McDermott Will & Schulte

Healthcare Regulatory Check-Up

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August regulatory update summary

This issue of McDermott Will & Schulte's *Healthcare Regulatory Check-Up* highlights regulatory activity for August 2025, including the formation of a joint Healthcare Advisory Committee between the US Department of Health and Human Services (HHS) and the Centers for Medicare & Medicaid Services (CMS), the launch of the US Food and Drug Administration (FDA) PreCheck program to boost domestic pharmaceutical manufacturing, and the latest legal challenges to executive orders targeting gender-affirming care. We review enforcement actions focusing on allegations under the federal Anti-Kickback Statute (AKS), the False Claims Act (FCA), and other fraud and abuse laws, and examine an advisory opinion issued by the HHS Office of Inspector General (OIG) regarding the AKS small entity investment safe harbor. We also discuss recent court developments in FCA litigation, new CMS oversight initiatives targeting risk adjustment and eligibility compliance, and continuing OIG scrutiny of remote patient monitoring and global surgery valuation.

Notable cases, settlements, and related agency activity

DOJ CAN PURSUE ALTERNATE THEORY IN FCA CASE AFTER FIRST CIRCUIT RULING ON BUT-FOR CAUSATION

On August 4, 2025, the US District Court for the District of Massachusetts ruled that the government may proceed with an alternative theory in its FCA kickback case against Regeneron Pharmaceuticals Inc., allowing prosecutors another opportunity to seek a pretrial victory following a US Court of Appeals for the First Circuit decision that marked a "critical shift" in the legal landscape. In February 2025, in an interlocutory appeal, the First Circuit adopted a strict "but-for" causation standard and held that to prove a violation of the AKS, the government had to show that providers prescribed Regeneron's more expensive drug only because of payments disguised as copay assistance. *United States v. Regeneron Pharms., Inc.*, 128 F.4th 324, 334 (1st Cir. 2025). After that ruling, the government sought permission to file a second motion for partial summary judgment under a "false certification" theory of FCA liability, focusing on falsity, materiality, and causation. The government also asked to reopen discovery on a limited basis to submit additional evidence on those issues.

The district court granted the government's motions, allowing the US Department of Justice (DOJ) to take a different approach. The government will pursue a theory of false certification under the FCA, stating it can show that Regeneron misrepresented that it complied with the AKS on federal forms. Under the false-certification theory, a defendant can be

held liable under the FCA when the defendant falsely represents AKS compliance on a federal agency form. Under this theory, the government must also demonstrate that the defendant's misrepresentation of AKS compliance was material to the government's payment decision.

The judge noted that the "reevaluation of a core legal issue underlying the government's claims" (specifically, the standard for causation) gave the government the right to adjust its case. The court acknowledged that this change in the law "undeniably made proving an FCA claim" more challenging and granted the government's requests to briefly reopen discovery and submit a new motion for summary judgment.

BEHAVIORAL MEDICINE PROVIDER WILL PAY $2.75 MILLION TO RESOLVE ALLEGED FALSE CLAIMS FOR PSYCHOTHERAPY SERVICES

A California behavioral medicine provider agreed to pay $2.75 million to resolve allegations that it violated the FCA by submitting false claims to government healthcare payors for certain psychotherapy services. The provider furnishes behavioral medicine services to individuals and families in the state of California. From 2015 to 2022, the provider and its healthcare professionals allegedly submitted claims to government payors using Current Procedural Terminology (CPT) codes 90833 and 90836. These add-on codes are intended to be used only when psychotherapy services are provided alongside an evaluation and management visit and require specific documentation. The United States and California alleged that the provider improperly submitted claims using these CPT codes because some or all of the services were not actually provided or were not properly documented.

Takeaway: Add-on codes and modifiers used with evaluation and management services are a frequent target of enforcement actions. Compliance programs should include periodic auditing and education efforts on the correct use of these add-on codes.

STATE ATTORNEYS GENERAL CHALLENGE FEDERAL ACTIONS ON GENDER-AFFIRMING CARE

A coalition of state attorneys general argued in a suit filed on August 1, 2025, that the Trump administration has improperly "weaponized" federal laws against drug misbranding, false claims, and female genital mutilation as part of a pressure campaign to undermine state protections for gender-affirming care. In their 79-page complaint, the attorneys general of California, New York, and a dozen other states took aim at subpoenas issued to doctors and other DOJ actions implementing Executive Order 14187, "Protecting Children from Chemical and Surgical Mutilation," issued by US President Donald Trump on January 28, 2025. Section 8 of the executive order instructs DOJ to prioritize enforcement of protections under the Female Genital Mutilation Act (FGMA) and investigations under the Food, Drug, and Cosmetic Act (FDCA). The executive order is broadly targeted at preventing gender-affirming care for individuals under the age of 19. For more information on the executive order, please see our previous client alerts.

