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

Contents

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Outlook 2026

Outlook 2026: Prior Authorization, AI Take Center Stage; CMS Kills Skin Substitute LCD

With 10,000 employed physicians, Trinity Health is turning to AI this year to review the medical necessity of procedures performed by high-productivity physicians. Although it's early days, Andrei Costantino, vice president of integrity and compliance, said the hope is that AI can cover exponentially more ground than manual reviews in flagging physicians who are above the 90th percentile of utilization in their specialty.

"We are just starting to get our feet wet," Costantino said. "We want our doctors to be highly productive, but we know the government" is scrutinizing utilization. He noted that humans will be in the loop: first when medical-group presidents sign an attestation vouching for certain highly productive physicians identified by AI—sparing them an audit—and second when compliance auditors dive deeper into the others, vetting their medical records against national and local coverage determinations and payments on the Open Payments database. "We have so many doctors I'm starting with Michigan first and will move across the country," Costantino said.

Busy December Sets Stage for 2026

It's a sign of the times, with AI sticking its nose in everybody's business. CMS is also betting big on AI to improve program integrity and move away from pay and chase, and its use is escalating in prior authorization, a hot potato for 2026.

"Program integrity is a large bucket we will see HHS and CMS focusing on," said Claire Ernst, director of government relations and public policy at Hooper, Lundy & Bookman.

While people were decking the halls with boughs of holly, many things in the regulatory, audit and enforcement world were set in motion for 2026. To name a few: CMS withdrew the national version of a skin substitute local coverage determination (LCD).[1] The Drug Enforcement Administration (DEA) again extended its temporary moratorium on the in-person visit requirement for virtually prescribing controlled substances.[2] The U.S. Senate confirmed a new HHS Inspector General (IG), Thomas March Bell, who is expected to massage its mission in line with Trump administration priorities. PEPPER—the Program for Evaluating Payment Patterns Electronic Report, CMS's free compliance monitoring tool—resumed for short-term acute care hospitals after a two-year pause. A slew of new Medicare value-based payment models have been rolled out, along with the Wasteful and Inappropriate Service Reduction (WISeR) model that advances prior authorization in original Medicare.

Companion enforcement developments are under way that could shake up 2026 and beyond. Among other things, False Claims Act (FCA) cases on Medicare Advantage (MA) and kickbacks are expected to dominate and states are ramping up enforcement actions. Meanwhile, potentially watershed decisions on the FCA are percolating in the courts (see enforcement story, p. 5).

Tumult Continues With Skin Substitutes

A big surprise is CMS's about-face on its skin substitutes coverage policy. About 10 days after announcing that its national LCD would take effect Jan. 1 in seven Medicare administrative contractor jurisdictions, CMS scrapped it on Dec. 24. The LCD would have established national coverage criteria for certain wound care procedures with skin substitutes—already a hotbed of audits and enforcement actions—and limited coverage to 18 products. What happened? A CMS spokesperson told *RMC* it pulled the LCD "after carefully considering feedback from

stakeholders about the combined impact of major payment changes and coverage limitations on patient access." CMS's 2026 outpatient prospective payment system and Medicare Physician Fee Schedule rules overhauled the payment methodology for most skin substitutes after years of shelling out astronomical sums. In addition to reimbursement for the procedure, Medicare will now pay $127 per square centimeter of skin substitutes as incident-to supplies, a 90% drop from the pre-2026 payment rate.

Even though skin substitutes aren't a goldmine anymore, audits will continue. "CMS will closely monitor patient access, outcomes, and billing practices in this space in 2026," the spokesperson said.

