Report on Medicare Compliance

Volume 35, Number 13 • April 6, 2026

Weekly News and Compliance Strategies on Federal Regulations, Enforcement Actions and Audits

Contents

Page 3
Checklist to Help Assess Compliance With the Controlled Substances Act

Page 4
Oz to Fraudsters: 'We're Coming for You'; Hospice Cases, Policy Announced

Page 5
Revocation List Is New Screening Tool; Beware Enrollment Crackdown

Page 6
Response to Audit Findings May Be More Effective With Change in 'Mindset'

Page 7
CMS Transmittals and *Federal Register* Regulations, March 27-April 2, 2026

Page 8
News Briefs

Managing Editor
Nina Youngstrom
nina.youngstrom@hcca-info.org

Copy Editor
Jack Hittinger
jack.hittinger@hcca-info.org

Sutter Health Agrees to Pay $3.2M Over Alleged CSA Violations; Drug Waste Is a Vulnerability

It was the December 2020 death of a pediatric anesthesiologist at Sutter Medical Center, Sacramento (SMCS) in California that sparked a Drug Enforcement Administration (DEA) investigation of its compliance with the Controlled Substances Act (CSA). More than five years later, SMCS and Sutter Fairfield Surgery Center have agreed to pay $3.2 million to settle allegations they violated the CSA 628 times, allegedly dropping the ball with recordkeeping and other measures to prevent diversion of controlled substances, the U.S. Attorney's Office for the Eastern District of California said March 24.[1]

The settlement is a reminder of the risks that DEA registrants, such as hospitals and pharmacies, face with respect to documentation requirements, controls and procedures designed to prevent and detect drug diversion. Without attention to the processes, they could run afoul of the CSA and invite a DEA investigation, and some states have even stricter requirements, said Luke Overmire, owner of Diversion Specialists LLC. It's not just a question of paperwork. Drug diversion poses a risk to everyone in the health system, including patients, staff and providers.

Death Probably Will Result in Review

"In cases where there's a death associated, there almost certainly will be an external review," Overmire said.

According to the *Sacramento Bee*, the Sacramento County Coroner's Office said the anesthesiologist's death was ruled accidental.[2] The obituary of the anesthesiologist stated she was a member of the Central Anesthesia Service Exchange Medical Group in Sacramento and treated patients at Sutter Medical Center.[3]

SMCS and the surgery center didn't admit liability in the settlement. In a statement, a Sutter Health spokesperson said, "Sutter Health is committed to safeguarding medications and protecting our employees and patients. We cooperated fully with the DEA's investigation and resolved the matter with no findings of wrongdoing or liability. We continue to prioritize enhanced documentation, training, and security measures, and the use of advanced technology to detect and prevent diversion." Sutter Health declined to elaborate.

DEA: CSOS Not Linked to Original Order

In January 2021 or so, DEA began investigating the pharmacy at SMCS, which is the DEA registrant, according to the settlement.[4] DEA alleged it found 360 violations of the CSA. Most of them were for neglecting to electronically link the controlled substance ordering system (CSOS) to the original order. Specifically, DEA concluded that SMCS failed to electronically archive and note the date and quantity received on electronic DEA-222 order forms between Nov. 4, 2019, and March 9, 2021. The four other alleged violations involved failure to inform DEA of theft/losses of controlled substances, which is a security violation.

DEA investigated the Sutter Fairfield Surgery Center, also a DEA registrant. DEA audited the surgery center's controlled substance records for March 9, 2016, to Dec. 18, 2019, and found 268 alleged CSA violations. Here are some of them:

- One violation for failure to report diversion.

- 135 violations for not accurately keeping records of Schedules II – V controlled substances "administered in the lawful course of professional practice."
- 22 violations for not reporting the date of receipt of controlled substances and three for not documenting the date of receipt on a DEA-222 form.
- 50 violations for failure to electronically link CSOS to the original order.
- Two security violations for not having effective controls against diversion and for not reporting theft or loss within a day of discovering it.

Hospitals and other health care organizations often misunderstand CSA requirements or lack processes to help ensure compliance, Overmire said (see box, p. 3).[5] One of them is a biennial inventory of controlled substances. "I have been to several places recently where they didn't have a record of the biennial inventory that was conducted on hand, and that's always required," he noted. Sometimes hospitals don't do an inventory at all, or they rely on an automated count from Pyxis, an automated medication dispensing cabinet. Syringes, vials, tablets—they all must be tallied. "You can't just run a report and say, 'Our electronic system says there are 20 on the shelf,'" Overmire said. "You have to physically count it." If the inventory isn't dated, DEA counts that as a violation.

