McDermott Will & Schulte

Healthcare Regulatory Check-Up

IN THIS DECEMBER 2025 ISSUE

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December regulatory update summary

This issue of McDermott Will & Schulte's *Healthcare Regulatory Check-Up* highlights regulatory activity from December 2025. The end of the year brought a significant number of newly proposed Centers for Medicare & Medicaid Services (CMS) rules and Innovation Center models, as well as several new Office of the Inspector General (OIG) reports and an advisory opinion. We discuss enforcement actions focusing on allegations under the Anti-Kickback Statute (AKS), the False Claims Act (FCA), and other fraud and abuse laws, including allegations related to laboratory testing, wound grafts, and marketing schemes. This issue also discusses recent executive orders (EOs) related to artificial intelligence (AI) and medical marijuana research.

Notable cases, settlements, and related agency activity

WOUND GRAFT COMPANY OWNERS SENTENCED FOR $1.2B FRAUD, AGREE TO PAY $309M TO RESOLVE FCA LIABILITY

In a landmark prosecution, the owners of Arizona-based wound graft companies were sentenced to 15.5 and 14 years in prison, respectively, for orchestrating a $1.2 billion healthcare fraud scheme. From 2022 to 2024, the company owners submitted more than $960 million in false claims to Medicare and other insurers for unnecessary wound grafts, driven by illegal kickbacks. The owners also employed untrained sales representatives to target elderly patients and ordered oversized grafts regardless of medical necessity. Both owners pleaded guilty to committing healthcare fraud, resulting in substantial restitution and forfeiture orders, alongside civil liabilities under the FCA.

PAIN MANAGEMENT DOCTOR, PRACTICE TO PAY $13M+ FOR ALLEGED URINE DRUG TESTING FALSE CLAIMS

A Texas-based pain medicine practice and its physician founder entered into a settlement of more than $13 million to resolve allegations of false claims submissions to federal and state healthcare programs. The United States alleged that the physician and practice knowingly billed federal and state healthcare programs for concurrent presumptive and

definitive urine drug testing, for the same patient and on the same date of service, without first reviewing the presumptive test to determine medically necessity. The US also claimed that the practice and physician knowingly submitted false claims to the US Department of Veterans Affairs for definitive drug testing by using separate CPT codes for individual analytes. As part of the settlement, the practice entered into a five-year Corporate Integrity Agreement requiring it to maintain a compliance program, implement a risk assessment process, and engage an independent review organization to review its claims. This settlement is the latest in a long series of enforcement actions concerning urine drug testing. Organizations that provide this testing should ensure appropriate compliance controls to mitigate risk.

HEALTHCARE SOFTWARE CEO SENTENCED FOR $1B TELEMARKETING FRAUD SCHEME

In one of the largest telemarketing Medicare fraud cases ever tried to verdict, the CEO of a marketing and software company was convicted of healthcare fraud, conspiracy to commit healthcare fraud and wire fraud, and related kickback and false statement charges. The CEO was sentenced to 15 years in prison and ordered to pay more than $452 million in restitution for leading a scheme that generated fraudulent doctors' orders and defrauded federal health programs of more than $1 billion. The company used misleading mailers, television advertisements, and calls from offshore centers to target hundreds of thousands of Medicare beneficiaries who agreed to accept medically unnecessary items (*e.g.*, orthotic braces, pain creams). The scheme involved connecting pharmacies and durable medical equipment suppliers to telemedicine companies that would accept illegal kickbacks and bribes in exchange for signed doctors' orders transmitted through the platform. The doctors' orders falsely represented that a doctor had examined and treated the beneficiary when in reality, the telemedicine companies paid doctors to sign the orders without regard to medical necessity, based on little to no interaction with the beneficiary.

ELEVENTH CIRCUIT EVALUATES CONSTITUTIONALITY OF FCA

On December 12, 2025, the US Court of Appeals for the Eleventh Circuit heard oral arguments for an appeal of a district court decision that the *qui tam* provision of the FCA violates the Appointments Clause of the US Constitution. The district court held that the relator qualified as an "officer" who wielded significant federal authority despite lacking proper appointment. The US Department of Justice and relators countered this argument by stating that *qui tam* suits are akin to private litigation and are historically rooted in US law, citing centuries of precedent and prior court rulings.

