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Assoc. of Healthcare Internal Auditors

NEW PERSPECTIVES

on Healthcare Risk Management, Control and Governance

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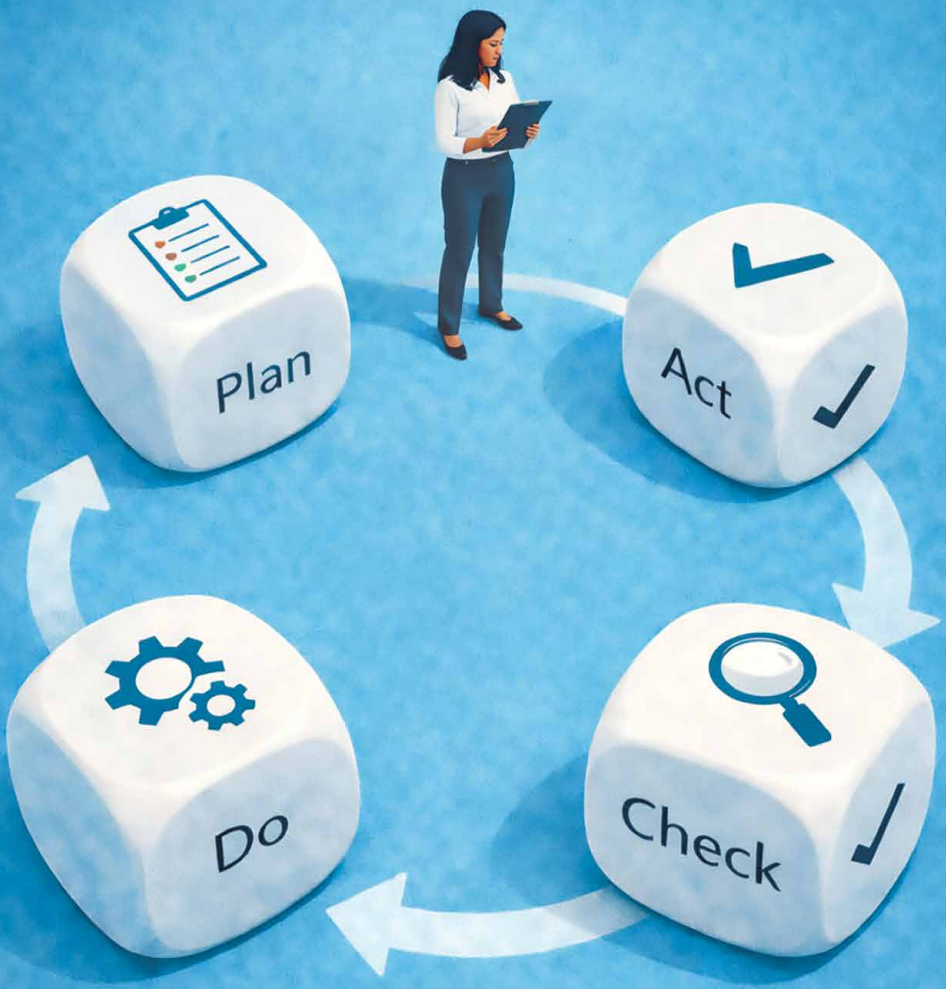

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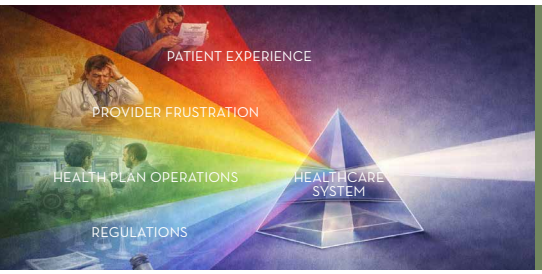

FROM THE EDITOR

Keep the Change

By Jen Conley

"Change can be scary! Leave it with us."

– tip jar at my local coffeehouse

As all good homonyms do, the word *change* pulls double duty in the English language. As money, it can be the coins that fall into the couch or clang around in the washing machine. Some coins may eventually make it into a jar that's ambitiously labeled "vacation fund." As a verb, change can be an intimidating concept that makes people clutch their old processes even when improvement is the goal.

Funny enough, both meanings inspire the same reaction: mild annoyance, a little suspicion, and cautious hope for a valuable return. Whether or not it's worth it to keep the change is often open to debate. In this issue, we contemplate several changes.

In 2025, the AHIA Board of Directors transitioned from a three- to four-year executive track, giving Heather Zundel two years of Vice Chair experience before she stepped into her new leadership role. In her chair's column, Heather reflects on the accomplishments of 2025 and shares a preview of changes ahead in 2026. She highlights the Board's key priorities and areas of focus, all supported by our management company and an impressive—and much appreciated—army of volunteers.

Because audit action plans are inherently about change, it's no wonder that audit clients approach them warily. Their resistance can make audit follow-up one of the hardest parts of an auditor's job. Steve Sokol and Summer Buchanan talked with internal audit leaders to find better ways to help management embrace the positive change that audit action plans are designed to deliver. What they discovered is that meaningful progress may start with making a few small, intentional changes to the follow-up process itself.

Not all change generates a positive return. In fact, because it costs 3.69 cents to make a single 1-cent coin, the U.S. government effectively ended the production of new pennies in late 2025. Fatimah Muhammad applied a similar cost-benefit lens in her evaluation of the nearly implemented 340B Rebate Program. She breaks down the challenges this change to the 340B drug pricing program would have created. Her article prompts reflection as to whether your organization was prepared on January 1, or just lucky the rebate program stalled. She also explains why auditors can take a momentary sigh of relief, but emphasizes the importance of continued attention to this and other proposed regulatory changes.

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NEW PERSPECTIVES
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FROM THE CHAIR

Growing to Serve in 2026

By Heather Zundel

I'm thrilled to serve as the chair of AHIA this year and excited to get to work on the new priorities the Board has set for 2026. These priorities reflect both the realities of today's environment and our aspiration to continue delivering value to our members and the healthcare internal audit profession.

AHIA's focus for 2026: Strengthening the foundation while growing to serve

As we turn the page on another year, it is worth pausing to recognize what AHIA has accomplished—and, more importantly, to look ahead with intention. The past several years have tested healthcare organizations and professional associations alike. Through discipline, adaptability, and the extraordinary commitment of our volunteers, AHIA has not only endured but positioned itself for the next phase of growth.

Rebuilding and sustaining financial strength

A top priority for AHIA in 2026 is strengthening our financial sustainability. The post-COVID landscape has changed how associations operate, deliver content, and engage members. Over the past few years, AHIA has exercised strong financial discipline—making thoughtful decisions, managing costs carefully, and responding head-on to these changes.

In 2026, we will continue this disciplined approach while also focusing on innovation. Financial sustainability is not just about restraint; it is about resilience. That means exploring new and diversified revenue streams, modernizing how we deliver value, and ensuring that AHIA remains well-positioned to support members for years to come. Our goal is to balance stewardship with creativity—protecting the organization's financial health while enabling thoughtful growth.

Getting back to basics: process, consistency, and cadence

Another important focus for 2026 is reinforcing the fundamentals of how AHIA operates. The transition to a new management company introduced challenges in re-establishing consistent processes and workflows. While such transitions are never easy, we are seeing meaningful improvement, and we expect that momentum to continue.

In the coming months, we will be engaging leadership and committees in an exercise to assess and strengthen our foundational processes. This includes clarifying roles, improving consistency, and establishing a clear organizational cadence that allows AHIA to operate more efficiently and predictably. Strong fundamentals free our volunteers to focus on strategy, innovation, and service rather than operational friction.

Advancing a shared strategic vision: grow and serve

Finally, 2026 will be a year of renewed strategic focus. Last August, the board introduced the theme of *Grow and Serve*, reflecting both our ambition and our responsibility as a professional association. In 2026, our goal is to translate that theme into a clear, actionable strategy.

We are working toward a collective vision that aligns board leadership, committees, and volunteers around common priorities. With the support of dedicated volunteers bringing fresh perspectives and structure to the process, we will engage committees in shaping the strategic focus for the year ahead and beyond. Our intent is to complete this work early in the year so it can guide decision-making, resource allocation, and member engagement throughout 2026.

Powered by volunteers, focused on the future

AHIA's success has always been driven by its volunteers. Every milestone we reach is the result of members who are willing to give their time, expertise, and passion to advance the profession. In 2026, that spirit of service remains our greatest strength.

By reinforcing our financial foundation, strengthening our operational basics, and aligning around a shared strategic vision, AHIA is positioning itself to grow thoughtfully and serve more effectively. I am excited about what lies ahead and grateful to work alongside such a committed and talented community.

Here's to building an even stronger AHIA in 2026. **NP**

Keep the Change

continued from page 4

Public opinion of the value of a penny and of health plans has eroded, but the consequences for health plans have been far more personal. The unique dysfunction of the U.S. healthcare system has contributed to hostility, and sometimes harm, directed toward health plan employees.

In his opinion article, Tom Shankle offers a more hopeful perspective by sharing his insider's view of the dedicated individuals behind health plans and the complex environment they navigate. He also calls out the positive changes that could improve the system and outcomes. His voice invites greater understanding and reminds us of the people and purpose at the heart of healthcare.