It's not a big mystery how to navigate this area without the LCD, said attorney Stephen Bittinger, with Polsinelli. Providers who comply with the Medicare definition of medical necessity or existing LCDs—for example, they don't apply skin substitutes until exhausting more conservative treatments—should be OK. At the same time, "units of service are something to watch out for," said Jess Franzese, coding and compliance consultant at Polsinelli. "Providers need to use the minimum amount necessary to cover the wound and not slap 16 square centimeters on a two-square centimeter wound because that negates the medical necessity," she said. And forget about billing for discarded skin substitutes. In updated FAQs, CMS said it won't pay for wasted amounts of incident-to supplies.[3]

Welcome to the 'Year of Prior Authorization'

Prior authorization will advance in 2026, with new models in original Medicare for hospitals, physicians and ambulatory surgery centers. "2026 will be the year of prior authorization," said Ronald Hirsch, M.D., vice president of R1 RCM. As of Jan. 5, CMS requires providers in six states to request prior authorization of 13 procedure categories, including skin substitutes, for dates of service on or after Jan. 15. (The Dec. 23 update to the WISeR operational guide delays implementation of Percutaneous Image-Guided Lumbar Decompression for Spinal Stenosis.)[4] CMS selected six AI vendors to decide whether to grant prior authorization requests largely based on their compliance with LCDs and national coverage determinations (NCDs).

WISeR is a sign that CMS is counting on AI to "crush fraud," to use its slogan. Medicare watchdogs are "putting a lot of hope in hiring AI companies," said attorney Colette Matzzie, with Phillips & Cohen. Another is the Chili Cook-Off, a quest for AI/machine learning proposals to "detect anomalies and trends in Medicare Fee-for-Service (FFS) claims data that can be translated into novel indicators of fraud" in original Medicare claims for Part B, hospice and durable medical equipment.

But CMS's enthusiasm for AI may backfire on providers, who are dubious they'll get a fair shake from an algorithm. "I think there will be a holy war over AI prior authorizations," Bittinger said. The same applies to prior authorization required by private payers. "It's going to be a story of the haves and have-nots," he said. Health care organizations large enough to create tools that push back on prior authorization will get by, while "small providers are left in the dust."

The uncertainty of AI in this context is why providers may skip WISeR prior authorization and opt for prepayment review instead, Hirsch said. "While WISeR requires a human to review any denial, experience tells us sometimes those things just get signed off on without true review," he noted. "Hospitals have to be very careful if they receive nonaffirmed services." They should take a close look at the denials "and hold companies accountable if they're overrelying on their AI systems." Hirsch also is disturbed about what he says are promises not kept by the AI contractors, formally known as model participants. Their portals for prior authorization requests were supposed to be up and running by Jan. 5, but not all of them have materialized.

Meanwhile, many MA plans have promised to scale back prior authorization, but there's little upside for providers, said Robert Oubre, M.D., medical director of clinical documentation integrity at St. Tammany Health System. The way he sees it, providers can perform the procedure but MA plans "may deny it. It moves everything from the front end of the revenue cycle to the back end."

Audit Activity Isn't Letting Up

Audits are alive and kicking. In the original Medicare realm, there's a "huge increase" in contractor activity from unified program integrity contractors and the supplemental medical review contractor (SMRC) in particular, Costantino said. "No matter if it's Democrat or Republican," audits roll on "because the rate of return is so good." CMS is trying to move

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away from pay and chase—pursuing ill-gotten gains after the fact —and ramp up prevention. Costantino is particularly concerned about SMRC audits of post-acute care (PAC), including hospice and home health. "You could do reviews and the records could look pristine," but what's happening on the ground may be different, he noted. Some PAC employers put transponders on their employees' cars to determine whether they showed up at the patient's home, Costantino said. It's proof positive oversight may require more than verifying the paperwork. Meanwhile, home health agencies may want to think twice about sign-on bonuses for employees in the wake of an unfavorable Jan. 7 advisory opinion from the HHS Office of Inspector General (OIG).[5]

Even with the shiny new things, providers should keep their eye on compliance fundamentals, said former federal prosecutor Robert Trusiak, with Trusiak Law. "Plan the work and work the plan," he advised. "Your work plan tells a story. Is the story a work of fiction or a work of nonfiction?" In other words, work plans shouldn't just be "rote audits of the same billing activity" as the year before, Trusiak explained. "There's an infinite number of risk variables in any hospital or provider group. Let's use some imagination and move onto the next" if a particular risk area had a low error rate the previous year.