The oral arguments had judges balancing historical acceptance of the FCA against modern concerns about *qui tam* claims and the large volume of cases brought under the FCA. A Supreme Court of the United States review appears likely considering more defendants across the US are raising constitutionality arguments challenging *qui tam* provisions in the FCA. If *qui tam* actions are considered unconstitutional, FCA enforcement could shift dramatically. The change could limit relators, reduce case volume, and force the government to allocate more resources to maintain the FCA's role as a major revenue generator.

FIRST CIRCUIT CLARIFIES FCA MEDICAL NECESSITY STANDARDS

On December 1, 2025, the US Court of Appeals for the First Circuit declined to revive a lawsuit alleging that a laboratory knowingly submitted false Medicare claims by billing for expensive polymerase chain reaction (PCR) tests for urinary tract infections when cheaper and allegedly equally effective bacterial urine culture (BUC) tests were available. To build the fraud case, a physician practice, acting as a relator, intentionally sent hundreds of test requests to the laboratory and instructed its staff to always order the more expensive PCR tests, even when doctors wanted the less costly BUC test.

The First Circuit found that as a matter of first impression, labs may generally rely on a doctor's order to show that a test is "reasonable and necessary," which inherently shifts the burden to relators to prove otherwise. Here, the relator failed to establish that the laboratory acted knowingly in violation of the FCA, given they were fulfilling specific doctors' orders.

The Court warned that adopting the relator's theory of the case could lead to dangerous consequences (*e.g.*, labs second-guessing physician orders).

SIXTH CIRCUIT LIMITS FRAUD RESTITUTION PAYMENTS UNDER MVRA

The US Court of Appeals for the Sixth Circuit upheld the convictions of a pharmaceutical sales company cofounder but significantly altered the district court's calculation of restitution. The cofounder was convicted of healthcare fraud, conspiracy to commit healthcare fraud, and making a false statement to the Internal Revenue Service, based on a scheme that involved recruiting patients and "sales representatives" by offering commissions from commercial insurance reimbursements for compounded pain and scar creams. The scheme did not involve payments from state or federal healthcare programs, so the FCA and AKS were not implicated in this case.

The Sixth Circuit analyzed the Mandatory Victims Restitution Act (MVRA) and vacated the district court's restitution award to the self-insured company that paid all of the claims at issue in the case. The district court found that claims "procured by kickbacks, whether they are medically necessary or not . . . are subject to restitution" under the MVRA. The Court determined this was a legal error: Since the MVRA only requires the defendant to restore a victim to their prior position, and since the medically necessary claims would have been covered by the company's insurance account regardless of the defendant's conduct, the defendant's restitution payment to the company should only include the medically unnecessary claims. Requiring payment for medically necessary claims would result in a windfall. This standard differs somewhat from FCA cases, where claims "resulting from" a kickback scheme are rendered false. The prevailing circuit interpretation of the "resulting from" standard requires that the kickback be the "but-for" cause of the claim. This standard may not be met when the physician would have prescribed the product because it was medically necessary notwithstanding the kickback. Furthermore, the Sixth Circuit held that the district court's apportionment of restitution was erroneous, as the district court's order for the cofounder to pay 90% of the restitution, based on his codefendant's plea agreement, failed to consider each defendant's contribution to losses and their economic circumstances as required by 18 U.S.C. § 3664(h).

CMS regulatory updates

CMS ESTABLISHES ORHT, AWARDS INITIAL GRANTS IN $50B PROGRAM

Following the creation of the Rural Health Transformation (RHT) Program, which was tasked with dispensing $50 billion to states in support of rural health over the next five years, CMS established the Office of Rural Health Transformation (ORHT) within its organizational structure. The office will oversee the RHT Program by providing technical assistance for states, coordinating state and federal partnerships, and providing program accountability.

ORHT announced its initial awards on December 29, 2025; all 50 states received awards under the program. Awards ranged from $147 million to $281 million and averaged around $200 million per state. Funding awards will be used to support the expansion of rural healthcare services and emergency response, fund workforce training and retention incentives, and invest in facility and equipment modernization. The RHT Program is intended to offset other federal budget cuts to rural hospitals, but also ties some funding to the implementation of the Trump administration's health policy priorities.