Finally, our Ethics at Work columnist, Marianne Jennings, reminds us that sometimes the more things change, the more they stay the same. She is celebrating the 20th anniversary of the publication of her book about the signs of ethical collapse at failed companies like Enron and WorldCom. But she's not celebrating the fact that these warning signs still weren't heeded during the past 20 years, as companies like Theranos, Wells Fargo, and Boeing created their own ethical dilemmas. In the first of a four-part series, she explains how auditors can reroute their organizations off the path of collapse.

Thank you to this issue's authors, who—like my neighborhood baristas—have given me great new insights on change. **NP**

About *New Perspectives*

New Perspectives (NP) is a refereed and peer-reviewed journal that focuses on up-to-date information, trends and issues in the healthcare industry and the internal auditing profession. Practical guidance is provided on risks and controls that can be applied by internal audit professionals in their jobs.

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Action Plan Follow-Up

Achieve your best during the worst part of our jobs

By Steve Sokol, CHIAP, CIA, CPA, CFE, and Summer Buchanan, CHIAP

The importance of following up on audit recommendations or action plans is something internal auditors can agree on. Beyond meeting a requirement of The Institute of Internal Auditors (IIA) Global Internal Audit Standards, management's follow-up actions are the real change that happens in an organization. The power of a great audit comes alive when others see the value in change and move beyond talk to action.

Ongoing engagement with audit clients through follow-up is part of why audits don't really have an endpoint. Once you issue the audit report, you have just started the change process. The project and relationships continue through follow-up, then the mitigated risk assessment, and eventually, the next audit.

We interviewed leaders of internal audit functions at nine healthcare organizations to find out more about their follow-up processes, strategies, and approaches. Clearly, this sample is too small for projecting results, but we identified valuable insights and numerous best practices. Because several organizations did not want to be named, these results are presented with anonymity.

Quick Tips
Follow up, Follow-up, Followup: Which One is Right?

- Using it as a verb? Put a space between the two words, and no hyphen: *follow up*.
- Using it as a noun or adjective? Put a hyphen between the two words: *follow-up*.
- Writing it as *followup*? Don't.

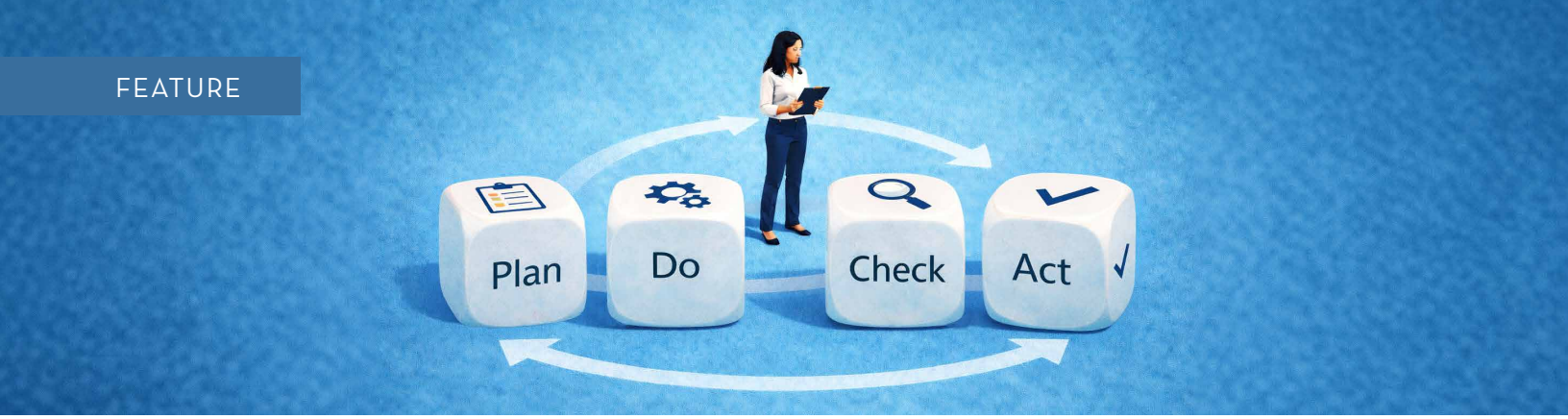
Insights

Several leaders commented that follow-up is "the most important part of the audit," but nearly everyone was dissatisfied with their follow-up processes and results. Reasons for dissatisfaction included the following:

- Not enough change resulting from closed management action plans
- Change not sticking—in fact, one organization does another round of testing six months after follow-up is concluded, and that round of testing often resurfaces the same problems as the original audit.
- The follow-up process isn't popular with auditors or audit clients.

Although he was not a respondent to our interviews, we even found that Richard Chambers, who served for over a decade as the president and CEO of the IIA, suffered similar dissatisfaction back in his auditing days. He recalled that "Issuing a new audit report was cause for celebration. But nothing was more demoralizing than when I would invariably undertake the required follow-up audit only to discover that my carefully crafted recommendations or management action plans were never implemented. After all, management had agreed to the proposed corrective actions...So why did they fail so often to follow through? There were always plenty of excuses from management when the follow-up audits disclosed that 'problems had not been corrected':

- We underestimated the complexity of the action we agreed to take.
- Guess what? Your recommendations were not feasible!
- We didn't realize how long it would take to implement the promised actions.
- Circumstances changed, and the actions we agreed on are no longer valid.
- It turned out we didn't have the resources to correct the problems.



Despite common dissatisfiers, some positives were noted in our interview results. At least occasionally, audit clients are energized by corrective actions and finally see the point of the audit.

Every organization agreed that open communication is critical to the process, both with management, who is responsible for remediating issues, and with the board or committee receiving audit status updates.

Because the follow-up process is important AND not satisfying, this is an area for focused improvement by nearly all internal audit functions. Universally, auditors were hesitant to share their processes because they felt that they needed to be improved.

Logistics

The Standards don't specify exactly how or when internal audit functions must follow up, as shown in Exhibit 1, but most interviewed internal audit leaders organized their department's follow-up around management's action plans. The following questions identified other commonalities.

Who does follow-up?

The auditor who did the audit follow up with the audit client is usually the one who determines action plan status. However, some organizations have a separate team in internal audit focused on follow-up. One internal audit function did not conduct its own follow-up and delegated that process to another compliance control and risk management group within the organization.

- Advantages of having the auditor who is already involved act as the point of contact for follow-up: The auditor can continue to build trust and expand the relationship. The auditor already understands the audit issue and corrective actions, so the process should be more efficient. Management's favorite auditor was "the last one" (they prefer people they already know).
- Advantages of someone else: A new person can bring new perspectives, and their involvement enforces independence and objectivity.

How are implementation dates set?

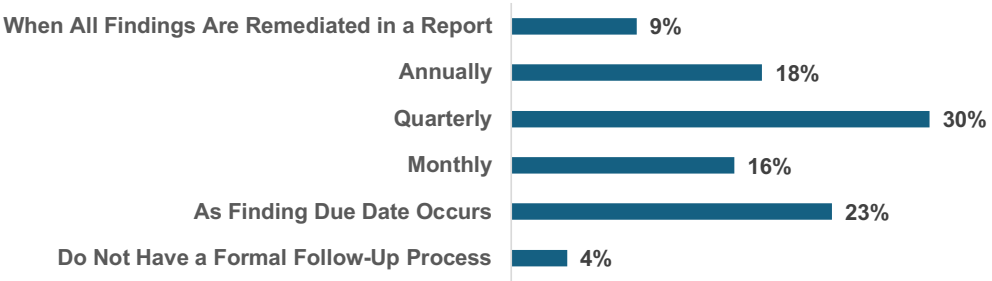
Most internal audit teams let management pick their implementation dates if they are reasonable and realistic. One organization had standard due dates based on the risk rating of the observations (e.g., clients have 12 months to remediate medium risk, six months for high risk).

How frequent is communication?

Most internal audit teams communicated monthly with the audit client to determine the status of open action items. The least frequent communication timeline is whenever the action plan due date comes around. Many teams report quarterly or similar, aligned with audit committee meetings.

Protiviti and the Association of Healthcare Internal Auditors (AHIA) partner to conduct an annual study examining internal audit functions across a wide range of healthcare provider, payer and integrated delivery systems. The internal audit department benchmarking data from that study is summarized in "Evolving Risk Landscape Refocuses Healthcare Audit Priorities Part 2 – Internal Audit Benchmarks," which you can find in *New Perspectives* Volume 44, Issue 4. From that article, Exhibit 19 is reproduced here.

Frequency of following up on outstanding action plans



From Exhibit 19 of "Evolving Risk Landscape Refocuses Healthcare Audit Priorities Part 2 – Internal Audit Benchmarks," New Perspectives *Volume 44, Issue 4*

Who is action plan status and closure reported to?

Everyone interviewed reported back to action plan owners (i.e., management) when they agree that an action plan can be closed. Nearly all internal audit functions reported to senior leadership and the audit committee. However, the level of reporting detail varies. Each group emphasized that past-due and problematic items are of main concern to everyone involved. Most organizations report the total number of open, closed, and extended or past-due action plans to both senior leadership and the audit committee.

Is process technology enabled?

Everyone interviewed used their electronic workpaper system to capture and track open items. However, nobody used pre-populated tables for reporting to senior leaders or the audit committee. Instead, manual presentation slides or reports are created by the internal audit or another follow-up group.