'Waste Is a Huge Issue'

Drug waste is another compliance tripwire. "Waste is a huge issue," Overmire noted. "If I had to name a gateway, someone intent on diverting, waste typically is the first path they exploit." The DEA requires drug waste to be rendered irretrievable, which means its physical and/or chemical structure is altered to the point that it's unusable. Although DEA "doesn't specifically define what that means," a best practice is for organizations to use waste receptables with a solution that binds to the controlled substance to neutralize it, Overmire said. They should have controlled-substance waste receptacles and train staff on monitoring for appropriate wasting, he said.

Drug waste also must be witnessed and documented. "Organizations, such as pharmacies, hospitals, clinics, and others, who handle and dispense controlled substances are required to maintain a system for keeping records about the use and destruction of these substances in order to document the controlled substance prescribed, the amount actually used, and the leftover amount destroyed," according to an article in the journal *Cureus*.[6]

Waste may manifest in different ways. Sometimes it flows from supply chain issues. Suppose the hospital is only able to buy 4-mg vials of morphine, but patients typically get 2 mgs and an employee keeps the leftover instead of discarding it, Overmire said. Or a nurse could unilaterally waste a drug (e.g., put the syringe in the Sharps container) and then call a colleague to attest to the wasting after the fact. The colleague figures it's fine—they've been friends for years—but they shouldn't attest to the waste without seeing it firsthand. Otherwise, they're perjuring themselves in the eyes of the DEA, and it could have implications for the witness with the licensing board, Overmire explained.

Diversion Has Changed Somewhat

There's been some evolution in the mechanics of diversion, Overmire said. "I see a lot more diversion with large volumes," such as fentanyl and ketamine infusions. Pre-COVID 19, it seemed more about single doses of drugs, but software tools have led people to "change the ways in which they defeat the system," he explained. In the past five years or so, Overmire estimates that nothing was unaccounted for in 95% of drug diversion incidents he's investigated. Sometimes people are diluting fentanyl with saline, for example, or substituting Tylenol for oxycodone. But outliers are still often identified. He worked on a case where a nurse was flagged because she took four times more morphine than her peers from Pyxis. "She came in and eventually confessed to diverting morphine," Overmire said.

That's an example of why he recommends the use of data analytics in drug diversion prevention and detection programs. Although the DEA is not going

Report on Medicare Compliance (ISSN: 1094-3307) is published 45 times a year by the Health Care Compliance Association, 6462 City West Parkway, Eden Prairie, MN 55344. 888.580.8373, hcca-info.org.

Copyright © 2026 by the Society of Corporate Compliance and Ethics & Health Care Compliance Association. All rights reserved. On an occasional basis, it is okay to copy, fax or email an article from *RMC*. Unless you have HCCA's permission, it violates federal law to make copies of, fax or email an entire issue; share your subscriber password; or post newsletter content on any website or network. To obtain permission to transmit, make copies or post stories from *RMC* at no charge, please contact customer service at 888.580.8373 or service@hcca-info.org. Contact Paule Hocker at paule.hocker@corporatecompliance.org or 888.580.8373 if you'd like to review our reasonable rates for bulk or site licenses that will permit weekly redistributions of entire issues.

Report on Medicare Compliance is published with the understanding that the publisher is not engaged in rendering legal, accounting or other professional services. If legal advice or other expert assistance is required, the services of a competent professional person should be sought.

Subscriptions to *RMC* include free electronic delivery in addition to the print copy.

To order an annual subscription to **Report on Medicare Compliance** ($665 for HCCA members; $895 for nonmembers), call 888.580.8373 (major credit cards accepted) or order online at hcca-info.org.

Subscribers to this newsletter can receive 20 nonlive Continuing Education Units (CEUs) per year toward certification by the Compliance Certification Board (CCB)®. Contact CCB at 888.580.8373.

EDITORIAL ADVISORY BOARD: ***JEFFREY FITZGERALD,*** Polsinelli PC; ***EDWARD GAINES, Esq.,*** Zotec-MMP; ***DEBI HINSON,*** Compliance Content Developer, Healthstream; ***RICHARD KUSSEROW,*** President, Strategic Management Systems; ***RICHELLE MARTING, JD,*** Marting Law, LLC; ***MARK PASTIN, PhD,*** Council of Ethical Organizations; ***ANDREW RUSKIN, Esq.,*** K&L Gates; ***WENDY TROUT, CHC, CCS-P,*** Director, Corporate Compliance, WellSpan Health; ***LARRY VERNAGLIA,*** Foley & Lardner LLP; ***BOB WADE, Esq.,*** Nelson Mullins.

