McDermott Will & Schulte

Healthcare Regulatory Check-Up

IN THIS SEPTEMBER 2025 ISSUE

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September regulatory update summary

This issue of McDermott Will & Schulte's *Healthcare Regulatory Check-Up* highlights regulatory activity for September 2025, including an update on the Centers for Medicare & Medicaid Services (CMS) Rural Health Transformation (RHT) Program and a new prior authorization demonstration for certain cosmetic services provided in ambulatory surgical centers (ASCs). We review enforcement actions focusing on allegations under the federal Anti-Kickback Statute (AKS) and False Claims Act (FCA), and examine the latest advisory opinion (AO) and reports from the US Department of Health and Human Services (HHS) Office of Inspector General (OIG). We also discuss HHS's enforcement crackdown on information blocking, the Make American Healthy Again (MAHA) Commission's recent "Make Our Children Healthy Again" strategy document, the upcoming US Food and Drug Administration (FDA) Digital Health Advisory Committee meeting on artificial intelligence (AI)-enabled mental health devices, and more.

Notable cases, settlements, and related agency activity

DEVICE MANUFACTURER, DISTRIBUTOR PAY NEARLY $37M TO RESOLVE FCA ALLEGATIONS

A device manufacturer agreed to pay $29.75 million, and its former distributor agreed to pay $7.2 million, to resolve allegations that they violated the FCA by causing the submission of false claims to Medicare for photoplethysmography tests performed using its devices in connection with the diagnosis of peripheral arterial disease. The allegations were originally brought in a lawsuit filed by two *qui tam* relators.

To qualify for Medicare reimbursement, peripheral arterial disease testing must satisfy the requirements of CPT code 93922, 92923, or 93924. Each of these billing codes requires that a provider conduct an ankle brachial index (ABI) test plus certain additional testing. Medicare national coverage determinations and local coverage determinations (LCDs) also prohibit reimbursement for noninvasive vascular tests that use photoelectric plethysmography (also known as photoplethysmography) because of concerns about accuracy and reproducibility.

According to the US Department of Justice (DOJ), when the FDA cleared the devices, the FDA told the manufacturer that the devices did not perform an ABI and could not be called a "digital ABI." Additionally, DOJ alleged that the manufacturer knew the tests did not satisfy the CPT codes because they do not perform an ABI and that Medicare reimbursement was barred because the devices use photoelectric plethysmography. DOJ alleged that the manufacturer

nevertheless represented to providers that Medicare would reimburse the tests, and continued to make such representations even after hearing concerns from its distributor, customers, and third parties, including the American Medical Association and Society for Vascular Ultrasounds.

In addition to the civil settlement, the manufacturer entered into a five-year Corporate Integrity Agreement with OIG, which obligates the company to undertake substantial internal compliance reforms.

LAB CEO, MARKETERS, PHYSICIANS SETTLE ALLEGATIONS OF MSO AND TESTING KICKBACKS FOR $6M+

A laboratory CEO agreed to pay $4.25 million to resolve allegations of illegal payments to doctors for laboratory referrals in violation of the AKS. Two physicians and seven marketers agreed to pay an additional $1.8 million to settle kickback allegations. These settlement amounts are in addition to the amounts the physicians and marketers were ordered to pay in criminal proceedings.

The settlement resolves allegations that the CEO caused false claims for laboratory testing to be submitted to Medicare, Medicaid, and TRICARE from January 2015 to May 2018. The CEO allegedly agreed to a kickback scheme in which marketers, including the laboratory company's own employees, offered and paid doctors kickbacks disguised as management service organization (MSO) distributions to induce laboratory testing referrals. The settlement also resolves allegations that the CEO arranged for the laboratory company to pay kickbacks disguised as consulting fees, processing and handling fees, and waivers of copayments and deductibles, to induce laboratory testing referrals. The case arose from *qui tam* lawsuit. When DOJ intervened, it added claims against additional defendants, some of which are still ongoing.

DOJ continues to focus on laboratory kickback schemes. With these settlements, DOJ has secured more than $59 million in civil FCA settlements for kickbacks to healthcare providers disguised as MSO investment distributions, including recoveries from 50 physicians.

CMS regulatory updates

CMS LAUCHES $50B RURAL HEALTH TRANSFORMATION PROGRAM

The One Big Beautiful Bill Act created a $50 billion RHT Program to strengthen healthcare across the rural United States. The RHT Program aims to advance five strategic goals: improving health outcomes, supporting rural health innovations, enhancing sustainable access, developing the healthcare workforce, and fostering innovative care models and technologies. The $50 billion fund will be allocated to approved states, with 50% of the funding distributed equally across all states that have approved applications and the other 50% distributed by CMS based on a variety of factors. CMS released a notice of funding opportunity with application details; applications are due by November 5, 2025, with awards to be decided by December 31, 2025. While only states are eligible to apply, many states are soliciting feedback and comments from stakeholders on how RHT Program funds should be used.