Some risk areas, however, require routine eyeballing, such as incident-to billing and medical necessity. Another is medical device credits. "We put a big fix in place, but over time it pops up again," Costantino said. The same goes for transcatheter aortic valve replacement. "You have to follow the NCD to the letter." It requires, among other things, having two surgeons at the procedure. "We are seeing that we are doing a lot better and now maybe will do audits every other year," he said.

The scope of Risk Adjustment Data Validation (RADV) audits of MA plans hangs in the balance this year. CMS announced plans last year to audit all eligible MA contracts for every payment year and speed up audits of payment years 2018 through 2024. Presumably its expectations for overpayment recoupment were high because of a 2023 RADV rule that allowed CMS to extrapolate MA overpayments for the first time, but a federal court vacated the RADV rule in a November decision, which CMS has appealed, said Brian Murphy, branding director at Norwood Solutions.[6] MA plans shouldn't get complacent: The court decision was about the rulemaking being flawed, not the substance of the law, said attorney Max Voldman, with Whistleblower Partners LLP. "RADV extrapolation is likely coming back in some way," he predicted. CMS just needs "a better notice and comment process."

A New Inspector General Is on Board

Audits, evaluations and investigations may soon have a different flavor now that Bell has taken the reins of OIG. A new IG "is an inflection point for a number of major projects OIG has been working on," said Benjamin Wallfisch, a former OIG senior counsel. "The biggest one I am keeping an eye on is the overhaul of compliance program guidance documents." OIG already updated the *General Compliance Program Guidance* in 2023 and industry-segment specific compliance program guidance (ICPG) for nursing facilities in 2024. Its plan to release more ICPGs last year didn't pan out. "This is something the new IG and his leadership team are going to need to confront because it's something the agency is committed to and put a lot of resources in," said Wallfisch, with Polsinelli.

Lisa Re, former assistant IG for legal affairs, doubts more ICPGs are coming because OIG's hands are tied by a January executive order (EO) on "Unleashing Prosperity through Deregulation."[7] The EO requires federal agencies to dump 10 regulations, including guidance, for every one that's added, said Re, with Arnold & Porter. "I don't see that calculus working for them."

But Wallfisch said the EO may not apply. "This is not a new set of requirements," he said. CPGs simply suggest ways to comply with legal obligations.

Another thing to watch is whether Bell changes OIG's strategic plans. Under former IG Christi Grimm, the three priorities in the strategic plan for 2025-2030 are MA, nursing homes and grants and contracts. "The real question will be what are his core projects," Re said. "Will they continue or will they be replaced with new or additional priorities?" For example, OIG earlier this year issued an enforcement alert on information blocking. "It is a key priority for Secretary Kennedy. I have to assume that will continue under Bell," Re said.

Also brand new: OIG may exclude individuals and entities from federal health care programs for performing gender-affirming care under an HHS Dec. 10 declaration that warns of exclusion if they don't meet "professionally recognized standards of care"—in other words, they provide what the government now calls "sex-rejecting procedures" (SRPs) to minors.[8] Re noted this is "very different than anything we have seen, but it's obviously a priority." The prospect of exclusions is up in the air, however, because 18 states filed a complaint Dec. 23 to block enforcement of the declaration, said attorney Larry Vernaglia, with Foley & Lardner LLP.[9] Among other things, the complaint alleges HHS's declaration didn't follow rulemaking procedures under Medicare and the Administrative Procedures Act.

"I think OIG will look different next year at this time, with different priorities, but the core will remain the same," Re predicted. "The bread and butter work of OIG will continue."

'Really Busy With Health Policy'

On the health policy front, "2026, like 2025, is going to be really busy with health policy," Ernst said.