Checklist to Help Assess Compliance With the Controlled Substances Act

This checklist was developed by Luke Overmire, owner of Diversion Specialists LLC (see story, p. 1).[1] Contact Overmire at luke@diversionspecialists.com.

- Is there a DEA registration for each physical location where controlled substances are stored?
- If a hospital or clinician, is the DEA registrant an officer of the corporation?
- Do you have a diversion prevention, detection and response program?
  - Is there an active oversight committee?
  - Is there a diversion response team that is activated quickly for each event?
- Do you have a system-wide diversion prevention, detection and response policy?
- Do you have a system-wide controlled substance policy?
- Is there a dedicated diversion program resource (sometimes referred to as a program manger or diversion specialist)?
- Does the diversion program report to a neutral third party, such as compliance, risk or quality?
- Do you have an advanced analytics platform?
  - If yes, do you have defined policy/procedure for day to day usage to promote consistency?
- Are other ADC reports (discrepancies, overrides, etc.) being reviewed regularly?

Per federal regulations, the controlled substance records that must be maintained include:

21 CFR § 1300.01

1. Executed official order forms (DEA Form 222) or the electronic equivalent.
2. Unexecuted official order forms (DEA Form 222).
3. Power of attorney authorization to sign order forms, if applicable.
4. Receipts and/or invoices for schedules III, IV and V controlled substances.
5. Records of controlled substances distributed (i.e., sales to other registrants, returns to vendors, distributions to reverse distributors).
6. Records of dispensing/administration.
7. All inventory records of controlled substances, including the initial and biennial inventories, dated as beginning or close of business.
8. Reports of theft or significant loss (DEA Form 106), if applicable.
9. Inventory of drugs surrendered for disposal (DEA Form 41), if applicable. 21 CFR § 1304.22(c).

Endnotes

1 Nina Youngstrom, "Sutter Health Agrees to Pay $3.2M Over Alleged CSA Violations; Drug Waste Is a Vulnerability," *Report on Medicare Compliance* 35, no. 13 (April 6, 2026).

to tell organizations to use them, analytics are the gold standard, he noted. Analytics have gotten more sophisticated, with the ability to compare usage data from automated dispensing cabinets (e.g., Pyxis) to medication administration records.

Was it Diversion? Cameras Help Answer the Question

Overmire said compliance is challenging partly because "there's not a lot of clarity" around certain CSA requirements. DEA "typically will tell you something is wrong but not necessarily what to do to correct it," he said. "They expect you to have appropriate security measures, but there's widespread misunderstanding of what that means."

Overmire recommends cameras where controlled substances are stored or administered even though the footage isn't reviewed in real-time. The benefit is the footage tends to clear up any questions about possible drug diversion and usually proves nothing inappropriate happened, he said. For example, a physician may remove two syringes instead of one. While it could be fishy, the camera shows the physician set the second one aside and forgot to return it rather than taking it for his own use. "That's probably what happens 90% of the time and the other 10% implicates" the physician.

Frequent errors also pop up around DEA registration, Overmire said. Every location where controlled substances are stored must be registered. Suppose a hospital with a surgery center in another ZIP code receives drug shipments and sends them to the surgery center. "That's illegal," although DEA usually allows a single registration for connected buildings (e.g., with a bridge), he said. "But if it's down the street or in a different ZIP code," DEA requires separate registration. He recommends a separate DEA registration for every address.

Disregarding Orders Is Another Red Flag

Another warning sign of drug diversion is lack of adherence to physician orders, Overmire said. Suppose the physician orders oxycodone for the patient every four hours if the patient's pain ratings are four to six on a scale of one to 10. If the pain rating drops to three, only the prescriber has the authority to order another dose. "Some of the advanced analytics can help you with that," he said. "Otherwise, you do a manual review and you'd

know every time the person took out oxycodone, there was no pain score or it was given too soon." This is a "huge compliance issue also because" it also comes up in Joint Commission accreditation surveys and violates the Nurse Practice Act (NPA) "in every state I'm aware of. The NPAs typically require nurses to follow an order unless that have prescription privileges."

