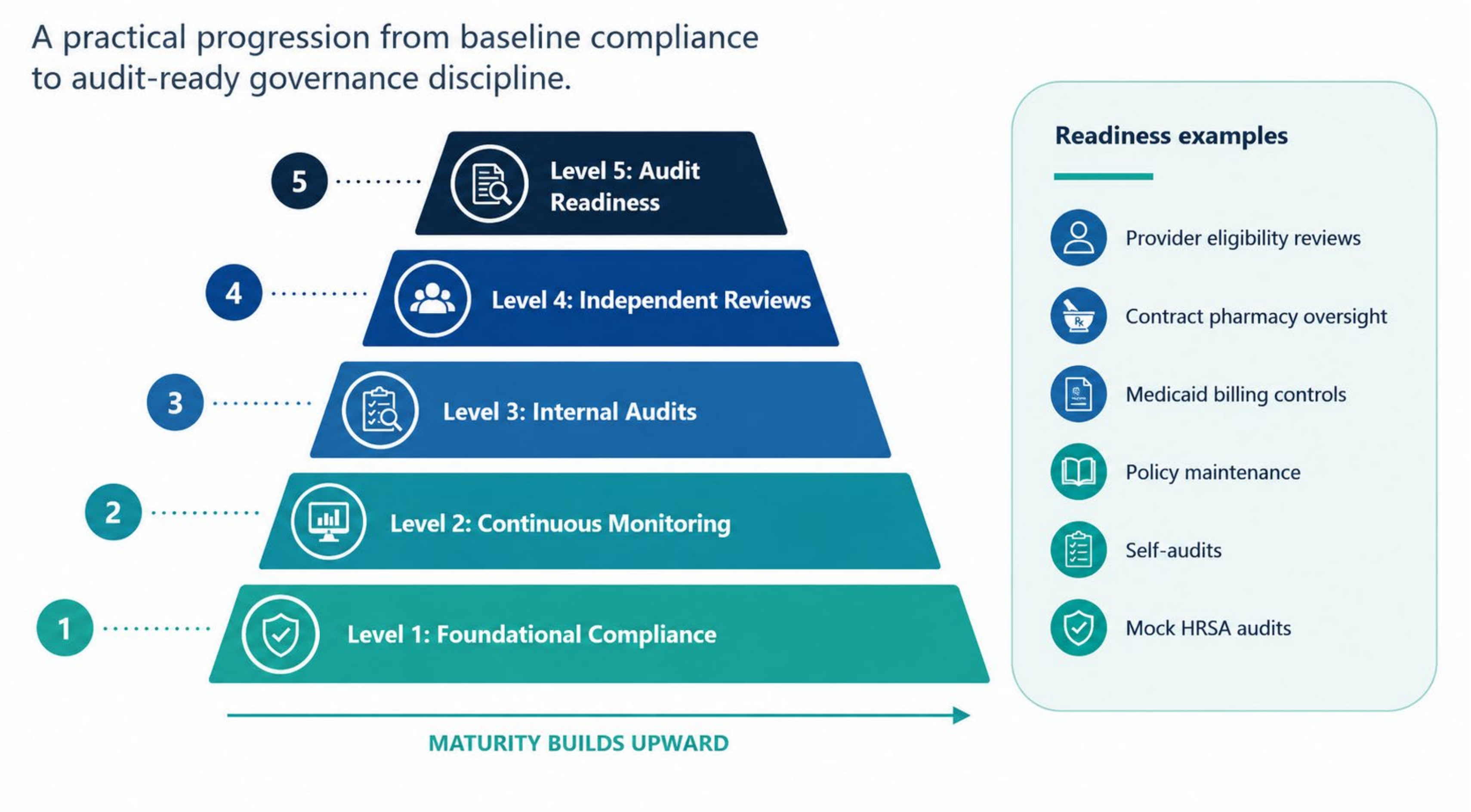
The Hidden Cost of Audit Findings



The operational burden of remediation often exceeds the audit itself.

AUDIT READINESS MATURITY MODEL

Building Audit Readiness Before HRSA Calls



Audit readiness is not a scramble — it is the result of repeatable controls, evidence, and governance habits.

CLOSING SUMMARY

Key Takeaways

Three disciplines keep covered entities ready before, during, and after HRSA review.

1 Understand the Process

Know what to expect before, during, and after an audit.

2 Focus Beyond Audit Day

The most significant impacts often arise from post-audit remediation.

3 Build Readiness Continuously

Ongoing oversight is the strongest defense against audit risk.

We're Here to Help!

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