The complaint alleges that the executive order and subsequent DOJ directives, including a memorandum issued by Attorney General Pamela Bondi on April 2022, 2025, titled "Preventing the Mutilation of American Children," and a memorandum issued by Assistant Attorney General Brett A. Shumate on June 11, 2025, titled "Civil Enforcement Priorities," misrepresent the prevailing medical consensus, interfere with state authority to regulate the practice of medicine, and are intended to intimidate healthcare providers through unfounded threats of civil and criminal liability under statutes such as the FCA, FGMA, and FDCA. The complaint alleges that these federal actions caused hospitals to reduce or discontinue gender-affirming care for adolescents, resulting in significant harm to patients and undermining state laws that protect access to such care.

The states argue that the Trump administration has improperly invoked the FCA, FGMA, and FDCA to interfere with state laws prohibiting discrimination against transgender people. The suit, filed in the US District Court for the District of Massachusetts, seeks declaratory relief holding that Section 8 of the executive order is unlawful and that the provision of gender-affirming healthcare does not violate the FCA, FGMA, or FDCA. Plaintiffs further request that the court set aside the Bondi and Shumate memorandums and enjoin defendants from enforcing them in any manner inconsistent with the requested declaratory relief.

CMS regulatory updates

HHS, CMS FORM HEALTHCARE ADVISORY COMMITTEE

HHS and CMS announced the formation of a new Healthcare Advisory Committee tasked with providing strategic recommendations to improve care delivery and financing across Medicare, Medicaid, the Children's Health Insurance Program (CHIP), and the Health Insurance Marketplace. Led by HHS Secretary Robert F. Kennedy Jr. and CMS Administrator Mehmet Oz, the committee's mission is to restore patient-centered care by cutting bureaucracy, reducing costs, expanding preventive services, and modernizing healthcare systems. The stated goals include developing policies to better prevent and manage chronic diseases, creating a regulatory framework to reduce red tape and enhance provider accountability, advancing real-time data systems for faster claims processing and quality measurement, improving care quality for vulnerable Medicaid populations, and strengthening the Medicare Advantage program through updated risk adjustment and quality metrics.

CMS INCREASES OVERSIGHT OF CITIZENSHIP VERIFICATION IN MEDICAID, CHIP

CMS launched a nationwide initiative aimed at ensuring that all Medicaid and CHIP enrollees meet citizenship or immigration eligibility requirements, with the stated goal of protecting program integrity and safeguarding taxpayer funds. As part of the effort, CMS began sending monthly reports to states identifying enrollees whose citizenship or immigration status could not be verified through federal systems such as the US Department of Homeland Security SAVE program. States must review these cases, request additional documentation when necessary, and take appropriate action (such as adjusting or terminating coverage) if individuals are found to be ineligible. CMS is closely monitoring state progress on a monthly basis.

OIG updates

OIG ISSUES FAVORABLE AO ON PHYSICIAN-OWNER COMPENSATION ARRANGEMENT BASED ON SMALL ENTITY SAFE HARBOR

OIG issued a favorable advisory opinion (AO No. 25-09) regarding a physician investment arrangement in a privately held medical device company, determining that the arrangement met all eight elements of the small entity investment safe harbor under 42 C.F.R. § 1001.952(a)(2) of the AKS. While OIG found that the arrangement implicated the AKS because of the physician-investors' ability to refer, purchase, or recommend the company's devices and benefit financially from their use, OIG concluded that the structure and terms of the investment complied with the AKS safe harbor requirements based on the requestor's factual certifications.

The requestor is a medical device company that develops, manufactures, and sells devices used in emergency stroke treatment. Its ownership structure includes both physicians (including the devices' inventor) and non-physician, non-referral-source investors. OIG has previously expressed concerns regarding physician-owned entities that generate income by selling or arranging for the sale of medical devices ordered by the physician owners for use in procedures performed by the physician owners. OIG issued a 2013 Special Fraud Alert on these physician-owned entities, referred to as physician-owned distributorships (PODs). The Special Fraud Alert focused on PODs with certain factors that OIG views as inherently suspect under the AKS, including the selection and retention of investors, the solicitation of capital contributions, and the distribution of profits.