Hospitals also may push back on DEA reporting requirements, Overmire said. DEA requires organizations to report the "significant loss" or theft of a controlled substance in writing within one business day of discovery. "The safest bet is to report," even if there's room for debate about the word "significant." All diversion is considered theft.

Contact Overmire at luke@diversionspecialists.com. ✧

Endnotes

1. U.S. Department of Justice, U.S. Attorney's Office for the Eastern District of California, "Sutter Facilities Agree to Pay $3.2 Million to Resolve Alleged Controlled Substances Act Violations," news release, March 24, 2026, https://bit.ly/4sbolmK.
2. Emma Hall, "Sacramento's Sutter Health settles feds' drug violations probe at two facilities," The Sacramento Bee, March 30, 2026, https://bit.ly/4bMtrAW.
3. "Obituary for Jessie July Budzinski, M.D.," *The Union* (Grass Valley, Calif.), March 29, 2021, https://bit.ly/4v5qlzm.
4. Settlement Agreement, United States v. Sutter Valley Hosps., d/b/a Sutter Med. Ctr., Sacramento & Sutter Fairfield Surgery Ctr., LLC, (E.D. Cal. Mar. 16, 2026), https://bit.ly/4sRyt56.
5. Nina Youngstrom, "Checklist to Help Assess Compliance With the Controlled Substances Act," *Report on Medicare Compliance* 35, no. 13 (April 6, 2026).
6. Frank Breve, Jo Ann K. LeQuang, and Lisa Batastini, "Controlled Substance Waste: Concerns, Controversies, Solutions," *Cureus* 14, no. 2 (February 24, 2022), https://bit.ly/4dYhFVj.

Oz to Fraudsters: 'We're Coming for You'; Hospice Cases, Policy Announced

At an April 2 press conference announcing a health fraud takedown, CMS Administrator Mehmet Oz said in so many words that the Trump administration is mad as hell about health care fraud and not going to take it anymore.

"If you're defrauding Medicare, start running because we're coming for you," Oz said. Most of the cases in the takedown focus on hospice fraud.

"What you are witnessing is a seismic shift in how the Trump administration is going to change what was going on in the Biden administration," Oz said. On the same day, CMS proposed hospice policies that are designed to identify "potential inappropriate utilization, quality of care, and compliance concerns."[1]

The U.S. Attorney's Office for the Central District of California, which held the press conference with other Trump administration officials, announced Operation Never Say Die. To kick it off, eight people were arrested, including three nurses, a psychologist and a chiropractor, on charges they cheated Medicare and other payers out of $50 million."[2]

California hospices and other entities were targeted in the takedown. "The FBI recognizes the Southern California region as a high-risk environment for hospice-related health fraud," said Akil Davis, the assistant director in charge of the FBI's Los Angeles Field Office.

Oz asserted that one-third of the nation's 6,000 hospices are in Los Angeles County. "You should be incredulous," he said. "We are going after these folks." He put other hospices on notice if they have certain hallmarks of fraud. For example, if more than 50% of a hospice's Medicare patients are discharged alive, "you have a problem" because the hospice benefit is reserved for people with fewer than six months to live. Another red flag is hospices sharing employee license numbers.

"Nothing is more important than rooting out corruption and fraud with tax dollars," said First Assistant U.S. Attorney Bill Essayli at the press conference. He and others mentioned the whole-of-government approach to fraud enforcement. The Trump administration has created the U.S. Department of Justice Division for National Fraud Enforcement, which is tasked with enforcing federal criminal and civil laws against fraud affecting federal government programs. It's run by longtime federal prosecutor Colin McDonald, who was confirmed by the U.S. Senate March 24 as the assistant attorney general for fraud enforcement.

Oz added that fraudsters are harming people in addition to stealing money. "Human costs should not be forgotten," he noted. "If you're willing to steal money from the American people, you're willing to sacrifice their health."

Rate of Live Discharges Is Allegedly High

Here's a brief summary of some of the cases unveiled by the U.S. attorney's office:

- Lolita Beronilla Minerd, a licensed vocational nurse from Anaheim, was arrested on a charge of health care fraud. Minerd owned Topanga Hospice Care Inc. in Artesia. The hospice collected more than $8.5 million from Medicare from July 2020 to April 2025. "Through Topanga, Minerd billed Medicare for hospice services for beneficiaries who were not terminally ill," the U.S. attorney's office alleged. About 85% of its patients were discharged alive, which is almost five times the national average.
- Nita Almuete Paddit Palma, who had been previously convicted of health care fraud and was excluded from Medicare, and her husband,

Adolfo Catbagan, are charged with 11 counts in connection with operating three fraudulent hospices. Palma, who is sitting in a federal prison, allegedly ran the hospices while she was free on bond awaiting trial, the U.S. attorney's office said. "Catbagan was named as the nominal owner and CEO of the three hospices when Palma in fact owned and exercised operating control of them—despite her exclusion—so Medicare would not deny the companies' claims," the U.S. attorney's office said. The couple allegedly billed Medicare for beneficiaries who weren't terminally ill and Medicare paid them $4.2 million.