For one thing, brace for another telehealth cliffhanger because the congressional extension of flexibilities expires Jan. 30. With telehealth flexibilities typically embedded in government funding bills, their fate is uncertain—although Congress is now working on a series of "mini-bus" appropriation packages. There has been action, however,

on DEA telehealth. On the day before it expired, a fourth temporary extension of COVID-19 telehealth flexibilities for prescribing controlled substances was announced for 2026. While DEA continues to consider a permanent regulatory solution, it again gave prescribing practitioners permission to prescribe Schedule II-V medications by telemedicine for another year "without having conducted an in-person medical evaluation of the patient."

Regulatory surprises are on the horizon along with new payment models. Some were previewed in a Dec. 2 letter to providers from Chris Klomp, director of the Center for Medicare at CMS.[10] Here are a few of CMS's promises for 2026, according to the letter:

- Reduce administrative burden: "CMS has begun streamlining its reporting requirements. For example, we have a goal of reducing the number of quality measures by 5% year over year."
- Reduce regulatory burden: For example, CMS is phasing out the inpatient-only (IPO) list. As of Jan. 1, 285 mostly musculoskeletal procedures are gone from the IPO list and now subject to the Two-Midnight Rule.
- Improve program integrity "through changes in payment policy and significant investment in next-gen technology to identify and eliminate fraud and abuse in real-time."
- Leverage technology "to provide revenue certainty at point-of-care and make longitudinal patient information more readily available." One example: CMS's Health Tech Ecosystem.
- Align payment and outcomes through value-based care models to make them more appealing to providers.

Final Cybersecurity Reporting Rule Is Expected

The models are coming fast and furious from the CMS Innovation Center. One example: the Advancing Chronic Care with Effective, Scalable Solutions (ACCESS) model, which offers rewards for better outcomes with high blood pressure, diabetes, chronic musculoskeletal pain and depression.

Ernst noted that providers are more likely to embrace them as an opportunity if they're voluntary. "Things like the ACCESS model could provide an opportunity to be more creative with reimbursement." But even as CMS touts administrative burden reduction, it's adding some with WISeR, she said.

Also keep an eye out for key regulations. For example, HHS said it will finalize some version of the HIPAA Security Rule update. The proposed rule requires covered entities (CEs) to up their cybersecurity game and removes the distinction between "required" and "addressable" implementation specifications, said attorney Debra Geroux, with Butzel Long.

Other cybersecurity rules are on the agenda this year. For example, the Cybersecurity and Infrastructure Security Agency (CISA) is expected to finalize regulations on the Cyber Incident Reporting for Critical Infrastructure Act of 2022, Geroux said. "It has very robust reporting requirements for covered cybersecurity incidents," she noted. CEs have 72 hours to report an incident to CISA and 24 hours to report a ransom payment to a threat actor.

Although a federal court last year voided most of the HIPAA reproductive privacy rule, some surviving requirements will take effect Feb. 16, Geroux said. For example, the Notice of Privacy Practices must incorporate language on substance use disorder confidentiality under Part 2.

More regulations are anticipated, including final versions of Dec. 18 proposed regulations on gender-affirming care that would kill Medicaid funding and empower CMS to throw providers out of Medicare and Medicaid if they perform SRPs.[11]

Rising Tensions Between Providers and Payers

Tensions will continue to rise between providers and payers. There will be "an increasing number of payer tactics to lower how much they have to pay providers," Hirsch predicts. Part of it stems from AI use. Many people see AI as "some kind of panacea," and while it's a boon in certain cases, payers use it to deny exponentially more claims, Murphy said. For example, he said a big payer in Massachusetts is using AI to "autodowncode" evaluation and management claims. If the payer sees an abundance of level fives, it knocks them down to level fours without human review, Murphy said. "There's an appeals process," but providers only have so much bandwidth to fight back. States may come to the rescue, however (e.g., the California Artificial Intelligence Transparency Act).