For more information on the RHT Program, please see our client alert.

CMS ANNOUNCES PRIOR AUTHORIZATION DEMONSTRATION FOR CERTAIN ASC SERVICES

CMS announced that it will start a five-year prior authorization demonstration for certain cosmetic services provided in ASCs in California, Florida, Texas, Arizona, Ohio, Tennessee, Pennsylvania, Maryland, Georgia, and New York. The demonstration targets blepharoplasty, botulinum toxin injections, panniculectomy, rhinoplasty, and vein ablation procedures. Providers can submit prior authorization requests beginning on December 1, 2025, for dates of service on or after December 15, 2025. While prior authorization is voluntary, if a provider elects to bypass prior authorization, applicable ASC claims will be subject to a prepayment medical review.

OIG updates

OIG ISSUES FAVORABLE AO ON FINANCIAL CONTRIBUTIONS TO RELATED CHARITABLE FOUNDATION

OIG published a favorable AO on September 11, 2025, stating that a healthcare provider's contributions to a related charitable foundation would not be grounds for civil monetary penalties or exclusion from federal healthcare programs under the Beneficiary Inducement Statute or the AKS. The requestor provides therapy in connection with children with a particular disorder. As part of its treatment program, the provider uses a "family-powered" therapy model under which parents and caregivers receive necessary training to participate in therapy for their children. This model typically requires parents and caregivers to commit to 15 or more hours of therapy each week, including during working hours, which can create a financial burden, particularly for lower-income families. Certain provider employees (including an executive) formed a charitable foundation to provide grants to help offset some of the expenses for families who participate in the provider's family-powered therapy model.

To receive funds from the foundation, each family must:

- Meet certain household income limits
- Have a child receiving the requisite therapy on a certain therapy plan, although the child is not required to receive therapy from the requestor or any other therapy provider
- Not receive any other compensation related to the family's participation in the program.

The provider has donated about $300,000 to the foundation, and the provider and foundation certified that the donations were not contingent on referrals and that the foundation has full autonomous control over use of the funds. The provider and foundation also certified that the provider does not solicit or receive any data from the foundation about how the donations are used.

OIG asserted that the arrangement includes two types of remuneration that implicate the AKS: the provider's investment of resources to establish and initially operate the foundation (including monetary donations), and the foundation's use of donations to fund grants for families. OIG noted that the grants implicate the beneficiary inducement statute. However, OIG concluded that the arrangement presents a sufficiently low risk of fraud and abuse. OIG concluded that arrangement is unlikely to lead "overutilization or inappropriately increased costs to [f]ederal health care programs." Critical to this conclusion was that the grant funding is not likely incentivize a healthcare provider to prescribe unnecessary therapy for children, because the families receive the grants (not the providers) and the grants are not required to be used for cost-sharing amounts.

OIG also concluded that the arrangement is unlikely to lead to inappropriate steering or unfair competition because:

- The donations are unrestricted and not contingent on referrals by the foundation.
- The foundation is a nonprofit and tax-exempt organization that awards grants to family in an objective way, and the provider no longer has employees serving on the foundation's board of directors and by the end of 2025 will not have any employees who work or volunteer for the foundation.
- The foundation's grants are not dependent on the use of the provider or an affiliate for therapy services (*i.e.*, the patient can seek services from independent providers).

Therefore, OIG concluded that the risk of fraud and abuse or beneficiary inducement is low and issued the favorable AO. The AO is limited to the requestor and its specific situation, but OIG laid out general factors to consider if a healthcare provider makes payments to a related charitable organization that provides grants to the provider's patients.

OIG FLAGS FRAUD, ABUSE CONCERNS RAISED BY SKIN SUBSTITUTES

OIG issued a report highlighting the significant growth of Medicare payments for skin substitutes and calling for action to address fraud, waste, and abuse in skin substitute billing. Part B expenditures for skin substitutes provided in noninstitutional settings have increased by more than 640% over the last two years, according to OIG. Medicare Part B paid more than $10 billion for skin substitutes in 2024, meaning these products accounted for more than 15% of Medicare's spending on all Part B drugs that year.

The report raises concerns regarding several aspects of Part B spending trends for skin substitutes, including:

- Large increases in the number of enrollees with skin substitute claims and the amount of product billed for each enrollee, particularly in connection with in-home care.
- A large gap in spending between Part B and Medicare Advantage (MA).
- A steep rise in the cost of individual skin substitutes combined with providers' propensity to shift to more expensive products.

OIG detailed factors that may be driving these trends, including manufacturers' ability to quickly bring new skin substitutes to the market compared to typical products paid using Average Sales Price, and financial incentives that make certain products more attractive to providers under Medicare's reimbursement system. Under the current payment system, Part B often pays providers for skin substitutes at much higher rates than the providers' purchase prices. According to OIG, this creates an incentive to bill for more units of skin substitutes and to choose products with the greatest profit.