In New Rule, CMS Plans More Hospice Oversight

Meanwhile, in the 2027 proposed rule on Hospice Wage Index and Payment Rate Update and Hospice Quality Reporting Program Requirements released April 2, CMS floats measures to improve hospice program integrity. For example, CMS proposed a new scoring system, the service and spending variation index (SSVI), to compare spending and delivery metrics among hospices. The SSVI would be posted on the Care Compare website. Also, a new "consumer-friendly icon" would appear on Care Compare "to identify hospices that did not meet requirements under the Hospice Quality Reporting Program," CMS said. Another proposed measure would require hospices to give all Medicare beneficiaries the hospice election statement addendum when they choose hospice care, "providing them with increased transparency regarding non-covered items, services, and drugs." ✧

Endnotes

1 Centers for Medicare & Medicaid Services, "CMS Proposes New Transparency Measures to Strengthen Oversight of Hospice Providers," news release, April 2, 2026, https://go.cms.gov/3PFjFle.

2 U.S. Department of Justice, U.S. Attorney's Office for the Central District of California, "8 Arrested in Health Care Fraud Takedown, Including Owners of Hospices that Billed Taxpayers Millions of Dollars to Serve the 'Dying'," news release, April 2, 2026, https://bit.ly/4tktHgb.

Revocation List Is New Screening Tool; Beware Enrollment Crackdown

With a list of revoked providers and suppliers now at their disposal, health care organizations have another tool to screen physicians and other clinicians for the Medicare version of a scarlet letter. CMS for the first time is providing the public with a searchable database of providers and suppliers whose Medicare billing privileges have been revoked.[1] It's the latest source of data that factors into an organization's billing for services, along with Medicare's opt-out list and the HHS Office of Inspector General's List of Excluded Individuals and Entities (LEIE), among other resources, and advances CMS's use of enrollment as a form of enforcement.

"Having this transparency is really helpful," said attorney Judy Waltz, with Foley & Lardner LLP. "This ultimately should be a credentialing tool in the same way the exclusion list is." Whether a provider is in CMS's good graces also affects their ability to participate with Medicare Advantage because the revocation can trigger preclusion and with commercial payers that use Medicare enrollment in credentialing, Waltz explained.

"As time has gone on, there's more information and more access to information in electronic formats," said Christa Bernacchia, principal and director of credentialing services at BerryDunn. She recommends hospitals and other health care organizations check the opt-out list.[2] "You may have a provider not necessarily barred from Medicare, but who doesn't want to participate in the program. That means you can't bill for their services."

At the same time, the use of Medicare enrollment and revalidation to crack down on supposedly wayward providers can go overboard, said attorney David Glaser, with Fredrikson & Byron. "All indications are the 855 enrollment forms are some sort of new Russian roulette." CMS is essentially kicking some providers out of Medicare for relatively trivial reasons, he contends. For example, when a hospice added new medical directors but didn't update its 855 enrollment form accordingly, its Medicare administrative contractor (MAC) proposed a 10-year revocation and said the hospice isn't entitled to two years of reimbursement covering the time when the new medical directors came on board the hospice but weren't added to the 855.

"It's crazy," Glaser said. "It's important to recognize that not all enforcement" flows from the False Claims Act and the U.S. Department of Justice. Retroactively disenrolling a provider "is not an FCA thing but feels like it."

Do Hospitals Know About All Tools?

Although more screening tools are available, they're not necessarily in use, Bernacchia said. With the revocation list, for example, "I would venture a lot of organizations don't even know it's there," she said. More awareness will help them vet employees and avoid reimbursement losses. "The number of people being put on these lists is growing, and the information is only as good as the frequency of the data being looked at," Bernacchia said. For example, a hospital could take a big hit if it finds a provider on the revocation, exclusion or other screening list a year in. The lists are updated "at different cadences, so it could be onerous" to stay on top of them all. About 7,500 providers and suppliers are in the searchable revocation database, but it's

unclear how often the revocation list will be updated, Bernacchia noted.