It's not just AI-generated denials putting people on edge. "At the forefront of everybody's mind now in the revenue cycle integrity world is denials," Oubre said. One example: Aetna's new "Level of Severity Inpatient Payment Policy" for its MA and Special Needs Plans, which creates "a new reimbursement approach for hospital stays of 1+ midnight in cases where a member is urgently or emergently admitted to a hospital and the provider has submitted an inpatient order." Aetna will "approve the inpatient stay without a medical necessity review and pay the claim at a lower level of severity rate that's comparable to your rate for observation services." Some physician advisors think the policy violates the spirit, if not the law, of the Two-Midnight Rule by presenting the change of status in payment terms only.

If MA plans skirt CMS rules, providers have an avenue for complaint that CMS updated Dec. 22. The portal is a recourse when MA plans allegedly don't comply with various requirements, including the 2024 and 2026 rules on policy and technical changes to MA. MA plans are on notice they must, among other things, comply with the Two-Midnight Rule and include concurrent services in organization determinations.

This year, ambient AI scribes, which have taken hold in the outpatient space, will "hopefully move into the inpatient space," Oubre said. That will advance conversations about what is and isn't a query and where compliance comes down on it. Hirsch, meanwhile, is worried about the increasing role of AI in producing medical documentation. "It will create compliance issues because AI hallucinates," he said. "It fills

in the blanks with what it sees as the right answer, but it may not be the right answer."

Providers also may find it helpful to review recent AI guidance from The Joint Commission and the Coalition for Healthcare AI.[12] "It's a pretty important piece to consider when designing your own guidance documents," Vernaglia said.

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Outlook 2026: Enforcers Will Strike New and Old Targets; 'Resources Are a Wild Card'

Whether the Trump administration's health fraud enforcement reach exceeds its grasp this year because of shifting priorities and staff departures at the U.S. Department of Justice (DOJ) remains to be seen. On the one hand, DOJ is expected to use a lot of its False Claims Act (FCA) bandwidth in nontraditional areas, such as diversity, equity and inclusion (DEI) practices and gender-affirming care. On the other, DOJ and HHS have revived their FCA working group and whistleblowers are a force to be reckoned with, attorneys say.

"Resources are a wild card in terms of the scope of DOJ FCA efforts moving forward," said Michael Granston, former director of DOJ's Civil Fraud Section and a 30-year DOJ veteran. Both DOJ's civil fraud section and U.S. attorneys' offices have "suffered from some attrition since January last year," when Trump 2.0 kicked off. Staff at the civil division, for example, is down more than 25%, and other DOJ components have been hit harder, said Granston, now with Covington & Burling. While he doubts the attrition will block pursuit of administration priorities, traditional health fraud enforcement targets may be affected. "They won't be able to do it all," Granston said. Fraud cases also will be hampered by less support from HHS and its Office of Inspector General (OIG), said attorney Mary Inman, with Whistleblower Partners LLP. Fewer resources translate into DOJ declining more "meritorious cases" from whistleblowers, added attorney Colette Matzzie, with Phillips & Cohen LLP. "You will see increased litigation of declined cases."

That being said, the return of the FCA working group indicates "the FCA remains a significant priority," said attorney Matt Krueger, a former U.S. attorney in Wisconsin. "DOJ has said they view the FCA as a tool to enforce various administration priorities even outside the health care realm." The working group has named its six targets, "and most of these areas are not new to FCA enforcement," Granston noted. They include Medicare Advantage (MA), kickbacks and manipulation of electronic medical records.

"There's definitely evidence the administration appears to be committed to continued enforcement in fairly traditional areas of health care fraud," Matzzie said. "A record number of qui tam cases were filed last year," added Krueger, with Foley & Lardner LLP.