Exhibit 1
The Global Internal Audit Standards published January 9, 2024

Standard 15.2 Confirming the Implementation of Recommendations or Action Plans

Requirements

Internal auditors must confirm that management has implemented internal auditors' recommendations or management's action plans following an established methodology, which includes:

- Inquiring about progress on the implementation.
- Performing follow-up assessments using a risk-based approach.
- Updating the status of management's actions in a tracking system.

The extent of these procedures must consider the significance of the finding.

If management has not progressed in implementing the actions according to the established completion dates, internal auditors must obtain and document an explanation from management and discuss the issue with the chief audit executive. The chief audit executive is responsible for determining whether senior management, by delay or inaction, has accepted a risk that exceeds the risk tolerance.

Considerations for implementation

Internal auditors may use a software program, spreadsheet, or system to track whether management's action plans are implemented according to the established timelines. The tracking system indicates whether action plans remain open or are past due and provides a useful tool for internal auditors to communicate with the board and senior management. In addition, a program or system may automate the workflow from risk assessment to action plan completion. For example, the workflow may include automated emails that notify the appropriate parties regarding action plans that are nearing their target completion dates.

The methodology for confirming the implementation of management's action plans should include criteria for determining when to perform follow-up assessments to confirm that management's action plans have effectively addressed findings. Follow-up assessments may be performed for completed action plans selectively, depending on the risk's significance. Under certain circumstances, regulators may require reporting on management's action plans.

If management decides on an alternative action plan and internal auditors agree that the alternative plan is satisfactory or better than the original action plan, then progress on the alternative plan should be tracked until completion.

Examples of evidence of conformance

- A routinely updated tracking system (for example, a spreadsheet, database, or other tool) that contains the finding, associated corrective action plan, status, and internal audit's confirmation.
- Corrective action status reports prepared for the board and senior management.

Leading practices

Based on our interviews, we identified the following leading practices for consideration as you, like everyone else, are likely working to improve your follow-up processes.

Who should follow up?

The person following up should generally be the person with the client relationship and background knowledge. This facilitates collaboration and relationship-building with the client. Additionally, the auditor has background knowledge to ensure that the risk has been mitigated appropriately.

When should internal audit begin the follow-up process?

Consider the due dates first to develop a follow-up methodology. Here are various practices to choose from as they best suit your organization:

- Allow management to select the expected implementation date, within reason.
  - Pros: Management feels they can pick the best date for them. Management has some control over the timing of their response.
  - Cons: Internal audit may be continually following up on action items.
- Suggest predetermined due dates close to management's proposed date, based on reporting requirements by internal audit (e.g., audit committee meeting or elevation to executive leadership).
  - Pros: Internal audit staff can plan dedicated follow-up time and consider it while scheduling audit engagements. Additionally, meetings/communication with action plan owners can be pre-scheduled.
  - Cons: Timeframe may not work for management.
- More complicated management action plans may require an extended implementation date. In this case, consider setting milestone dates to ensure that management is making progress.

How should internal audit's follow-up process work?

Standardize as much as possible!

- Consider developing consistent communication for follow-up.
  - Use the same language/format for each action plan to reduce confusion and frustration from audit clients.
  - Have internal audit consolidate communications and meetings if multiple action items are open for multiple engagements.
- Consider the use of a liaison (this requires executive leadership buy-in). This provides a single point of contact for internal audit to elevate obstacles. This also provides accountability for action plan owners, knowing that senior leadership, or a designee, is aware of the status of action items.
- Internal audit should have criteria to follow so they know when and how to close out follow-up items, specifically what information is needed to determine that an action item is closed. Determine if the criteria change is based on the significance of the observation. For example:
  - Low significance may require only verbal confirmation from the client that the action plan was completed.
  - Moderate significance may require internal audit to ask for supporting documentation showing implementation.
  - High significance may require internal audit to reperform testing to evaluate whether risk is appropriately mitigated.
- Consider what is needed to extend management action plans. For example, does an extension need to be approved by senior leadership? What are reasonable reasons for extension?
- Decide if there is a limit to how many times an action plan implementation date can be extended and determine what escalation procedures should be followed.

Other professional opinions

Two globally recognized thought leaders in internal audit have shared their staunch opinions on certain follow-up processes.

Richard Chambers, former president and CEO of the IIA, commented on the IIA's earlier (but similar) version of the follow-up process standard – *The chief audit executive*

Shift the focus of follow-up from outputs to outcomes.

Critically assess your action plan development processes.

must establish a follow-up process to monitor and ensure that management actions have been effectively implemented or that senior management has accepted the risk of not taking action. He wrote that complete follow-up audits are a waste of time, and progress is better monitored by shifting the focus from outputs (follow-up audits) to outcomes (appropriate disposition of audit findings and action plans). His comments generally coincide with the approaches taken by our interview respondents.

He also recommended that internal audit functions critically assess their action plan development processes. "If, after careful assessment, follow-up audits often seem justified, you might want to ask yourself why your organization's implementation plans keep going astray. Were your recommendations vague? Were you unpersuasive? Did you fail to listen to management or to take their objections seriously? Are recommendations or management action plans unclear or nonspecific? Is there a culture of noncompliance within the organization?"

Norman Marks, a member of the IIA's Hall of Distinguished Practitioners, took things a step further when he objected strongly to Standard 15.2 because he believes "all we can do as internal auditors is tell the board what management has told us. They need to hear directly from management when significant action items have not been completed as agreed!" He recommends the following follow-up process:

1. Agree with the board and top management that completing agreed action items, including periodic monitoring and reporting their status to top management and the board/audit committee, is a management responsibility.
2. Work with management to ensure they have an effective process for doing that.
3. Periodically, based on risk, audit and report on the effectiveness of that process.
4. Consider the above an improvement on conformance to the Standard.

He summarized, "In other words, teach management how and help them to fish, then audit their fishing processes."

Summary

Each organization will have different requirements and preferences for tracking and reporting action plan follow-up based on:

- Organizational structure
- Resource availability
- Leadership and audit committee involvement
- Risk appetite

By carefully considering your processes and their impact, you can certainly improve your follow-up processes. Improvement is a journey. Instead of pursuing the theoretical ultimate solution, consider what small change you can make to improve. **NP**

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"Life is really simple, but we insist on making it complicated." – Confucius

FEATURE

340B Rebate Pilot: Auditing the Unauditable

Recognize how the rebate model would have created unprecedented compliance risks

By Fatimah Muhammad, FHFMA, CSBI, CHFP, CSPR, CRCR

On July 31, 2025, the Health Resources and Services Administration (HRSA) announced the availability of a voluntary 340B Rebate Model Pilot Program that would have reformed the program from an upfront discount to a post-sale rebate for an initial group of 10 drugs starting January 1, 2026. As the program approached implementation, healthcare internal auditors faced a fundamental challenge: How do you audit a process when you cannot independently verify the most critical elements of compliance? This wasn't a theoretical question in late December 2025; it was the reality facing every internal audit department at 340B covered entities.

On December 29, 2025, U.S. District Judge Lance E. Walker temporarily blocked the program, and on January 17, 2026, the federal government voluntarily dismissed its appeal, ending for now what would have been an audit and compliance nightmare. The plaintiffs demonstrated that this nightmare would bring an estimated $400 million in compliance costs and irreparable harm, including the reduction of safety-net services. As internal auditors, we must understand what we narrowly avoided and prepare for the possibility that a revised rebate model may emerge.

Existing 340B Drug Pricing Program Overview

In 1992, Congress enacted Section 340B of the Public Health Service Act, which requires pharmaceutical manufacturers to enter into a pharmaceutical pricing agreement (PPA) with the Department of Health and Human Services (HHS) Secretary in exchange for having their drugs covered by Medicaid and Medicare Part B. Under the PPA, the manufacturer agrees to provide front-end discounts on covered outpatient drugs purchased by specified providers, called covered entities, that serve the nation's most vulnerable patient populations. The Office of Pharmacy Affairs (OPA), which is part of the HRSA within HHS, administers the program.

According to congressional report language, the purpose of the 340B program is to enable covered entities "to stretch scarce federal resources as far as possible, reaching more eligible patients and providing more comprehensive services." Pharmaceutical prices available through the 340B program are significantly lower than both retail and wholesale prices. In 2015, the Government Accountability Office reported that program participants can save an estimated 20–50 percent off drug costs.

Once admitted into the program, covered entities are entitled to receive discounts on all eligible covered outpatient drugs. A manufacturer may not charge covered entities more than the 340B ceiling price, which is the average manufacturer price (AMP) reduced by the unit rebate amount (URA). In addition, covered entities are free to negotiate prices that are lower than the 340B ceiling price (i.e., sub-ceiling prices). In 2019, HRSA launched a secure, limited-access website that lists 340B ceiling prices for covered entities interested in validating the prices they pay for 340B drugs.

The 340B statute explicitly authorizes HRSA to audit covered entities and manufacturers to make sure they are compliant

The current 340B program's key compliance requirements are well-established.

with 340B statutory requirements. HRSA began auditing covered entities in 2012 and conducts approximately 200 audits of covered entities per year. Covered-entity compliance is also enforced through the annual recertification process.