A safe bet is for organizations to check it every month or so. "It has some pretty detailed information," including the National Provider Identifier of the revoked providers, the reason they were revoked and how long the revocation will last, Bernacchia said.

The list of revocations should help hospitals and other organizations identify providers whose Medicare billing numbers were taken away before or after hiring them. Revocation hurts their ability to get hospital privileges because hospitals expect clinicians to be in good standing with Medicare, "and some hospital bylaws expressly require that," Waltz said. "After the date of the revocation, which may be retroactive, CMS won't pay the revoked practitioner." CMS and its contractors may refuse payment to the related hospital as well.

CMS has taken other steps to protect Medicare from what it considers bad apples. In February, CMS shut Medicare's door to new durable medical equipment (DME) suppliers nationally for six months as part of the Trump administration's "major crackdown on health care fraud."[3]

Other health care certification and accreditation bodies, such as the National Committee for Quality Assurance (NCQA), are "sharpening their focus" on screening providers, Bernacchia said. NCQA implemented a sweeping update to standards and guidelines in 2025, "and put additional emphasis on organizations to look at the exclusion list and make sure their providers were continuously screened" through the LEIE, SAM.gov for government debarments, state Medicaid agency suspensions, and licensing sanctions, she said.

Corrective Action Not Always on the Table

Providers may be able to fend off revocations with a corrective action plan (CAP). When MACs inform providers they're facing revocation of their Medicare billing privileges, they have historically offered two options: appeal if they think the MAC misunderstood the circumstances that led to the revocation, or if that wasn't the case, offer a plan of correction, Glaser said March 23 on the RACmonitor.com webcast. But CAPs are now very limited because of a 2014 regulatory change, Waltz noted.[4]

In a letter Glaser reviewed in mid-March that was sent to the hospice facing revocation, the MAC didn't offer a CAP. "This is an enormous problem," Glaser noted. "The plan of correction has been the tool that prevents minor administrative mistakes from resulting in the Medicare death penalty." The MAC did approve a CAP, however, for another client, a DME supplier, that failed to fingerprint an owner. And the MAC allowed a physician clinic to revalidate after it overlooked the revalidation notification and missed the deadline, but the clinic is losing eight weeks' worth of reimbursement.

CMS narrowed the scope of CAPs in the 2014 regulation "to something relatively minor," Waltz noted. "CAPs are only available for noncompliance (as set forth in (a)(1). It won't be available for the other grounds for revocation," such as providing false or misleading information, misuse of a billing number or failure to report. "The deficiencies contemplated by (a)(1) would be things that can be readily fixed," such as a license that expired because the provider forgot to renew or other conduct "that doesn't pose a risk to the program or its beneficiaries," Waltz explained.

Glaser suggests providers and suppliers review their enrollment forms very carefully. "It's super easy to forget to submit corrections," Glaser noted. For example, at a clinic with fewer than 20 physician shareholders, "every buy-in or buyout will trigger the need to update enrollment" because that's a Medicare requirement for a 5% change in ownership. CMS requires providers and suppliers to update enrollment forms for other reasons, including the opening or closing of a new location.

Contact Bernacchia at cbernacchia@berrydunn.com, Glaser at dglaser@fredlaw.com and Waltz at JWaltz@foley.com. ✧

Endnotes

1 Centers for Medicare & Medicaid Services, "Search Results for 'Revoked Medicare Providers and Suppliers'," accessed March 13, 2026, https://bit.ly/47u3J1i.

2 Centers for Medicare & Medicaid Services, "Provider Opt-Out Affidavits Look-Up Tool," CMS Data, accessed April 2, 2026, https://bit.ly/4bXoXpL.

3 Centers for Medicare & Medicaid Services, "Trump Administration Prioritizes Affordability by Announcing Major Crackdown on Health Care Fraud," news release, February 25, 2026, https://go.cms.gov/4aYNiv2.

4 Medicare Program; Requirements for the Medicare Incentive Reward Program and Provider Enrollment , 79 Fed. Reg. 72,500 (Dec. 5, 2014), https://bit.ly/4dspJxs.

Response to Audit Findings May Be More Effective With Change in 'Mindset'

An organization's response to unfavorable audit findings will change for the better with a shift in the compliance team's "mindset." Instead of pointing fingers at a person as the cause of a failure, organizations should move to revamping systems that set the stage for a failure, according to a compliance auditor.