Expect FCA Cases on Gender-Affirming Care

Consistent with Trump administration priorities, DOJ is going full bore after gender-affirming care and DEI. DOJ has subpoenaed information from hospitals and physicians on their gender-affirming care—what the administration now calls sex-rejecting procedures—although not always successfully. Federal district courts have quashed subpoenas or civil investigative demands three times, Matzzie said. In November, for example, a federal district court rebuffed a subpoena served on Children's Hospital of Pennsylvania.[1]

Striking down a subpoena is rare, Matzzie said. "You can always narrow the subpoena so perhaps they will do that, but to the extent [they] were counting on those investigations to develop evidence, they have run into three district courts to stop them." But there are other types of potential consequences besides an FCA lawsuit. HHS has referred Seattle Children's Hospital to OIG for possible exclusion from federal health care programs for what it says is failure to meet professionally recognized standards of health care under a Dec. 18 HHS declaration "that sex-rejecting procedures for children and adolescents are neither safe nor effective," according to an HHS official's Dec. 26 post on X.[2] The prospect of exclusion for gender-affirming care is being challenged, however, in a Dec. 23 multistate lawsuit against HHS.[3]

DOJ also is investigating workplace diversity programs at several companies under the FCA, according to a Dec. 28 *Wall Street Journal* article.[4]

"I would think in 2026 you will see a number of FCA cases that become public at some point relating to DEI," and areas that connect to DEI, such as gender identity, religion and antisemitism, said attorney Craig Leen, former director of the Office of Federal Contract Compliance Programs in the first Trump administration. "I think they view it as the same genre of enforcement actions."

Lying About DEI 'Could be Material to Payment'

DOJ set the table for its plans in recent memos. In May, DOJ announced the new Civil Rights Fraud Initiative, which points the FCA at federal contractors and recipients of federal funds (e.g., Medicare) that "knowingly" violate civil rights laws and falsely certify compliance with them.[5] In July, U.S. Attorney General Pam Bondi shed more light on how federal anti-discrimination laws apply to "unlawful" DEI programs and other practices, setting the stage for enforcement actions against entities that receive federal money (e.g., Medicare payments).[6] Leen noted the Equal Employment Opportunity Commission (EEOC) also is very focused on DEI. "The real risk to companies is DOJ and the EEOC," he noted. "You will see action on it before the midterms."

Some attorneys say DOJ will have a hard time building FCA cases on the back of memos and executive orders. It will be a stretch to show materiality, the magic word for proving the submission of false claims. Materiality connects the dots between noncompliance and government payment.

But Leen said the government has long viewed civil rights obligations as material terms that could trigger debarment if breached, including under a revoked executive order (11246), although the Trump administration, with its focus on white men, Christians and Jews, has put a different spin on discrimination than prior administrations. If entities accept federal funds but lie to the government about discrimination, "there's risk that could be material to payment," said Leen, with K&L Gates. And the FCA isn't the only thing to worry about; making false statements to the government can be a crime.

Because an FCA violation requires proving intent (including reckless disregard or deliberate ignorance), Leen suggests companies perform DEI audits. "You just have to make sure you're not excluding a group based on race, sex, religion or other protected ground."

More FCA Cases From State AGs?

The next FCA subpoena to land on an organization's doorstep may come from a state attorney general (AG), Matzzie said. About 30 states have their own FCAs and most include whistleblower provisions. Depleted resources at DOJ are partly driving this trend.

"We can expect to see this year a robust expansion in state-level enforcement," Matzzie said. "State AGs are very interested in ensuring robust enforcement around Medicaid fraud." For example, "California has a really strong AG's office to take the lead in cases." Multistate investigations are under way against labs, medical devices and other health care/life sciences companies. If state AGs don't intervene in FCA complaints brought by whistleblowers, they can proceed unilaterally, Matzzie said. Other lawyers share her prediction. "A lot of enforcement is moving to the states," Inman said.

But attorney Reuben Guttman doubts state AGs will fill any vacuum left by DOJ. Although it stands to reason that AGs would pick up the slack, AG resources "have been diverted to deal with the Trump administration," said Guttman, with Guttman Buschner LLP.