Like covered entities, manufacturers are subject to audits by HRSA to ensure compliance with 340B requirements. Covered entities have no authority to audit manufacturers, and there is no annual recertification process for manufacturers. Both covered entities and manufacturers are subject to penalties if they violate 340B program requirements. For covered entities, the penalty for failing to comply with the program's diversion and duplicate discount provisions is repayment of the discounts back to the manufacturer and, if the diversion violation is systematic and egregious as well as knowing and intentional, a covered entity may be disqualified from 340B participation.

What is a covered entity?

Covered entities include disproportionate share hospitals (DSHs), children's hospitals and cancer hospitals exempt from the Medicare prospective payment system, sole community hospitals, rural referral centers, and critical access hospitals. Hospitals in each of the categories must be (1) owned or operated by state or local government, (2) a public or private nonprofit corporation that is formally granted governmental powers by state or local government, or (3) a private nonprofit organization that has a contract with a state or local government to provide care to low-income individuals who do not qualify for Medicaid or Medicare. In addition, except for critical access hospitals, hospitals must meet payer-mix criteria related to the Medicare DSH program.

Current known risks, established controls

The current 340B program, despite its complexity, operates within a framework that internal auditors can effectively evaluate. The program's key compliance requirements are well-established: patient eligibility determination, prevention of duplicate discounts and diversion, accurate ceiling price calculations, proper inventory management, and appropriate split-billing methodologies. While these requirements are technically complex and subject to varying interpretations, they share a critical characteristic: they are auditable.

Internal auditors can review patient eligibility by examining medical records, provider relationships, and facility qualifications. We can test duplicate discount prevention by analyzing Medicaid billing files and claims data. We can validate proper purchasing by comparing acquisition costs to published ceiling prices. We can trace medication dispensing from receipt to patient administration. We can evaluate split-billing algorithms against HRSA guidance. In each case, the evidence exists within our organization's systems, and we can design control activities that provide reasonable assurance of compliance.

Manufacturer audits, while sometimes contentious, follow established protocols. HRSA-authorized auditors request transaction data, covered entities provide documentation, and disputes are resolved through established channels with HRSA oversight. The 340B Administrative Dispute Resolution process, while imperfect, provides a formal mechanism for addressing compliance disagreements. This framework creates audit trails, establishes accountability, and allows internal audit departments to fulfill their fundamental responsibility: providing independent assurance that the organization complies with program requirements and that controls are operating effectively.

The rebate model: Transferring control beyond audit reach

The rebate pilot would have fundamentally altered this framework by transferring control over the most critical element of 340B compliance—the receipt of the statutory discount—from covered entities to pharmaceutical manufacturers. Under the rebate model, covered entities would purchase medications at Wholesale Acquisition Cost (WAC), submit claims data to manufacturers, and wait for rebate approval. This seemingly administrative change would have created profound audit implications that many stakeholders failed to fully appreciate.

Consider the internal auditor's fundamental question: How do we provide assurance that our organization received the 340B discount it was entitled to receive? Under the current model, this is straightforward; we verify that the purchase price matches the published ceiling price, confirm the medication is eligible, and validate proper ordering through the correct wholesaler account. We have access to all relevant information, we can test controls at each step, and we can quantify any identified discrepancies.

Under the rebate model, this question becomes nearly impossible to answer with any degree of audit certainty. The rebate approval process occurs entirely outside our organization, within manufacturer systems we cannot access, applying criteria that may not be fully disclosed, using data validation processes we cannot observe, and producing decisions we cannot independently verify. How do you audit a black box?

Specific audit challenges the rebate model would have created

Inability to independently verify rebate calculations

The rebate model would have required manufacturers to calculate the difference between WAC and the 340B ceiling price, then reimburse covered entities. But how would internal auditors verify these calculations? We would not have access to the manufacturer's ceiling price methodology, we could not observe their data validation processes, and we would have no visibility into whether they applied the correct discount percentage. If a manufacturer's rebate seemed too low, what recourse would we have? We could request an explanation, but manufacturers are not subject to our audit authority. This creates an untestable control and a fundamental failure in any audit framework.

Documentation requirements beyond our control

Effective internal controls require clear documentation standards. Under the current 340B model, HRSA establishes requirements and we design controls to meet them. Under the rebate model, each manufacturer could potentially impose different documentation requirements for rebate approval. Manufacturer A might require detailed patient eligibility attestations, Manufacturer B specific contract pharmacy validation, and Manufacturer C prescriber verification. How do we design a control environment when the compliance requirements vary by manufacturer and could change without notice? How do we provide assurance that we've met standards that may not be clearly defined until a rebate is denied?

Rebate denial audit trail problem

When an internal control fails, auditors investigate to determine the root cause, evaluate whether the failure was isolated or systemic, and recommend corrective action. But what happens when a manufacturer denies a rebate? Was it because our organization failed to meet program requirements (a true compliance failure we need to address), or because the manufacturer applied overly restrictive criteria (a dispute rather than a control deficiency)? Without access to the manufacturer's decision-making process, we cannot determine which scenario occurred. This ambiguity would have made it virtually impossible to write meaningful audit findings or recommend effective corrective actions.

Timing verification and reconciliation complexity

The rebate model would have required manufacturers to submit rebates within 10 days but provided limited enforcement mechanisms. How would internal auditors test this control? We could track submission dates and rebate receipt dates, but if rebates arrive late, is that a manufacturer noncompliance issue or a problem with our submission?

We would need to maintain complex tracking systems for potentially hundreds of rebate submissions monthly, reconcile partial rebates against expected amounts, follow up on delays, and distinguish between legitimate processing

The rebate program would create an untestable control and a fundamental failure in any audit framework.

Ambiguity would have made it virtually impossible to write meaningful audit findings or recommend effective corrective actions.

time and manufacturer noncompliance. This reconciliation burden would have consumed audit resources while providing limited assurance value.

Contract pharmacy compliance verification

Many covered entities rely heavily on contract pharmacy arrangements, which manufacturers have aggressively challenged in recent years. The rebate model would have given manufacturers direct visibility into contract pharmacy utilization through rebate claim data. If a manufacturer denies rebates for contract pharmacy claims, citing alleged noncompliance, how does an internal auditor evaluate this? We would need to audit not only our own contract pharmacy agreements and oversight processes but also verify that the manufacturer's rejection was based on legitimate compliance concerns rather than its ongoing campaign to restrict contract pharmacy access. This puts internal auditors in an impossible position of adjudicating policy disputes while lacking the authority or information to do so effectively.

Data security and privacy risks

The rebate model would have required covered entities to submit detailed claims data to manufacturers, potentially including information that could be used to identify patients, prescribers, and utilization patterns. From an internal audit perspective, this creates new risks that would require control activities: ensuring data is properly de-identified before transmission, validating that manufacturer data security standards are adequate, monitoring for potential misuse of submitted data, and ensuring compliance with HIPAA and state privacy laws. These controls would have needed to be designed and tested without clear regulatory guidance about what constitutes adequate protection in this novel context.

Existing 340B compliance safeguards and why they matter

The current 340B program includes several critical compliance safeguards that enable effective auditing and protect program integrity. Understanding these safeguards helps illustrate what the rebate model would have jeopardized.

HRSA oversight and guidance

HRSA publishes policy releases, guidance documents, and FAQs that establish clear compliance standards applicable to all covered entities and manufacturers. While these documents sometimes require interpretation, they provide a consistent framework that internal auditors can reference when evaluating controls. The rebate model would have introduced manufacturer-specific requirements that could contradict HRSA guidance, creating compliance confusion.

Published ceiling prices

HRSA publishes quarterly ceiling prices, allowing covered entities to verify they received appropriate discounts. This transparency is fundamental to audit effectiveness. We can independently calculate what price we should have paid and compare it to what we actually paid. The rebate model would have eliminated this transparency, replacing published prices with manufacturer-calculated rebates that we could not independently verify.

Administrative dispute resolution (ADR)

When disputes arise between covered entities and manufacturers, the 340B ADR process provides a formal mechanism for resolution with HRSA as arbiter. This creates accountability and establishes precedent. The rebate model provided no equivalent dispute resolution mechanism for denied rebates, leaving covered entities without effective recourse when manufacturers reject claims.

Manufacturer audit protocols

Manufacturer audits of covered entities follow established protocols with defined scope, information requests, timelines, and dispute resolution processes. Internal auditors can prepare for these audits, ensure appropriate documentation is available, and challenge findings that appear inconsistent with HRSA guidance. Under the rebate model, manufacturers would conduct ongoing claims review without formal audit protocols, making it difficult to distinguish between legitimate compliance review and arbitrary claim denial.

Recertification and annual requirements

HRSA's recertification process and annual reporting

requirements create natural audit checkpoints where internal auditors can review program compliance, validate registration accuracy, and ensure controls remain effective. These periodic reviews would have become more complex under the rebate model, as we would have needed to audit not only our compliance with HRSA requirements but also our compliance with potentially divergent manufacturer requirements.

Self-disclosure and corrective action

When covered entities identify compliance issues, they can self-disclose to HRSA and implement corrective actions. This demonstrates good faith and can mitigate penalties. The rebate model would have complicated self-disclosure because violations might result in denied rebates rather than clear compliance failures, making it unclear what should be disclosed and to whom.

What we avoided with the appeal dismissal

The government's voluntary dismissal of its appeal on January 17, 2026, spared internal audit departments from unprecedented challenges. Consider what we would have faced had the rebate pilot taken effect.