OIG's report acknowledges that this profit is the product of the reimbursement system and recommends that CMS change the system. The report notes that CMS has recently taken steps to address these concerns, including:

- Proposing changes to the Part B payment methodology for skin substitutes in the CY 2026 Physician Fee Schedule. CMS estimates that under the proposals, Medicare Part B spending for skin substitutes would be reduced by $9.4 billion in CY 2026.
- Launching the WISeR model, which uses utilization management and AI technologies to implement and streamline prior authorization for potentially fraudulent, wasteful, or harmful high-cost services in Medicare Part B, including skin substitutes.

CMS also announced on April 25, 2024, that the Medicare Administrative Contractors had proposed a new LCD specifically addressing the use of skin substitutes for chronic, non-healing diabetic foot ulcers and venous leg ulcers. These updated policies would introduce more stringent coverage criteria, including a defined list of covered and noncovered products, and would set forth limitations for determining medical necessity. One of the most notable changes in the proposed LCD is a significant reduction in the number of covered skin substitute products. Originally scheduled to take effect on February 12, 2025, implementation of the new LCD was postponed to April 13, 2025, in accordance with the Trump administration's "regulatory freeze" executive order. On April 11, 2025, CMS issued a press release announcing a further delay, pushing the effective date to January 1, 2026. CMS also invited stakeholders to submit peer-reviewed publications and high-quality clinical findings related to skin substitute products by November 1, 2025. These submissions will be reviewed to determine whether further revisions to the LCD are warranted.

These changes would significantly impact Part B Medicare reimbursement for skin substitutes and could result in restricted access to these products for beneficiaries.

OIG ISSUES REPORT ON PROVIDER RELIEF FUND BALANCE BILLING REQUIREMENTS

OIG published a report summarizing its audit of hospitals that received Provider Relief Fund distributions during the COVID-19 public health emergency and their compliance with the balance billing requirement. Upon accepting funds, recipients agreed to not collect or try to collect out-of-pocket payments from patients who sought treatment for actual or presumptive COVID-19 from an out-of-network hospital. OIG reviewed 25 hospitals that received funds and found that 17 either did not comply or may not have complied with this requirement.

The audited hospitals indicated that the improper or potentially improper billings occurred because they were uncertain about how to comply with the balance billing requirement because of insufficient guidance from the Health Resources and Services Administration (HRSA). OIG recommended that HRSA review whether the audited hospitals made refunds to the identified patients and perform post-payment reviews of hospitals for balance billing requirements. HRSA noted in response that it agrees with OIG's recommendations, which may indicate that a broader review of hospital compliance with the Provider Relief Fund balance billing requirement is forthcoming.

OIG ADDS MA ENROLLMENT MANIPULATION SCHEMES TO WORKPLAN

OIG updated its work plan to include a review of MA enrollment manipulation schemes. OIG noted that the MA program is vulnerable to schemes designed to increase MA organization profits by improperly influencing enrollment. Examples of such schemes include enrolling people into MA plans without their consent, structuring incentive payments to agents to minimize enrollment of people with disabilities, and paying kickbacks to providers in exchange for enrollments. OIG noted that enrollment manipulation schemes have been identified primarily through whistleblowers, with minimal visibility into schemes that go unreported. To address this gap, OIG plans to conduct a large-scale analysis of enrollment and disenrollment data to identify aberrant patterns that may signal improper MA organization actions to influence enrollment. OIG expects to issue its report in fiscal year 2027.

Other notable developments

HHS ANNOUNCES ENFORCEMENT CRACKDOWN ON INFORMATION BLOCKING

HHS recently announced that it will increase resources dedicated to "curbing the harmful practice" of information blocking. HHS followed its press release with a joint enforcement alert with OIG and the Assistant Secretary for Technology Policy/Office of the National Coordinator (ASTP/ONC), the HHS regulatory body that oversees technology, data, and interoperability initiatives. The press release and enforcement alert state that ASTP/ONC and OIG will lead this initiative.

The information blocking provisions, established in the 21st Century Cures Act and implemented through subsequent HHS rulemaking, apply to certified health information technology (IT) developers, health information networks and exchanges, and healthcare providers. Violations of information blocking rules have varying and potentially steep penalties, including:

- Civil monetary penalties up to $1 million (adjusted for inflation) for each violation by health IT developers of certified health IT and health information networks or health information exchanges
- Termination of health IT certification
- Disincentives for certain healthcare providers under various CMS programs.

For more information, see our in-depth review of the information blocking rules and the anticipated enforcement push.