FCA targets are all over the map, but Anti-Kickback Statute (AKS) violations and MA are a theme. In the MA arena, allegations of risk adjustment fraud will continue, but attorneys predict allegations will take other forms. MA is "a huge umbrella of an issue," said attorney Jeffrey Fitzgerald, with Polsinelli. Marketing, for example, may get more scrutiny this year, he said. OIG warned providers in a 2024 special fraud alert against crossing the line from sharing information with patients about MA plans to marketing them.[7]

AKS violations are "the biggest MA trend," said attorney Max Voldman, with Whistleblower Partners LLP. For example, DOJ filed an FCA complaint in May against Aetna Inc., Elevance Health Inc. and Humana Inc.—as well as three large insurance brokers—alleging the insurers shelled out hundreds of millions of dollars in illegal kickbacks to the brokers in return for enrollments in MA plans from 2016 to 2021.[8] The case was set in motion by a whistleblower.

At the same time, "risk adjustment fraud isn't going away," Inman said. Insurance companies that left the MA market are moving into accountable care organizations (ACOs), she said. "We are going to start seeing DOJ bringing cases on fraud in ACOs."

Hospital Allegedly Paid Oncologists for Referrals

Enforcement actions on violations of the Stark Law and AKS will continue to be a hot spot, attorneys say. Improper remuneration "cuts across every provider type," Granston noted.

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CMS Transmittals and *Federal Register* Regulations, Dec. 19, 2025-Jan. 8, 2026

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- Editing for Hospital Services Provided to Hospice Enrollees, Trans. 13,560 (Dec. 22, 2025)

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- Implementation of Wasteful and Inappropriate Service Reduction (WISeR) Model Prior Authorization and Medical Review Process and Establishment of New Quarterly Change Request (CR) Process for Possible Future Changes to Information Included in Attachments A, B, C, D, E, and F., Trans. 13,570 (Dec. 31, 2025)

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- Request for Information: Accelerating the Adoption and Use of Artificial Intelligence as Part of Clinical Care, 90 Fed. Reg. 60,108 (Dec. 23, 2025)

Proposed rules

- Medicaid Program; Prohibition on Federal Medicaid and Children's Health Insurance Program Funding for Sex-Rejecting Procedures Furnished to Children, 90 Fed. Reg. 59,441 (Dec. 19, 2025)
- Medicare and Medicaid Programs; Hospital Condition of Participation: Prohibiting Sex-Rejecting Procedures for Children, 90 Fed. Reg. 59,463 (Dec. 19, 2025)
- Nondiscrimination on the Basis of Disability in Programs or Activities Receiving Federal Financial Assistance, 90 Fed. Reg. 59,478 (Dec. 19, 2025)
- Global Benchmark for Efficient Drug Pricing (GLOBE) Model, 90 Fed. Reg. 60,244 (Dec. 23, 2025)
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- Transparency in Coverage, 90 Fed. Reg. 60,432 (Dec. 23, 2025)
- Health Data, Technology, and Interoperability: ASTP/ONC Deregulatory Actions To Unleash Prosperity, Fed. Reg. 60,970 (Dec. 29, 2025)

Proposed rules; withdrawal of non-finalized provisions

- Health Data, Technology, and Interoperability: Patient Engagement, Information Sharing, and Public Health Interoperability; Withdrawal, 90 Fed. Reg. 60,602 (Dec. 29, 2025)
- Medicare and Medicaid Programs; Hospital Condition of Participation: Prohibiting Sex-Rejecting Procedures for Children, 90 Fed. Reg. 59,463 (Dec. 19, 2025)

Temporary rule

- Fourth Temporary Extension of COVID–19 Telemedicine Flexibilities for Prescription of Controlled Medications, 90 Fed. Reg. 61,301 (Dec. 31, 2025)

For example, on Dec. 22, DOJ said New York-Presbyterian Hudson Valley Hospital agreed to pay $6.8 million to settle FCA allegations that it paid millions of dollars to an oncology practice to induce Medicare and Medicaid patient referrals.[9] The hospital had agreements with the oncology practice to work on proposed melanoma and breast cancer centers, among other things, "but in reality, many of these payments were not made in exchange for the services identified in the Agreements." The oncology practice often neglected to perform or document services described in the agreements, DOJ alleged. A whistleblower got the ball rolling in this case.