Impossible assurance opinions

Audit committee members and senior leadership would have asked us to provide assurance that the organization is compliant with 340B requirements and is receiving appropriate discounts. Under the rebate model, we would have been unable to provide that assurance with any reasonable degree of confidence. We could verify that we submitted rebate claims properly, but we could not verify that manufacturers processed them correctly, applied appropriate discount calculations, or approved all eligible claims. This would have put internal audit departments in an untenable position, forced to qualify our opinions to the point of meaninglessness or to provide assurance we couldn't support.

Audit committee reporting complexity

How would we have explained to audit committees that we cannot provide reasonable assurance on 340B compliance because critical controls are operated by manufacturers outside our oversight? How would we have quantified the risk when we lack data to even estimate the likelihood or magnitude of rebate denials? How would we have presented the findings if we could not determine whether the issues represent true compliance failures or manufacturer overreach? The rebate model would have made audit committee reporting extraordinarily complex while reducing the actionable value of our analysis.

Resource drain with limited value

Internal audit (or comparable) departments would have needed to dedicate significant resources to rebate tracking, reconciliation, and dispute management. These activities provide limited assurance value because we cannot control or independently verify the key compliance elements. These resources would have been diverted from other audit activities such as revenue cycle compliance, clinical documentation integrity, and fraud prevention. We would have been working harder while providing less assurance.

Control environment degradation

Effective internal controls require clear ownership, defined processes, and the ability to take corrective action. The rebate model would have created a control environment where the most critical compliance element, rebate approval, would have been outside our organization's control. This degrades the overall control environment and makes it difficult to maintain a culture of compliance when employees see that external parties control outcomes regardless of our internal processes.

Regulatory examination risk

Office of Inspector General reviews, HRSA audits, and other regulatory examinations would have become more challenging. Regulators would have expected covered entities to demonstrate compliance with rebate requirements, but we would have had limited evidence beyond submission confirmations and whatever documentation manufacturers deigned to provide. If regulators identified issues, we would have struggled to demonstrate that our controls were appropriately designed and operating effectively when the key control, rebate processing, was entirely external.

HRSA had not adequately explained the impact of a rebate model on 340B hospitals.

Internal audit departments should use this reprieve to prepare.

The court's recognition of implementation inadequacy

Judge Walker's decision blocking the rebate pilot included language that should resonate with every internal auditor. He noted that HRSA's administrative record was "threadbare" and failed to adequately consider the impact on covered entities. From an audit perspective, this inadequate administrative record meant there was no clear compliance framework, no established standards for evaluating controls, and no meaningful basis for designing audit procedures.

The judge specifically recognized that HRSA had not adequately explained "the impact of a rebate model on 340B hospitals, which rely on upfront price concessions to stretch few resources as far as possible." For internal auditors, this impact extends beyond financial concerns to fundamental questions of auditability and control effectiveness. A program that cannot be effectively audited cannot be effectively managed, and a program that cannot be effectively managed cannot achieve its statutory purpose.

Judge Walker's analysis was further validated on January 7, 2026, when the First Circuit Court of Appeals denied the federal government's request for a stay of the nationwide preliminary injunction barring implementation of the 340B Rebate Model Pilot Program, and the government dismissed its appeal on January 17. The government indicated it is considering returning manufacturer approvals to HRSA for reconsideration, which suggests any future rebate model may need to address the procedural and substantive deficiencies identified by the court, including, one hopes, the audit and compliance challenges that would have made the program nearly impossible to manage effectively.

Preparing internal audit departments for a potential revised rebate model

While the rebate pilot has been blocked, internal auditors cannot assume it will never resurface. HRSA retains statutory authority to implement a rebate model if it addresses the court's concerns and builds a more robust administrative record. Internal audit departments should use this reprieve to prepare.

Document current-state audit procedures

Create comprehensive documentation of your current 340B audit approach, including how you test key controls, verify compliance, and provide assurance. This documentation will be invaluable for explaining to stakeholders what would change under a rebate model and why those changes create audit challenges. It also preserves institutional knowledge if you need to quickly adapt procedures should a revised model be implemented.

Engage with leadersip early

Educate your audit committee, CFO, and senior leadership about the audit implications of a potential rebate model before it happens. Many leaders focus on financial and operational impacts without fully appreciating the compliance and assurance challenges. Make clear that a rebate model would fundamentally change your ability to provide assurance on 340B compliance and discuss what alternative assurance approaches might be possible.

Evaluate technology requirements

If a rebate model returns, you will need systems to track rebate submissions, monitor receipt and payment timing, reconcile expected vs. actual rebates, flag delays or denials, and maintain audit trails. Evaluate whether your current 340B technology platforms can support these requirements or whether you would need additional solutions. Internal audit should be included in vendor selection processes if new systems are considered.

Assess resource needs

A rebate model would require substantially more audit effort with less assurance value. Estimate the personnel impact, consider whether you would need auditors with specialized pharmaceutical or rebate processing expertise, and begin building the business case for additional resources should they be needed. Be prepared to advocate for appropriate staffing given the expanded scope and complexity.

Develop risk assessment frameworks

Create risk assessment methodologies that account for the unique challenges of auditing a rebate model, including risks outside your control. This framework should identify what you can audit (submission processes, documentation

completeness, timing tracking), what you cannot audit (manufacturer decision-making, rebate calculations, claims validation), and how you will address the gap in your assurance opinion.

Participate in policy advocacy

Internal auditors have unique insight into what makes programs auditable and controllable. Consider engaging with AHIA, state hospital associations, and advocacy groups to communicate the audit implications of rebate models. Your voice can help ensure that any revised program includes adequate transparency, clear compliance standards, and effective dispute resolution mechanisms.

The Risk Continues

On February 17, 2026, HRSA published a Request for Information (RFI) in the Federal Register seeking input on the potential implementation of a rebate model. This reflects HRSA's continued efforts to evaluate whether and how a rebate-based framework might operate within the 340B program.

Build manufacturer audit expertise

If rebate models become reality, understanding manufacturer audit practices will be critical. Ensure your team understands how manufacturers currently audit covered entities, what documentation they typically request, what findings they commonly cite, and how disputes are resolved. This knowledge will be essential for evaluating rebate denials and determining whether they reflect true compliance issues.

Strengthen current controls

The best defense against a problematic rebate model is a bulletproof current compliance program. Use this time to strengthen existing 340B controls, address any identified deficiencies, enhance documentation practices, and ensure your organization can demonstrate exemplary compliance with existing requirements. This positions you more favorably if manufacturer-controlled rebate processing becomes a reality.

The broader audit perspective: When policy undermines accountability

The 340B rebate pilot illustrates a concerning trend in healthcare policy: the implementation of programs and processes that look administratively clean on paper but create fundamental audit and accountability challenges in practice. As internal auditors, we must advocate for policies that not only achieve their stated objectives but also do so in ways that enable effective oversight, meaningful compliance verification, and genuine accountability.

A program that cannot be effectively audited cannot be effectively managed. When policy creates situations in which critical controls operate outside organizational oversight, compliance cannot be independently verified and corrective action cannot be taken even when problems are identified, so the entire accountability framework breaks down. This doesn't just create challenges for internal auditors; it creates risk for the organization, threatens program integrity, and ultimately harms the patients and communities the program is meant to serve.

The 340B program serves some of the most vulnerable patients in our healthcare system. Safety-net hospitals and health centers depend on the 340B margin to provide care to the uninsured, underinsured, and medically underserved. Internal auditors play a critical role in protecting this program by ensuring covered entities comply with requirements, maintain effective controls, and use 340B savings appropriately. We cannot fulfill this role if the program structure makes effective auditing impossible.

Conclusion: Auditing requires auditability

The temporary halt to the 340B rebate pilot and the government's decision to dismiss its appeal represent a victory not just for covered entities' revenue cycles but also for the fundamental principles of accountability and effective oversight. Internal auditors avoided being placed in an impossible position: being asked to provide assurance on compliance when key compliance elements are beyond our ability to audit or control.

The 340B rebate pilot illustrates a concerning trend in healthcare policy.

This doesn't just create challenges for internal auditors; it ultimately harms the patients and communities the program is meant to serve.

As we await potential reconsideration of manufacturer approvals by HRSA, internal audit professionals must remain engaged. If a revised rebate model emerges, it must include adequate transparency to enable independent verification of rebate calculations, clear and consistent compliance standards that do not vary by manufacturer, effective dispute resolution mechanisms when rebates are denied, reasonable documentation requirements that covered entities can meet, and sufficient implementation time for entities to design and test new controls.

Without these elements, any rebate model, regardless of its other merits, will be fundamentally unauditable and therefore unacceptable. Internal auditors have a professional and ethical obligation to speak up when policies undermine our ability to provide meaningful assurance. The 340B rebate pilot was such a policy, and we are fortunate it was blocked before implementation exposed its fatal flaws.

Our role is not to advocate for or against particular policy positions, but to ensure that any policies implemented can be effectively audited and controlled. The rebate pilot failed this fundamental test. Any future iteration must do better, or internal auditors must continue to raise concerns about the audit and accountability challenges it would create.