MAHA COMMISSION UNVEILS SWEEPING "MAKE OUR CHILDREN HEALTHY AGAIN" STRATEGY

The MAHA Commission released the "Make Our Children Healthy Again" strategy document, which outlines nearly 130 recommendations, calling for a wide range of executive actions and policy reforms to improve children's health and tackle rising chronic disease. A previous assessment from the MAHA Commission identified potential drivers of childhood chronic disease as poor diet, chemical exposure, lack of physical activity, chronic stress, and overmedicalization. The commission's recommendations include actions to advance research, realign incentives, restructure agencies, foster private-sector collaboration, and increase public awareness. The strategy would require action from HHS, CMS, FDA, the Centers for Disease Control and Prevention, the National Institutes of Health, the Environmental Protection Agency, and the US Department of Agriculture. If implemented, the strategy would have broad impacts on the healthcare system, including payors, hospitals, providers, manufacturers, and researchers.

FDA DIGITAL HEALTH ADVISORY COMMITTEE WILL EXAMINE AI-ENABLED MENTAL HEALTH MEDICAL DEVICES

The FDA Digital Health Advisory Committee will meet on November 6, 2025, to discuss and make recommendations on generative-AI-enabled digital mental health medical devices. FDA noted the increasing demand for mental health services in the US and insufficient access to mental health care providers, acknowledging such devices may be one way to help address gaps in care for people. The committee will discuss the benefits, risks to health, and risk mitigations that might be considered for these new devices, including premarket evidence and postmarket monitoring considerations. The committee meeting will be open to the public. Public comment will be open until December 8, 2025; comments received on or before October 17, 2025, will be provided to the committee in advance of the meeting.

HHS, FDA ANNOUNCE CRACKDOWN ON DECEPTIVE DRUG ADVERTISING

US President Donald Trump signed a presidential memorandum on September 9, 2025, directing HHS to ensure transparency and accuracy in direct-to-consumer (DTC) prescription drug advertisements, and directing FDA to take action to enforce existing prescription drug advertising laws to ensure that DTC ads are truthful and not misleading. The same day, FDA and HHS announced efforts to crack down on deceptive drug advertising, and released a fact sheet regarding their efforts. HHS and FDA stated that the "explosion of DTC pharmaceutical advertising following 1997 has led to (1) public deception from patient confusion, (2) patient harm via inappropriate demand for medications and misalignment of therapeutic choices with actual patient needs, and (3) harm to the public finances via misallocation of healthcare resources, including government spending."

FDA announced that it would begin aggressive enforcement of DTC violations. FDA sent thousands of letters warning pharmaceutical companies to remove misleading ads and issued about 100 cease-and-desist letters to companies with deceptive ads. FDA noted that going forward, it will aggressively deploy its available enforcement tools, including AI and other tech-enabled tools to proactively surveil and review drug ads.

FDA also announced that is initiating rulemaking to close the "adequate provision" loophole created in 1997. FDA claimed that drug companies have used the loophole to conceal critical safety risks in broadcast and digital ads, fueling inappropriate drug use and eroding public trust. Until 1997, pharmaceutical ads were required to report full contraindications, boxed warnings, and common precautions in advertisements. The "adequate provision" rules allows drug companies to provide a major risk statement and point viewers to a website, toll-free number, or print insert for more complete information. FDA also raised concerns about the use of digital and social media channels, including undisclosed paid influencer promotions.

HHS, CMS SEND DRUG PRICING PILOT TO WHITE HOUSE FOR REVIEW

On September 25, 2025, HHS and CMS sent a proposed drug pricing policy, the Global Benchmark for Efficient Drug Pricing Model, to the White House. HHS has not provided comments on the details of the policy, but prior to the government shutdown the policy was under review and will need to pass review by the Office of Management and

Budget before going into effect. This proposed policy is part of a larger focus on pharmaceutical pricing by the Trump administration. In May 2025, President Trump signed an executive order giving pharmaceutical drugmakers 30 days to lower prices, threatening "further action" if significant progress had not been made. The president also announced a 100% tariff on any pharmaceutical not manufactured in the US, effective October 1, 2025.

For more details on the administration's push to lower drug pricing, see our recent client alert.

FTC CHAIRMAN WARNS HEALTHCARE EMPLOYERS, STAFFING COMPANIES ABOUT NONCOMPETES

Federal Trade Commission (FTC) Chairman Andrew N. Ferguson issued letters to large healthcare employers warning that the FTC will take action against overly broad or unjustifiably restrictive noncompetes that limit worker mobility or patient choice. The letters encourage recipients to conduct a comprehensive review of employment agreements, including noncompetes and other post-employment restrictions, and eliminate provisions that are unfair or anticompetitive. The agency noted that enforcement will focus on roles such as nurses, physicians, and other medical professionals. With this move, the FTC signaled a shift toward case-by-case enforcement.

For more information on these letters and the FTC enforcement landscape, please see our recent client alert.

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