But kickbacks as a predicate act under the FCA are facing headwinds. "The causation standard of AKS violations in an FCA case" is the number one issue for attorneys, Fitzgerald noted. At issue is "but-for" causation, which is required by some federal appeals courts but not others, paving the way for a U.S. Supreme Court resolution. That likelihood has apparently increased in the wake of a Feb. 18, 2025, decision from the U.S. Court of Appeals for the First Circuit that requires but-for causation to show that kickbacks violate the FCA. But-for causation means DOJ or whistleblowers must prove that kickbacks directly cause the submission of false claims—in other words, without an inducement from a hospital, for example, the physician wouldn't have referred the patient to that hospital—and is a harder standard for DOJ and whistleblowers to meet than proximate causation.

The First Circuit decision came down in an FCA lawsuit against Regeneron Pharmaceuticals over copay assistance for its drug Eylea, which is a treatment for wet age-related macular degeneration. The tug-of-war among the circuits has its roots in an AKS amendment in the Affordable Care Act, which declared that all claims "resulting from" AKS violations are false claims. The meaning of "resulting from" has split the circuit courts.

There's a twist: the First Circuit opened another path for alleging FCA violations stemming from kickbacks, Matzzie said. It allows DOJ and whistleblowers to sidestep but-for causation by alleging the kickbacks amount to false certification of compliance. "That's encouraging for robust enforcement," she said.

Ruling on Fate of Whistleblowers Is Due Soon

Meanwhile, clouds are hanging over the longstanding authority of whistleblowers to pursue FCA cases on behalf of the government. They started to gather with the dismissal of an FCA lawsuit filed by whistleblower Clarissa Zafirov against Florida Medical Associates LLC and other defendants over alleged unsupported diagnosis codes submitted to MA plans.

Judge Kathryn Kimball Mizelle of the U.S. District Court for the Middle District of Florida ruled in 2024 that whistleblowers violate the Appointments Clause of the Constitution, which vests executive power in the president and, by extension, the executive branch. That ruling is now being challenged in the U.S. Court of Appeals for the 11th Circuit, with DOJ on the whistleblower's side. "We had oral arguments in December. We expect a decision in a few months," said Krueger, co-counsel for the defense. If the 11th Circuit rules the whistleblower provision is unconstitutional, "I think the case would definitely go to the Supreme Court," he said.

Over the years, courts have repeatedly affirmed the authority of whistleblowers, but the sand may be shifting. What remains to be seen is whether a win for the defense would preclude whistleblower cases under the FCA altogether or only whistleblower cases without DOJ intervention. Inman and Voldman think it's just the latter.

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Endnotes

1 In Re: Administrative Subpoena No. 25-1431-014, Eastern District of Pennsylvania (2025).

2 U.S. Department of Health and Human Services (@HHS), ".@HHSGCMikeStuart today referred Seattle Children's Hospital to @OIGatHHS for failure to meet professional recognized standards of health care as according to Secretary Kennedy's declaration that sex-rejecting procedures for children and adolescents are neither safe nor effective as a treatment modality for gender dysphoria, gender incongruence, or other related disorders in minors," X.com, December 26, 2025, https://bit.ly/49JSa7E.

3 State of Oregon, et al., v. Robert F. Kennedy, Jr., et al., No. 6:25-cv-02409-MTK (D. Ore. 2025), https://on.ny.gov/49z2oXw.

4 Gibson Dunn, "DEI Task Force Update (December 30, 2025)," Client Alert, https://bit.ly/3LCFQgi.

5 U.S. Department of Justice, Office of the Deputy Attorney General, "Civil Rights Fraud Initiative," memorandum, May 19, 2025, https://bit.ly/43tuyBr.

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7 U.S. Department of Health and Human Services, Office of Inspector General, "Special Fraud Alert: Suspect Payments in Marketing Arrangements Related to Medicare Advantage and Providers," December 11, 2024, https://bit.ly/3ButqCe.

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