The court bought us time. Let's use it to ensure any future 340B policy changes support, rather than undermine, the accountability frameworks that protect program integrity and ultimately serve patients and communities. **NP**

Key Audit Challenges the Rebate Model Would Have Created

Black box processing: Critical compliance decisions made in manufacturer systems outside audit reach

Unverifiable calculations: No ability to independently verify manufacturer rebate calculations

Varying standards: Manufacturer-specific requirements creating inconsistent control environment

Denial ambiguity: Inability to determine if rebate denials reflect compliance failures or manufacturer overreach

No dispute resolution: Limited recourse when manufacturers deny legitimate rebate claims

Resource drain: Significant audit effort required with minimal assurance value delivered

Impossible assurance: Inability to provide meaningful audit opinions when key controls are external

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ETHICS AT WORK

The Seven Signs of Ethical Collapse – Part 1

They are still alive, and all is not well!

By Marianne M. Jennings, JD

Twenty years ago, I published my book The Seven Signs of Ethical Collapse: How to spot moral meltdowns in companies...before it's too late. *It was aptly described as a "postmortem of the failings of American companies whose self-inflicted demise [is] a startling warning message...." There is sad news on this 20th anniversary: (1) The seven signs still hold true; and (2) There are even more examples of failed companies.*

"Predicting rain doesn't count; building arks does."

– Warren Buffett, from his 2001 letter to Berkshire Hathaway shareholders

From this sad news, there is good news. There is a pattern to ethical collapse, which can help auditors evaluate where your organization stands and if it is at risk. If you see signs in your organization, you can adjust your audit work and efforts to halt the march to collapse. This is the first of a four-part series where I'll review the seven signs with examples of organizational collapses that occurred since my book's publication for a refresher, some renewal, and rerouting from the path to collapse.

Sign #1: pressure to maintain the numbers

Pressure has enormous power over rational thought. Humans respond to the pressures and pains of the present. They can easily discount the future costs of poor decisions. When under pressure to meet goals from earnings to productivity levels to customer satisfaction scores, they often stretch to do whatever it takes to get there. Sometimes they

The Seven Signs

In this four-part series, I'll review the seven signs of ethical collapse that auditors, leaders, governance, investors, and other stakeholders can observe and must confront:

1. Pressure to maintain the numbers
2. Fear of silence
3. Young 'uns and a bigger-than-life Chief Executive Officer (CEO)
4. Weak board
5. Conflicts
6. Innovation like no other
7. Goodness in some areas atoning for evil in others

There is a pattern to ethical collapse, so auditors can evaluate where your organization stands and if it is at risk.

meet their goals through interpretations or sleights of hand that then ripen into manipulations, deceptions, and, finally, fraud. Catching pressure early in an organization halts the journey into fraud.

Feeling the pressure

The most widely accepted explanation for why some people commit fraud is known as the Fraud Triangle, which was developed by criminologist Dr. Donald Cressey. The Fraud Triangle hypothesizes that if three components are present—financial need (i.e., pressure), perceived opportunity, and rationalization—a person is highly likely to pursue fraudulent activities.

Some examples since the time of the Enron, WorldCom, and Tyco collapses explained in *Seven Signs* are even more bizarre than those of that era. Silicon Valley is infamous for living by the phrase, "Fake it until you make it." That is, spin financial statements and other yarns until you really do have a product and earnings.

Theranos – the pinprick complete blood analysis

Elizabeth Holmes and her skyrocketing Theranos company of the future managed to hornswoggle Walgreens, hospital systems, Rupert Murdoch, two former secretaries of state, two defense secretaries, and two former U.S. senators into investing in or serving on the board of Theranos.[1] The alleged Theranos technology promised to run complex blood analyses with just a few drops of blood. Ms. Holmes was the young, celebrated CEO of a new and alleged $9 billion company.

There was one major hurdle: No investors had ever seen the Theranos technology work. In fact, Theranos employees had not seen the technology work.[2] They were sending their collected blood samples out to third-party labs that were then represented as samples of what Theranos technology could analyze based on pinprick draws.

To add to the drama and financial strain, Theranos was paying premium prices for the third-party real analyses they obtained. The blood analysis numbers were real.[3] They just had not been done by Theranos. Pressure to simply develop the promised company product led to researchers and physicians faking results until they could produce real results.

The audit oversight for this type of trickery is physical presence. Get to the labs, the factory floor, the warehouses, and check expenses to determine if the work is being done and if the product is real. Physically check the inventory and loading docks to be sure there is real inventory (not wrapped bricks as *Seven Signs* documented with the MiniScribe fraud case). Verifying shipments, deliveries, inventory, and capital equipment, then comparing those with the paperwork, can reveal various fraud schemes.

Audit Evidence

The Public Company Accounting Oversight Board (PCAOB) Auditing Standard No. 15 provides this useful categorization of organizational financial assertions for audit oversight:

Existence or occurrence – Assets or liabilities of the organization exist at a given date, and recorded transactions have occurred during a given period.

Completeness – All transactions and accounts that should be presented are so included.

Valuation or allocation – All components have been included at appropriate amounts.

Rights and obligations – The organization holds or controls rights to assets, and liabilities represent obligations at a given date.

Presentation and disclosure – All components are properly classified, described, and disclosed.

[1] Jennifer Reingold, "Theranos Board: Plenty of Connections. Little Relevant Experience," *Fortune*, October 15, 2015, https://fortune.com/2015/10/15/theranos-board-leadership/ (subscription required).
[2] Heather Somerville, "Ex-Theranos Chemist Says CEO Knew of Test Issues," *Wall Street Journal*, September 18-19, 2021, p. B3.
[3] Sara Randazzo, "Theranos Jury Hears of Shortcuts," *Wall Street Journal*, October 20, 2021, p. B2.

Nikola – The really fast EV truck (on hills)

Electric vehicle (EV) startup Nikola had an alleged electric truck. Like Theranos, no one had really seen the truck trucking along.

Facing the pressure from investors and the market to show progress on its electric big rigs, Nikola released a video that showed one of the Nikola trucks hurtling down the interstate at a rapid clip. The video had been doctored. The truck was simply sent downhill—there was no engine in the truck in the video. Another "fake it until you make it" ploy. Viewers were watching a chassis fly downhill.[4]

A short seller broke the story.[5] If a small investor can uncover the truth, auditors with access to organizational operations should be able to spot this gap in performance.

Atlanta Public School System – Pressure to meet performance metrics

If there was no product development pressure, there were performance measures (i.e., goals for employees). For example, the Atlanta Public School (APS) system needed the test scores of their students to improve. They set goals for the scores each year, along with bonuses for reaching those goals.

The result was a 10-year astonishing climb in APS test scores. Between 2002 and 2009, math test scores for eighth graders rose 14 points—the greatest increase in any urban school in the United States.[6] APS was recognized and lauded nationally for its achievement of excellence.

The only problem was that the rising scores did not come from achievement. Teachers began by teaching to the test, but that strategy proved ineffective because it still demanded learning by the students—something APS had never quite achieved. Indeed, that was the root cause of the poor scores.

Thus came the strategy of cheating. Mild cheating included teachers walking around during the testing and encouraging students to change their answers. Some teachers returned the tests to the students to have them change answers.

As the test scores improved, the challenge became how to get higher scores to meet the new annual goals when the results were not real. They needed more cheating to get higher scores.

This academic issue was akin to inflated earnings reporting. Once organizations start, they cannot stop because the inflated earnings are not real. The ultimate cheating process came when teachers and administrators met at one of their homes, put on gloves, and changed test answers. Erasure rates identified by the eventual investigations were off the charts. Pressure dismisses all rational thinking.[7]

Boeing – The need for the 737 MAX

In some situations, the pressure comes from the need to keep up with the competition. Airbus and its A320 aircraft had become the choice of airlines for longer flights that could carry more passengers. Boeing's 737 aircraft, with its lower passenger numbers and smaller fuel capacity, was losing market share. The design of a new plane meant long development and approval times, as well as the cost of providing training for the pilots on a new aircraft. Boeing opted to redesign its 737 into the 737 MAX.

The redesign affected the plane's angle of attack, and economized production costs resulted in fewer warning sensors. Throughout production, the release of employee emails and Slack messages indicated their concerns about safety, design, and production quality.

Those concerns were either not shared up the line with executives or were ignored. But the plane squeaked through the FAA approval process and was flying throughout the world. Two back-to-back crashes killed all aboard the 737

Pressure to develop the product led to researchers and physicians faking results until they could produce real results.

[4] Ben Foldy and Micah Maindenberg, "SEC Studies Claim of Sales Deception by Truck Startup," *Wall Street Journal*, March 18, 2021, p. B3.

[5] Bernhard Warner, "A Whistle-Blower Turned Activist Short-Seller Gets His Day in Court," *New York Times*, October 24, 2022, p. B2.

[6] Kim Severson, "Systematic Cheating Is Found in Atlanta's School System," *New York Times*, June 5, 2011. https://www.nytimes.com/2011/07/06/education/06atlanta.html (subscription required).

[7] Governor's Report, CRCT (Criterion Referenced Competency Test) Investigation (hereinafter CRCT Report), April 2011, vol. 1. See page 6 at https://www.researchgate.net/ publication/305903343_Under_Pressure_in_Atlanta_School_Accountability_and_Special_Education_Practices_During_the_Cheating_Scandal

Do the numbers seem too good to be true?