In its advisory opinion, OIG concluded that unlike the PODs highlighted by the Special Fraud Alert, the arrangement satisfied all eight elements of the small entity investment safe harbor:

- **Investor ownership threshold.** The requestor's physician-investors hold approximately 35% of the investment interests in the company, below the safe harbor's 40% cap for referral-source ownership.

- **Equal investment terms.** The terms offered by the requestor to physician-investors are identical to those provided to non-physician investors, satisfying the requirement that all passive investors be treated equally.
- **No referral-based incentives.** Investment terms are not influenced by the volume or value of any past or anticipated referrals, services furnished, or business generated by the physician-investors.
- **No referral requirement.** Physician-investors are not required to refer patients, furnish services, or generate business in order to obtain or maintain their ownership interest.
- **Neutral marketing and provision.** The company markets and furnishes its products to investor and non-investor clinicians in the same manner, avoiding preferential treatment for physician-owners.
- **Revenue cap from investor-generated business.** The entity certified that no more than 40% of its gross revenue from healthcare items or services in the previous year came from referrals or business generated by its investors.
- **No investment loans or guarantees.** Neither the company nor any of its investors provide loans or loan guarantees to physician-investors to facilitate the purchase of ownership interests.
- **Proportional return on investment.** Although the requestor has not made profit distributions to any physician owners, the requestor certified that any profit distributions would be made strictly in proportion to the capital personally invested by each investor, including fair market value compensation for any pre-operational services provided.

Because the arrangement fully met the criteria set forth in the safe harbor, OIG stated it would not impose administrative sanctions or exclusions under the AKS. The agency emphasized that its conclusion applied only to the certified facts presented in this particular request. Similar arrangements that fail to satisfy all eight safe harbor conditions could raise significant fraud and abuse concerns according to OIG, including the potential for overutilization, biased clinical decision-making, or other threats to medical judgment.

OIG REVIEWS BILLING FOR REMOTE PATIENT MONITORING IN MEDICARE

OIG issued a report examining the growth of remote patient monitoring (RPM) practices in Medicare and recommending actions that CMS could take to monitor such practices and prevent fraud, waste, and abuse.

OIG's review found that the delivery of RPM services continued to grow rapidly in 2024, accounting for $536 million in Medicare payments, a 31% increase over 2023. Because RPM services seem poised to become a much larger contributor to Medicare expenditures over the next several years, OIG believes such services could be particularly vulnerable to fraud, waste, and abuse in the future. While OIG stated that the vast majority of practices billing for RPM services complied with program requirements, it also believed that some did not. In follow-up to its September 2024 recommendation that CMS implement additional oversight of RPM practices in Medicare, OIG's report specified several measures to safeguard the Medicare program from RPM-related fraud, waste, and abuse:

- Ensuring that medical practices have a prior relationship with patients before billing for RPM services.
- Scrutinizing practices with a high percentage of patients that do not receive treatment management services.
- Scrutinizing scenarios where multiple practices bill for RPM services for the same patient.
- Scrutinizing scenarios where practices bill Medicare for more than one RPM device per month per enrollee.

For more information on this report, see our client alert.

OIG TO AUDIT DIAGNOSIS CODES FOR MAO COMPLIANCE

OIG announced its intention to audit certain diagnoses submitted by Medicare Advantage Organizations (MAOs) to evaluate whether diagnosis codes, submitted for use in CMS's risk-adjustment program, complied with federal

substantiation requirements. The audit will reportedly focus on diagnoses that are more likely to be submitted without supporting medical records that document the condition via an appropriate face-to-face encounter.

OIG TO ISSUE WHITE PAPER ON DMEPOS FRAUD, WASTE, AND ABUSE

OIG announced its intention to publish a white paper discussing fraud, waste, and abuse in the Medicare program related to durable medical equipment, prosthetic devices, prosthetics, orthotics, and supplies (DMEPOS). Expected in fiscal year 2026, the white paper will reportedly provide background on DMEPOS fraud in Medicare, describe program vulnerabilities, and enumerate potential actions that CMS could take to safeguard program integrity.

OIG's decision to publish this white paper reflects its continuing scrutiny of the DMEPOS space, which it estimates accounts for more than $7 billion of fraudulent activity in Medicare each year. The announcement follows a July 2025 proposed rule through which CMS seeks to address certain DMEPOS-related program integrity risks. For more information on the proposed rule, please see our June *Healthcare Regulatory Check-Up*.