CMS PROPOSES HOSPITAL BAN ON GENDER-AFFIRMING CARE FOR MINORS

CMS proposed a new condition of participation that would prohibit hospitals from providing certain pharmaceutical or surgical interventions (referred to in the proposed rule as "sex-rejecting procedures") to transgender and transitioning patients under the age of 18. The proposed rule would implement an EO issued by the Trump administration in January 2025. Under the proposed rule, hospitals may not provide minors with pharmaceutical or surgical interventions that

attempt to intentionally disrupt or suppress the development of biological functions, or intentionally alter their physical appearance or body, with some exceptions. Comments on the proposed rule are due by February 17, 2026.

CMS INTRODUCES NEW INNOVATION CENTER MODELS

CMS recently announced several new and proposed Innovation Center models:

- The Advancing Chronic Care with Effective, Scalable Solutions (ACCESS) Model is a voluntary program that ties Outcome-Aligned Payments (OAPs) to chronic condition management using remote monitoring, virtual coaching, and digital health tools. Organizations participating in the model must be enrolled in Medicare Part B, or in the case of healthcare technology companies, must contract with an enrolled provider that participates in the ACCESS Model. Participating organizations will receive recurring OAPs for managing patients' qualifying conditions. The payments are not directly tied to the use of healthcare technology but are intended to help pay for technology-supported care. ACCESS will initially focus on conditions related to obesity, prediabetes, kidney disease, cardiovascular disease, chronic musculoskeletal pain, depression, and anxiety. The model will run for 10 years beginning July 5, 2026. For more information, review our recent webinar.

- The Make America Healthy Again: Enhancing Lifestyle and Evaluating Value-based Approaches Through Evidence (MAHA ELEVATE) Model tests lifestyle and nutrition interventions for Medicare beneficiaries. The program will fund pilot projects focused on improving health outcomes through nonmedical supports such as diet and physical activity. The model will provide approximately $100 million to fund three-year cooperative agreements for up to 30 proposals. The proposals will use evidence-based whole-person care approaches, including functional or lifestyle medicine interventions, that Original Medicare currently does not cover. These approaches are intended to support, not replace, the medical care received by Medicare beneficiaries. Results will help determine whether these approaches should be integrated into future Medicare coverage. CMS will release a Notice of Funding Opportunity in early 2026 for the first cohort, and the voluntary model will launch on September 1, 2026.

- The proposed Global Benchmark for Efficient Drug Pricing (GLOBE) and Guarding U.S. Medicare Against Rising Drug Costs (GUARD) Models would seek to lower costs for drugs covered by Medicare Part B and Part D, respectively. Both models would test new payment formulas for specific drugs. The GLOBE model would modify the Medicare Part B drug inflation rebate calculation for certain drugs using international drug pricing information to identify a benchmark that reflects prices paid in a set of economically comparable countries. The GUARD Model would price certain drugs by factoring in existing Medicare Part D manufacturer rebates and discounts. CMS would leverage its authority to test a change in the calculation of inflation rebates in Medicare Part D that accounts for how much certain drugs cost in economically similar countries. CMS seeks public comment on the GLOBE and GUARD models through February 23, 2026.

- The voluntary Better Approaches to Lifestyle and Nutrition for Comprehensive hEalth (BALANCE) Model is intended to expand access to GLP-1s and lifestyle interventions to support weight loss. CMS will negotiate lower prices directly with eligible GLP-1 manufacturers on behalf of state Medicaid agencies and Part D plans. Negotiations will also address eligibility criteria for patients. State Medicaid agencies can join the model beginning in May 2026, and Part D plans can join in January 2027. Model testing will conclude in December 2031.

DHS LIST, PHYSICIAN NONMONETARY COMPENSATION LIMITS UPDATED FOR 2026

CMS issued its new Physician Fee Schedule in November 2025, effective for services starting in January 2026. In the final rule, CMS issued its updated list of designated health services (DHS). Additions to the list include new lab tests and assays, remote therapeutic monitoring services, and several new radiation and imaging services. CMS also made changes to COVID-19 vaccine codes and removed certain radiation treatment delivery G-codes from the DHS list.