MAX jets. Faulty sensor data and the angle of attack issues led to uncontrollable nosedives.[8]

Time, cost, and production pressures created a series of bad decisions, such as when the chief pilot struggled on the simulator to correct the downward thrust, but production simply continued without addressing the risk.[9] The result was Boeing and the FAA grounding all 737 MAX planes for nearly two years and a deferred prosecution agreement that was in the making for five years as civil liability claims and other Boeing mishaps emerged.

Audit tools for Sign #1

This is where auditing by walking around comes in handy. Inspect products for existence, quality, and performance. Perform physical checks on inventory and shipments. Review data on terminations of employees. Check with human resources and compliance on the types of issues reported. Do the numbers seem too good to be true? Compare performance with industry metrics.

Don't let history repeat itself (again)

I'm not Nostradamus; I've simply studied business history and found the common factors that contribute to ethical collapse. Step back and do a candid evaluation of where your organization is. Once you identify a sign, use the suggested tools and your audit know-how to address it as quickly and completely as you can. **NP**

Profiled Organizations

In this four-part series, we'll consider the ethical and financial collapse of:

- Atlanta Public School system (APS)
- Boeing
- BP p.l.c. (formerly British Petroleum)
- Columbia University Medical School and New York Presbyterian Hospital
- FTX
- Madoff Investment Securities, LLC
- Nikola
- Theranos
- Wells Fargo
- WeWork

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[8] Chris Woodyard, "Boeing Lacked Backup for Max," *USA Today*," April 8, 2019, p. 1A.
[9] Andy Pasztor and Andrew Tangel, "Ex-Boeing Pilot Cited MAX Pressure," *Wall Street Journal*, October 24, 2019, p. B4.

OPINION

A Quiet Defense of Health Plans

Speaking up from the inside

By Tom Shankle

Editor's note: Tom Shankle understands the public's frustration with "the expensive and hard-to-navigate system that the average American is forced to face daily." But he also understands the dedication of health plan employees and the complexity of their industry. He's sharing his opinion with the hope of reframing the conversation.

Public frustration with the exploding cost and perceived cruelty of the U.S. healthcare system, particularly insurance companies, has spilled over into threats and violence. The shift reflects a broader erosion of trust in health insurers, driven largely by missing context, inaccurate projections of how we got here, and insurers' perceived inability to defend themselves publicly.

The perspective no one hears

I've had the privilege throughout my career of working with more than 100 unique health plans across quality improvement, risk adjustment, finance, product, clinical services, payment and revenue integrity, and care/case/utilization management. I also spent several years consulting and have represented a wide range of vendor solutions. Am I likely a bit biased in my admittedly narrow point of view? Certainly, and that connects to a point I make later.

At the same time, I've worked closely with countless health systems and provider groups, and I've watched each regulatory cycle shape the industry over the years. I understand, in a very real way, the frustrations felt across every corner of our healthcare ecosystem.

What's been churning inside me is a recurring, often unspoken theme: many people inside health plans are hesitant, or feel unable, to publicly defend themselves, even when the criticism is lacking context or simply incorrect. Have some plans deserved criticism? Absolutely. Have some been held accountable and forced the industry to change as a whole? Without question. Do providers have valid rationale to be immensely frustrated with payers? Yes. But framing payers as the singular villain in U.S. healthcare is not only inaccurate, it's immeasurably counterproductive.

Seeing the system through one lens leads to misunderstanding

Patients often blame "the system" without visibility into how it actually works. Providers often see payers as a massive source of friction, and in many situations, that frustration can be 100 percent valid.

But here's what's frequently missed and misunderstood: Health plan operations are largely dictated by continually and rapidly evolving regulations; it is not just some excuse. They are explicitly told what to measure, how to operate, and when to change. These regulatory shifts often come late, with little implementation runway, creating cascading issues that frustrate providers and patients alike.

Meanwhile, plans carry the weight of this collective frustration, with little ability to respond. Some payers attempt to lean on associations to get their voice out there; however, their lawyers and public relations (PR) teams sanitize their messaging until they almost lose the intended meaning.

Public comment periods for proposed regulatory changes often go unleveraged. It's concerning that only a small percentage of plans respond to requests for information or submit comments during public comment periods

I understand, in a very real way, the frustrations felt across every corner of our healthcare ecosystem.

Patients often blame "the system" without visibility into how it actually works.

for proposed regulatory changes. We need to step up, represent our teams, our organizations, and our point of view. And so, the narrative, in my opinion and observation, remains immensely one-sided.

The public perception problem

Clickbait headlines paint insurers as profit machines driven by malice, despite the reality that most plans operate on razor-thin margins, around or below 1 percent. My own family members send me headlines about "Billion Dollar Earnings!!" citing, "This is what is wrong with our healthcare system!"

My attempt to explain that those earnings overwhelmingly fund care, benefits, and medical expenses falls on deaf ears. Trying to convey that strong Medicare Advantage performance directly translates into a greater ability to reinvest in members is surprisingly difficult to explain even to people in our industry. People just can't wrap their heads around it, and with the non-stop drumbeat of *"Insurance BAD…"* the reaction you get is almost always frustrated, cross-eyed disbelief. If health insurance were the wildly profitable industry it's portrayed to be, capital markets would have piled in long ago across the board. It is simply not the case.

The public watches premiums skyrocket every year and assumes the answer is simply "Insurance BAD…" A recent example of this is the Affordable Care Act subsidy chaos. Both sides of the aisle played a clear and accountable role.

The gridlock in Washington left actuaries and plan leaders in an impossible position. They had to submit bids with massive question marks in their actuarial tables, not knowing whether subsidies would even exist. Were they supposed to price optimistically and risk going under a year later if the subsidies didn't come through? Do actuaries even have optimism in their dictionary? Many close provider friends of mine were telling me, "Payers should have just done the right thing and kept premiums flat and absorbed those losses... we all know there is plenty there to stay afloat."

The uncertainty inevitably drove steep premium hikes and reduced benefits. We have people's lives at stake. Yet again, payers were left holding the bag, painted as the villain of Gotham City, took all the blame, and did it quietly.

Again, some payer practices deserve scrutiny. We have seen plans misstep and teach the rest of the industry what to avoid operationally. But the overwhelming majority of plans operate compliantly and proudly, and they do the right thing when they can. Meanwhile, all plans get inaccurately lumped together as the collective "problem."

For those considering how internal audit can positively impact health plans, explore these *New Perspectives* articles for practical guidance.

- Health Plan Member Experience: Review Critical Functions and Initiatives (Volume 44, Number 3)
- Critical Pathways to Healthcare Information: Lock Down the Virtual Trails Leading to Your System's Data (Volume 44, Number 2)
- From Risk to Resilience: Navigate Workplace Violence Internal Audits (Volume 43, Number 3)
- Underwriting: Audit a Risky Health Plan Activity (Volume 42, Number 6)

The human side no one talks about

For 14 years, I've worked alongside people inside health plans, friends and colleagues who genuinely want to reduce

friction, improve outcomes, and help their members live healthier lives. Many are former clinicians and nurses who became burned out at the bedside and provider setting.

The system itself was built layer by layer through policy cycles, regulations, and political compromises. The layers were derived from human emotions and human decision-making cycles, which have exacerbated most of today's complexity. That complexity is then perceived as "payers are the problem." Policymakers had phenomenal intentions and were honestly doing their best; however, outcomes have been mixed. But, again, payers take the blame. And almost no one tells their story, and I keep asking myself, "Why am I constantly seeing only one side of this?"

Why silence?

Health plan leaders are understandably constrained by PR, job security considerations, and a belief, often proven true, that defending themselves publicly only backfires. So, they keep their heads down, absorb criticism, and quietly continue trying to move mountains while navigating constant regulatory upheaval. Shoot, I re-wrote this seven times with identical concerns, and I don't even work for a plan!

Meanwhile, an uncomfortable truth: We once had 3,000+ health plans a few decades ago. Now only a few hundred remain on my subscribed payer data list. Many closed because they couldn't keep up with operational and regulatory demands. They were financially forced into short sales: "BREAKING NEWS: X Health Plan Merges with Y Health Plan." This would be a really interesting case study. I have searched and haven't found anything related to assessing the payer market's mergers and acquisitions consolidation causality.

Health plans operate on a razor's edge. Most lack the advantage of owning pharmacy benefit managers (PBMs), physician groups, or diversified assets that can absorb losses. And even among the few that do have those capabilities, I still struggle to see any compelling rationale for why they would be targeted for simply performing well, compliantly, and within a system that is fundamentally designed to reward those precise outcomes. Most survive or die based on a margin so small it's measured in tenths of a percent. Yet they're portrayed as unstoppable giants plaguing the entire industry.

Editor's note

Inconsistent definitions and classifications of health plans (e.g., commercial, Medicare Advantage, self-insured, individual, group, etc.), variation in payer data categorization, and complex parent–subsidiary relationships make it difficult to reliably quantify the number of health plans in the United States.

In addition to the establishment of Medicare and Medicaid in the 1960s, more than 700 companies offered commercial health insurance plans. The recognition of health maintenance organizations (HMOs) in the 1970s further expanded the market, with at least 550 HMOs operating by 1991. Since 2000, however, the industry has undergone significant consolidation. Mergers and acquisitions, increased vertical integration with providers, pharmacies, and pharmacy benefit managers, and greater market specialization have reduced competition.