When audit findings are unfavorable, organizations tend to focus on three questions: who made the mistake, how fast it can be fixed and how soon they can schedule training. That may seem like organizations are taking

action to fix a problem, but corrective actions won't be effective without a root cause analysis, said Monteal Martin, a compliance auditor at Grady Health System in Atlanta, Georgia.

"This shift starts when you stop asking who made the error and start asking what produced this outcome. That single shift changes everything," Martin said at a March 31 HCCA webinar. If compliance departments focus on blaming individuals, they miss what's broken about the system, process, workflow, policy and/or protocols. "People operate within conditions they don't design. If those conditions stay the same regardless of who made those mistakes, it's the system that needs to be fixed. That's why focusing on people doesn't create lasting change."

The root cause of an error also will be uncovered faster when employees "are able to express themselves openly and freely without fear," Martin said. "Let them talk about pressures they're under, overcomplicated processes and potentially missing the feedback loop where communication is not happening the way it's supposed to."

The go-to response to errors often is more training, Martin said. But is it necessary? Maybe no one questioned whether knowledge gaps were driving the errors. "Education is very important, but if it's a workflow or staffing issue, education may not necessarily fix that."

Ramping up training is part of a pattern of ineffective outcomes from audit findings. Another pattern is skipping the root cause analysis or doing a partial one. "The symptom gets treated with a Band-Aid, but the underlying issue continues and hasn't been resolved, so the same errors keep showing up," Martin said.

A third pattern is failing to monitor improvements. The box is checked for a corrective action plan, "but nothing confirms the behavior has actually changed," said Martin, who is also a principal consultant with Insight Coding & Compliance Partners. "That is the gap between appearing compliant and being compliant."

Martin described her five-step approach to a root cause analysis:

- Gather all pertinent data (e.g., facts, patterns and context), she said. For example, if the risk has been audited before, review the findings and "resist the urge to jump to a conclusion."
- Identify the driver. Distinguish the symptoms of a problem from systemic contributors. "Keep asking questions until you get to the root reason for errors," Martin suggested.
- Validate the cause of the problem. "This is where organizations skip ahead and get in trouble."
- Develop a solution that fits perfectly with the validated driver (i.e., the actual cause of the problem).
- Assign one person as the owner of the outcomes rather than a team or a department.

"A corrective action plan is only as strong as the root cause analysis behind it," she noted.

Assessing the Level of Risk, Readiness

When the problem is confirmed in an audit, Martin suggests considering the implications of each finding in five dimensions:

- Regulatory exposure because "findings flagged by CMS, OIG or payers require immediate prioritization."

CMS Transmittals and *Federal Register* Regulations, March 27-April 2, 2026

Transmittals

Pub. 100-04, Medicare Claims Processing

- Update to the Internet Only Manual (IOM) Publication 100-04, Chapter 18, Section 170.1 and Chapter 32, sections 330.1 and 330.2 for Updates in Change Request (CR) 14356 - International Classification of Diseases, 10th Revision (ICD-10) and Other Coding Revisions to National Coverage Determinations (NCDs)-July 2026, Trans. 13,709 (April 2, 2026)
- April 2026 Integrated Outpatient Code Editor (I/OCE) Specifications Version 27.1, Trans. 13,715 (April 2, 2026)
- Update to the Internet Only Manual (IOM) Publication (Pub.) 100-04, Chapter 32, Section 10.1 Incorporating Manual Updates from Change Request (CR) 11650 - National Coverage Determination (NCD) 20.19 Ambulatory Blood Pressure Monitoring (ABPM) and CR 12376 – Revisions to Chapters 13, 18 and 32 To Update Coding, Trans. 13,700 (March 27, 2026)
- April 2026 Update of the Hospital Outpatient Prospective Payment System (OPPS), Trans. 13,702 (March 27, 2026)

Pub. 100-20, One-Time Notification

- Medicare Administrative Contractors (MACs) Part B, the Multi-Carrier System (MCS) and Durable Medicare Equipment (DME) MACs Updates on Processing Medicare Secondary Payer (MSP) Claims Containing Certain Claim Adjustment Reason Codes (CARCs), Trans. 13,706 (March 31, 2026)
- Extensions of Certain Temporary Changes to the Low-Volume Hospital Payment Adjustment and the Medicare-Dependent Hospital (MDH) Program under the Inpatient Prospective Payment System (IPPS) Provided by the Consolidated Appropriations Act, 2026, Trans. 13,703 (March 27, 2026)