Providers that use DHS categories as part of their physician compensation systems should review and incorporate the updated DHS list from CMS.

CMS made its annual inflation-adjusted updates to financial limits on physician nonmonetary compensation, medical staff incidental benefits, and the "limited remuneration" definition. These limits correspond to the Stark Law exceptions found at 42 CFR 411.357(k), (m), and (z), respectively. As of January 1, 2026, the nonmonetary compensation limit is $535 (up from $519), the medical staff incidental benefit limit is set at "[l]ess than $46" (up from $45), and the maximum limited remuneration amount is $6,237 (up from $6,055).

CMS INDEFINITELY SUSPENDS SNF ATTACHMENT DEADLINE

Under a 2023 CMS final rule, skilled nursing facilities (SNFs) are required to provide CMS with extensive managerial, ownership, and control information from additional disclosable parties that provide certain services to or exercise certain controls over SNFs. SNFs must provide this information as part of their Medicare enrollments using the CMS-855A SNF attachment, which was initially released in October 2024. Stakeholders have noted that these disclosures are complicated, far-reaching, and burdensome to obtain. Since the SNF attachment's release, CMS has pushed back the completion deadline three times. The most recent deadline was January 1, 2026, but on December 9, 2025, CMS indefinitely suspended the deadline for submitting the SNF attachment.

Although the deadline has been suspended, the requirement to submit additional disclosable party information still stands. CMS has indicated it will provide additional information in future updates. It remains to be seen whether CMS will modify its forms or its guidance regarding ADP disclosures.

Office of Inspector General updates

OIG ISSUES FAVORABLE ADVISORY OPINION ON DISCOUNTS

In Advisory Opinion No. 25-11, a biopharmaceutical manufacturer proposed a system to offer discounts and rebates on its vaccines to various customers, including pharmacies and healthcare organizations. OIG categorized the proposed discounts into four types: standard upfront discounts, discounts tied to previous purchases, bundled discounts linked to buying multiple vaccines, and rebates for meeting certain conditions. Although these arrangements could violate the AKS if intended to influence purchasing decisions, OIG found that most of the discounts qualified as "discounts" or "rebates" under relevant AKS safe harbors. Even discounts that did not satisfy the safe harbors were deemed to present a sufficiently low risk of fraud and abuse under the AKS, provided that no additional services or promotional activities were required as a condition of the discounts. As a result, OIG concluded that it would not impose administrative sanctions on the manufacturer for its proposed discount and rebate system.

OIG SOLICITS PROPOSALS FOR NEW AKS SAFE HARBORS

OIG published its annual notification soliciting proposals and recommendations for developing or modifying AKS safe harbors. OIG also seeks suggestions for new Special Fraud Alerts, which have historically served as an important source of subregulatory guidance on key fraud and abuse issues. When considering new or modified safe harbor provisions or Special Fraud Alerts, OIG evaluates whether the proposals will increase or decrease access to healthcare services, the quality of healthcare services, patient freedom of choice, provider competition, federal healthcare program costs, and potential overutilization of services, and whether they meet the needs of medically underserved areas and populations.

OIG AUDIT: MEDICAID AGENCIES MADE MILLIONS IN UNALLOWABLE CAPITATION PAYMENTS

An OIG audit covering July 2021 to June 2022 found $207.5 million in unallowable capitation payments to managed care organizations for deceased enrollees. In a sample, 99 out of 100 payments were improper, with about half

recovered before the review. OIG recommended that CMS share T-MSIS data with Medicaid agencies to recover improper payments and work with agencies to implement provisions of the One Big Beautiful Bill Act.

OIG AUDIT: ASSISTED LIVING FACILITIES DID NOT COMPLY WITH PROVIDER RELIEF FUND TERMS

An OIG audit of Provider Relief Fund payments to 30 assisted living facilities found that seven facilities claimed $283,000 in unallowable expenses and two inaccurately reported $11 million in lost revenues. These issues arose from clerical errors, misinterpretation of Health Resources and Services Administration (HRSA) guidance, and inadequate supporting documentation. OIG recommended that HRSA require facilities to return unallowable expenditures and improperly claimed lost revenue or otherwise ensure appropriate accounting for those funds.