OIG CONTINUES TO AUDIT MEDICARE GLOBAL SURGERY PAYMENT ACCURACY

Existing Medicare policy bundles payments for services furnished by providers for surgeries, including services provided before, during, and after the actual procedure, into a single payment. Pursuant to the Medicare Access and CHIP Reauthorization Act of 2015, CMS is required to gather information to assist in improving the accuracy of global surgery valuation. OIG has begun auditing CMS's collection of this claim information from providers and previously audited the accuracy of information that CMS gathers to value global surgery payment policy. To continue this work, OIG issued a new report comparing the number of postoperative procedures reported by practitioners to the number of procedures estimated in CMS's valuation of global surgery fees.

OIG's previous audit report, issued in June 2025, focused solely on global surgeries with reported postoperative visits and found vast discrepancies between the global surgery valuation fees and actual postoperative visits provided by practitioners. OIG's August 2025 audit was intended to determine whether reporting of postoperative visits for global surgeries accurately reflected the postoperative visits provided and whether the global surgery payment reflected the number of postoperative visits actually provided to patients for global surgeries.

OIG reviewed a simple random sample of 105 global surgeries for which no postoperative visits were reported. OIG found that for 98 of the sampled global surgeries, the global surgery fees did not reflect the number of postoperative visits provided. OIG also noted that nine of the sampled global surgeries had unreported postoperative visits, meaning that at least some postoperative visits were provided but were not fully reflected in CMS's claims data. Based on this sample, OIG estimated that Medicare paid more than $7.8 million more than it would have if the actual utilization of postoperative visits was reflected in global surgery payments. Pursuant to this and its previous audit findings, OIG recommended that CMS implement measures to improve practitioners' reporting of postoperative visits and consider actual data when creating its global surgery valuation. Because OIG's recommendations could have sizable implications for the level of reimbursement practitioners receive under Medicare's global surgery policy, providers should closely monitor any regulatory developments arising out of OIG's recommendations.

Providers that are expected to report postoperative visits should also ensure that Medicare claims appropriately include CPT codes for postoperative visits furnished to patients within the global surgery period. This is an important data point that will ultimately be reflected in future modifications to CMS's global surgery payment policies.

Other notable developments

NEW JERSEY EXPANDS CRIMINAL PATIENT BROKERING LAW

On August 11, 2025, amendments to New Jersey's patient brokering statute were signed into law. The amendments expanded New Jersey's existing patient brokering statute to include clinical laboratories and recovery residences and to

more explicitly parallel the federal Eliminating Kickbacks in Recovery Act (EKRA). As revised, the New Jersey patient brokering statute, N.J. Stat. Ann. § 2C:40A-6, prohibits any person from making, soliciting, offering, or receiving a payment to or from any person in connection with the referral of patients to, or in exchange for a patient using the services of, a substance use disorder facility or provider, recovery residence, or clinical laboratory. The amendments also provide stricter penalties for violations. New Jersey's patient brokering statute includes exceptions different than those available under EKRA.

FDA BEGINS REAL-TIME ADVERSE EVENT DATA REPORTING

On August 22, 2025, the FDA began publishing daily data from the FDA Adverse Event Reporting System (FAERS), which collects reports of adverse events, medication errors, and product quality issues related to prescription drugs and therapeutic biologics. This significant change to FDA's safety monitoring practices is part of the agency's broader data modernization strategy aimed at improving the efficiency and transparency of adverse event reporting. By increasing the frequency of data publication, the agency seeks to identify potential safety concerns more quickly and enhance public access to health information.

FDA LAUNCHES PRECHECK PROGRAM TO STRENGTHEN US DRUG MANUFACTURING

FDA also announced the launch of the FDA PreCheck program, a new initiative designed to bolster domestic pharmaceutical manufacturing and reduce the United States' reliance on foreign drug production. Currently, more than half of pharmaceuticals used in the United States, including the majority of active pharmaceutical ingredients, are sourced from overseas. Only 11% of active pharmaceutical ingredient manufacturers are based in the United States. FDA PreCheck aligns with Executive Order 14293 and aims to streamline and accelerate the approval process for US drug production. The program will roll out in two phases:

- The facility readiness phase encourages early FDA engagement during facility design and construction via a Type V Drug Master File.
- The application submission phase focuses on improving the efficiency of the chemistry, manufacturing, and controls portion of drug applications through pre-application meetings and targeted feedback.

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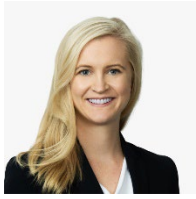

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