Although the National Association of Insurance Commissioners' 2024 Annual Results report 1,155 insurers filing health statements, many operate as subsidiaries of larger parent organizations. In 2024, the Government Accountability Office found that in at least 35 states, three or fewer insurers account for 80 percent or more of the individual and employer group markets. Nationally, the ten largest health insurers control 72 percent of the commercial market.

Everyone's personal lens is powerful, but can miss the complete context

Consider the following hypothetical but commonplace example.

- Patient John Smith was just notified of a denied claim after he recently saw a new specialty provider, so he feels abandoned.

It's concerning that only a small percentage of plans respond to requests for information during public comment periods for proposed regulatory changes.

I'm incredibly hopeful because positive changes are emerging.

- Specialist Dr. Jones sees new Patient Smith but then a prior authorization denial comes through, so he feels blocked and frustrated.
- The payer is missing Dr. Jones' clinical notes from the encounter and only sees Patient Smith's longitudinal five-year clinical history. The payer does not identify adequate documentation for the specialist referral or services, so they deny the claim. The health plan feels they've implemented a selective, efficient, compliant, and imperative operational strategy. They see the service authorization process as a precaution to prevent patient harm to their plan member.

All three experiences are valid. All three are highly emotional. All three lack the full picture.

Where my optimism comes from

Despite all of this, I'm incredibly hopeful because positive changes are emerging.

Interoperability is finally becoming real

By January 1, 2027, impacted payers and providers must be able to receive a Fast Healthcare Interoperability Resources (FHIR)® request and send back clinical data.

> **Are you ready for the CMS Interoperability and Prior Authorization final rule?**
>
> The final rule seeks to reduce patient, provider, and payer burden by streamlining prior authorization processes and moving the industry toward electronic prior authorization. Impacted payers were required to implement nontechnical provisions by January 1, 2026, and are required to meet the application programming interface development and enhancement requirements by January 1, 2027. Providers are being encouraged to adopt electronic authorization processes through a new measure in the final rule for eligible clinicians under the Promoting Interoperability performance category of the Merit-based Incentive Payment System (MIPS). The new rule also applies to eligible hospitals and critical access hospitals, under the Medicare Promoting Interoperability Program.

This is transformative. Clinical data black holes—the root of mistrust—are shrinking. With better data, trust can be rebuilt. And with trust, the payer–provider relationship can shift from adversarial back to collaborative. Believe it or not, that's the way it used to be.

A more prospective health system

With real-time clinical insight, patient John Smith and Dr. Jones' experience will be radically different. Dr. Jones will be presented, one week ahead of the scheduled encounter, with a full two-year look-back patient summary. As documentation occurs through the encounter, it will accompany the authorization request in real time with a single click, the payer will have near real-time access to the recent encounter data and will be able to automate the authorization. We can, should, and will reduce and eliminate the prior authorization frustrations.

Another story that I constantly think about is this: Last year, I listened in-person as the Chief Medical Officer (CMO) of the VA discussed a heart-pounding scenario of a veteran engaging with a police officer on the side of the road. The veteran is presenting with clear and defined suicidal ideations. The officer just wants to help the man, but the man is standoffish and the situation is escalating.

Thanks to the VA's sizable early investment and commitment to be active and operational on the Trusted Exchange Framework and Common Agreement's (TEFCA) FHIR network, the police officer can have dispatch call the local hospital, which is then able to immediately ping the VA's FHIR-based network. The hospital can validate that the man is a veteran, confirm he has two weeks of covered inpatient care, confirm there is no cost to the veteran, and coordinate the veteran's care with the VA. Data black holes are evaporating. I have never been more excited to see this change ripple through our healthcare system. It is here.

We can also reduce the overwhelming dependency on retrospective revenue reconciliation battles and move toward a more concurrent, patient-centered model with this operational evolution. We can get providers back to spending more time connecting with patients and improving their clinical outcomes.

Artificial Intelligence is accelerating this shift, and we are seeing this occur in real-time. However, virtually no one is publicizing these advancements. "If it bleeds, it leads" is a horrible measure by which to determine what's newsworthy. We need to combat that negativity with optimism and excitement, and steer this industry in the right direction, rather than operating quietly in our silos. We are losing the battle. And by losing, I mean the American public is beyond frustrated. It's on us—payers, providers, and the whole supporting ecosystem—to better collaborate.

Consumer empowerment and policy momentum

Price transparency, surprise billing rules, PBM reform, and evolving drug pricing policy are empowering consumers like never before. It is promising to see! At the same time, consumers are taking far more ownership of their health. Digital tools, connected devices, and reputable educational resources are helping people better understand complex clinical nuances and make better-informed decisions.

I have senior family members, truly as tech-averse as they come—they actually holster a giant magnifying glass on their belt to be able read their iPhone—who are now independently using continuous glucose monitors (CGMs). They're tracking, assessing, and internalizing how their daily choices directly affect their cardiometabolic health. That data is being sent from the CGM device to the plan and to the provider who has integrated that information into the ongoing care management plan.

At Thanksgiving, they were proudly showing everyone and talking about how their Medicare Advantage plan was instrumental in getting the device, training them to use it, and then taking the training wheels off so they could self-manage in the future. This is raw empowerment, versus prescribing a medication and saying good luck (which was their experience initially).

If you had polled CMOs in early 2019, I don't think a single one would have predicted this level of adoption or the sheer empowerment these tools and patient/member engagement modalities would create. This matters so much more than we acknowledge.

What else can internal audit do?

Whether you work within a healthcare payer, provider, or integrated organization, internal auditors can play a meaningful role in strengthening the healthcare industry's reputation by assessing:

- price transparency
- surprise billing
- claims processing, denials, and appeals
- authorization and pre-certification
- delegated services, including third-party administrators and PBMs
- case management and utilization review
- cybersecurity

Progress won't come from villainizing

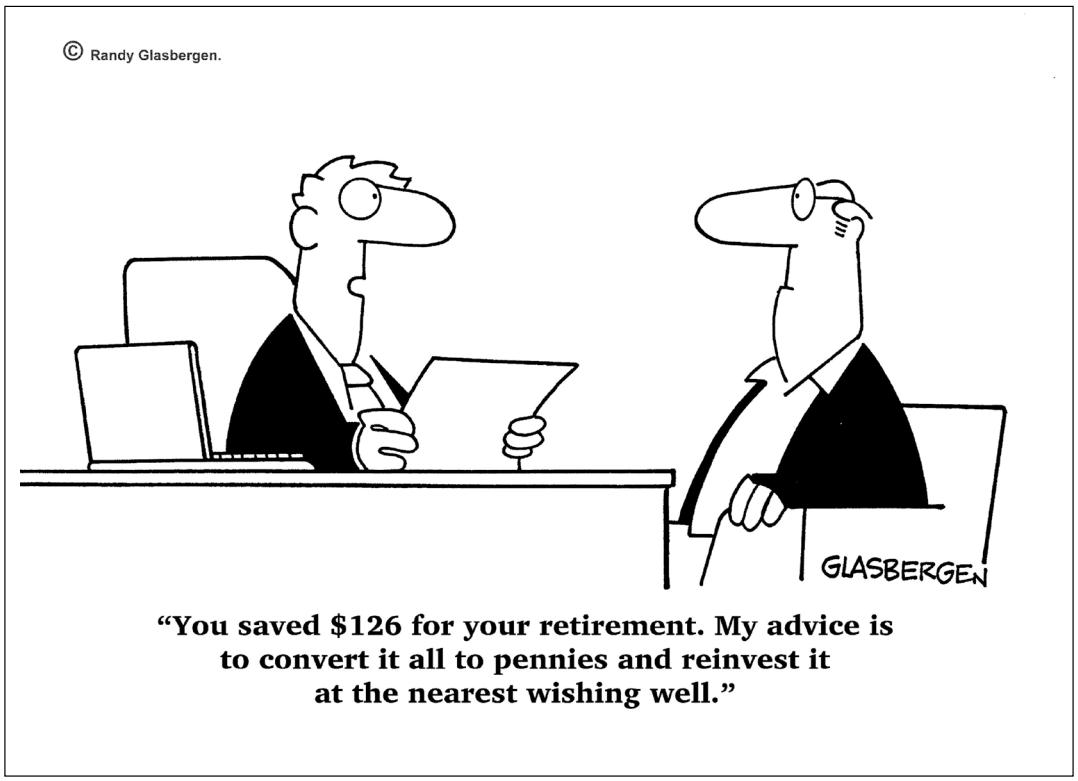
Improving healthcare requires:

- Understanding constraints
- Appreciating perspectives not your own
- Aligning incentives
- Recognizing that most people—payers, providers, and policymakers—are genuinely trying to do the right thing with the system they inherited.

We need to get back to the old days of payer/provider collaboration versus provocation. For too long, I've watched the one-sided swirl of negativity. I felt someone should say this out loud. **NP**

Tom Shankle is Vice President of Strategy and Success, Virtix Health. He leads his team to modernize health plan and provider operations to improve health outcomes. He leverages his 15+ years of experience in HEDIS, risk adjustment, clinical services, and consulting to guide plans and providers through the ever-evolving complexities of managed care. He is a husband, father, and on the American Diabetes Association Leadership board. You can find Tom's LinkedIn Profile at https://www.linkedin.com/in/tomshanklejr/

Consumers are taking far more ownership of their health.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to convert it all to pennies and reinvest it
at the nearest wishing well."

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