Pub. 100-06, Medicare Financial Management

- Creation of the 'PROVIDER-TERMINATED' Status at the Provider/Customer Level on the Healthcare Integrated General Ledger Accounting System (HIGLAS) Customer Status History Form, Trans. 13,708 (April 2, 2026)

Federal Register

Notice; request for information and comments

- Advancing the Use of Digital Health Technologies in Clinical Investigations for Drugs and Biological Products; Request for Information and Comments, 91 Fed. Reg. 16,006 (March 31, 2026)

Contact Paule Hocker at paule.hocker@corporatecompliance.org or 888.580.8373 to find out about our reasonable rates for individual and bulk subscriptions.

- Financial impact. "Quantify recoupment risk, denial volume and revenue cycle disruption to gauge financial materiality," she suggested.
- Patient safety. Findings that affect patient care move to the top of the list.
- Frequency. High-volume or repeat errors signal systemic drivers, not isolated incidents.
- Operational impact. Consider the downstream impact of the finding on staff workload, clinical workflows and continuity in care delivery, she said.

The organization then should perform risk and readiness assessments. That starts with assigning a risk level to the audit finding (low, medium or high) and deciding what's required to fix it, Martin said. For example, a finding is high risk if it involves unauthorized access to, or disclosure of, protected health information (PHI) that caused patient harm or a reportable event. It should be escalated ASAP and requires structural change. A low risk might be an isolated error with little financial impact, operational risk or PHI exposure that's amenable to a quick fix.

In terms of a readiness assessment, level one has a clear fix; level two requires the involvement of multiple stakeholders and process improvements; and level three calls for workflow redesign, process limitations and behavior change.

Unapproved AI Use Is High Risk

Here's an example of how risk and readiness assessments play out: A small compliance team has been strained since the COVID-19 pandemic but is expected to do the same number of investigations with fewer people. After leadership is unresponsive to a request for help, the team starts using a free cloud-based AI tool that helps them close investigations on time. "Within 30 days they are closing cases in half the time it took before," Martin said. It seems like a win, but there's a problem. No risk assessment was performed on the tool, and its use wasn't approved internally. "IT has no idea and leadership is in the dark," she said. If the organization runs the situation through the frameworks of risk and readiness, it would find the risk is high because PHI is stored on the unapproved AI tool and there's no business associate agreement governing its use.

As for readiness, Martin would rate this a level three because use of the tool "requires workflow redesigns and leadership-led change and oversight" and IT support. "So, you have a high risk and low readiness and that equals organizational risk."

Even when organizations do a good job with their root cause analysis, assign an accurate level of risk and readiness, and identify the right intervention, "execution is where things can fall apart," Martin said. That happens when, for example, there's no clear ownership and the corrective action plan falls by the wayside. "Without regular internal audits, the initial corrective active plan can be completed, but did it change anything? You won't know that unless you monitor and measure the outcomes."

Contact Martin at monteal.martin@outlook.com. ✧

NEWS BRIEFS

◆ **Trinity Hospital Holding Company has agreed to pay $1.7 million to settle allegations over improper financial relationships with two referring physicians, the U.S. Department of Justice (DOJ) said April 2.**[1] The settlement involves a Trinity hospital in Steubenville, Ohio. Trinity self-disclosed the arrangements at issue to the government. DOJ alleged that from 2014 through 2020, Trinity "made improper financial contributions to two referring physicians in the form of rental arrangements for office space. The United States alleged that these arrangements violated the Stark Law because the rental arrangements exceeded fair market value." Trinity received cooperation credit from the government because it did an internal compliance review and independent investigation, promptly took remedial action, "disclosed the relevant arrangements to the government, and cooperated with the government's investigation," DOJ said. Trinity didn't admit liability in the settlement.

◆ **Clarification:** Regarding a story in the March 30 issue of *RMC*, HHS's regulation on administrative simplification standards applies to providers that submit transactions electronically and, if health plans require transactions to be submitted electronically, they must also meet these standards. When a payer requires electronic attachment submissions, both the payer and the provider are required to use HIPAA-standardized attachment transactions by May 26, 2028, the compliance date of the rule.

Endnotes

1 U.S. Department of Justice, Office for Public Affairs, "Trinity Hospital Agrees to Pay $17M to Resolve Alleged Stark Law Violations," news release, November 21, 2019, https://bit.ly/48dTO0d.