OIG AUDIT: NEW JERSEY SHOULD IMPROVE OVERSIGHT OF NURSING HOME BACKGROUND CHECK COMPLIANCE

An OIG audit assessing compliance with federal requirements during the 2022 calendar year revealed that 11 out of 12 selected New Jersey nursing homes failed to comply with federal background check requirements, affecting 33 out of 120 employees. Noncompliance included allowing staff to work before completing background checks, employing staff without checks, and failure to provide documentation that a nursing home had performed checks for any of its staff. These deficiencies were due, in part, to the nursing homes' insufficient procedures to ensure that background checks were properly conducted. OIG recommended that New Jersey improve compliance monitoring and provide guidance on proper background check procedures.

Other notable developments

LOWER HEALTHCARE COSTS ACT INTRODUCED IN SENATE

On December 8, 2025, Senator Chuck Shumer (D-NY) introduced S. 3385, which would extend the American Rescue Plan Act of 2021 and the Inflation Reduction Act of 2022 for three years. These Acts generally expanded eligibility for, and increased the amount of, the premium tax credit. Through 2028, the bill would eliminate the 400% maximum income limit for premium tax credit eligibility as well as the inflation adjustment for applicable percentages.

HOUSE PASSES LOWER HEALTHCARE PREMIUMS FOR ALL AMERICANS ACT

On December 17, 2025, the US House of Representatives passed H.R. 6703, sending it to the US Senate the following day. The bill proposes amendments to the Employee Retirement Income Security Act of 1974 that would allow groups or associations of employers to establish health plans, regardless of industry, trade, or profession, provided specific criteria are met. Pursuant to the bill, the plans must not be controlled by health insurance issuers and would be prohibited from imposing eligibility rules or premium contributions based on health-status-related factors. The bill would allow plans to set base premium rates using a community rating methodology and would require pharmacy benefit managers to submit semiannual reports detailing drug pricing and spending. The bill would provide funding for cost-sharing reductions but would limit funding to plans that cover abortion, except under specified conditions, including rape, incest, and life endangerment.

FLORIDA OVERPAYMENT STATUTE GOES INTO EFFECT

Effective January 1, 2026, Florida healthcare practitioners and Agency for Health Care Administration-licensed facilities are required to refund overpayments made by patients within 30 days after the determination that there has been an overpayment. As of December 2025, no Florida board or agency has issued rules or regulations to guide

implementation of the law, but regulations will likely be issued in 2026. Healthcare providers and facilities in Florida should review their patient credit balance and refund policies in light of this new requirement.

ADMINISTRATION RELEASES EO AND RFI ON AI

On December 11, 2025, President Trump issued an EO that directs federal agencies to challenge state laws that conflict with national AI policy, asserting federal preemption over state-level regulation.

On December 23, 2025, the Office of the Deputy Secretary and Assistant Secretary for Technology Policy and Office of the National Coordinator for Health Information Technology published a request for information (RFI) seeking input on how to promote responsible and widespread adoption of AI tools in clinical settings. The RFI focuses on identifying barriers to integration, standards for safety and transparency, and methods to evaluate AI-driven decision support. Respondents are encouraged to provide recommendations on governance, workforce training, and strategies to ensure equitable and ethical use of AI in patient care. Comments are due by February 23, 2026.

EO CALLS FOR EXPANDING RESEARCH INTO MEDICAL MARIJUANA

On December 18, 2025, President Trump signed an EO that directs federal agencies to support expanded research into medical uses of marijuana and hemp-derived cannabinoids. The EO acknowledges US Food and Drug Administration findings that marijuana can treat conditions such as pain, nausea, and anorexia and notes the US Department of Health and Human Services' recommendation to reschedule marijuana from Schedule I to Schedule III to reduce research barriers. The EO directs agencies to expedite rescheduling, develop research frameworks, and work with Congress on regulating cannabidiol products to ensure safety and efficacy.

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