McDermott Will & Schulte

Healthcare Regulatory Check-Up

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January regulatory update summary

This issue of McDermott Will & Schulte's *Healthcare Regulatory Check-Up* highlights regulatory activity for January 2026. The US Department of Health and Human Services (HHS) Office of Inspector General (OIG) issued two advisory opinions and a special bulletin analyzing direct-to-consumer prescription drug platforms, including TrumpRx. The US Department of Justice (DOJ) issued two reports discussing enforcement activity in 2025. The Centers for Medicare & Medicaid Services (CMS) withdrew local coverage determinations for skin substitutes, released the Outpatient Prospective Payment System drug acquisition cost survey, introduced a new Innovation Center model, and published the advance notice of changes to calendar year (CY) 2027 Medicare Advantage (MA) and Part D rates. Several notable settlements also occurred in January, resulting from *qui tam* False Claims Act (FCA) investigations and civil cases.

OIG updates

OIG ISSUES UNFAVORABLE ADVISORY OPINION ON HOME CARE ATTENDANT SIGN-ON BONUSES

OIG issued Advisory Opinion 25-12, analyzing a proposal by a home care agency to advertise sign-on bonuses as a mechanism to recruit home care attendants. OIG concluded that the arrangement would implicate the federal Anti-Kickback Statute (AKS) because the attendants would typically be family members of the home care clients and in many cases would be in the position of helping select the home care agency from which those clients would receive services reimbursable by the state Medicaid program.

OIG determined that even though the attendants would be bona fide employees of the home care agency, the proposed sign-on bonus would not satisfy the AKS bona fide employee safe harbor. OIG saw an "inextricable link" between employment of the attendant and referral of clients, viewing the sign-on bonus as a means of securing business rather than simply compensating employees. OIG expressed concern that such bonuses could steer patients toward agencies offering higher payments, create unfair competition by pressuring agencies to increase bonuses, and lead attendants to choose agencies based on financial incentives rather than quality of care.

OIG also determined that the proposed arrangement would implicate the civil monetary penalty (CMP) provision prohibiting inducements to beneficiaries (known as the "Beneficiary Inducements CMP") because the sign-on bonus was

likely to influence attendants to select the home care agency for their family members for the provision of services reimbursable by Medicaid, rather than another agency. As a result, OIG concluded the proposed arrangement would constitute prohibited remuneration under both the AKS and the beneficiary inducements CMP, which would constitute grounds for the imposition of sanctions under both statutes if the requisite intent were present.

OIG ISSUES FAVORABLE ADVISORY OPINION ON CLINICAL LABORATORY'S WAIVER OF COST-SHARING OBLIGATIONS

OIG issued Advisory Opinion 26-01, concluding that a clinical laboratory's proposal to waive cost-sharing obligations for certain commercially insured patients receiving a US Food and Drug Administration (FDA)-approved colorectal cancer screening test would not pose significant fraud and abuse concerns under the federal AKS or the beneficiary inducements CMP. Although the FDA approved the test in 2024, it is not yet included in the US Preventive Services Task Force recommendations, meaning commercial insurers are not required to cover it without cost sharing. Federal healthcare program coverage is generally limited, with some exceptions for certain Medicaid programs and Medicaid managed care organizations.

Under the proposed arrangement, the laboratory would uniformly waive cost-sharing for commercially insured patients who do not qualify for its financial assistance policy, regardless of which provider ordered the test. The laboratory would not provide remuneration to ordering providers. OIG concluded that the AKS would not be implicated because the arrangement does not involve remuneration to induce the use of items or services reimbursable by federal healthcare programs. OIG also concluded that the Beneficiary Inducements CMP would not be implicated because no remuneration would be offered to federal healthcare program beneficiaries that could influence their selection of services.

This opinion may signal OIG's evolving views on arrangements that carve out federal healthcare program beneficiaries, particularly where federal healthcare program coverage is limited and for services such as lab tests that typically do not have copays when covered.

OIG ISSUES SPECIAL ADVISORY BULLETIN ON TRUMPRX

The Trump administration recently launched TrumpRx, a platform to connect cash-paying patients seeking lower-cost prescription drugs with direct-to-consumer (DTC) programs offered by manufacturers and other private companies. On January 27, 2026, OIG issued a Special Advisory Bulletin to address the application of the AKS to a pharmaceutical manufacturer's offer and sale of lower-cost prescription through a DTC program to cash-paying patients, including federal healthcare program enrollees. The bulletin outlines the circumstances in which an offer or sale may present low risk under the statute.

OIG identified two primary ways that pharmaceutical manufacturers' DTC sales to federal healthcare program enrollees could be problematic under the AKS:

- The pharmaceutical manufacturer might offer the federal healthcare program enrollee a prescription drug at a lower cost than otherwise may be available to the enrollee as a marketing tool to induce the enrollee to purchase other prescription drugs, items, or services manufactured or offered by that pharmaceutical manufacturer for which payment may be made, in whole or in part, by a federal healthcare program.

- The manufacturer might use the DTC program to influence enrollees to take the manufacturer's drug, with an expectation that the enrollees' federal healthcare program might be billed for the drug in the future (*e.g.*, if the drug became more affordable through the enrollee's federal healthcare program coverage), sometimes known as a seeding program.

OIG found that with respect to the financial arrangement between the pharmaceutical manufacturer and a cash-paying patient who is a federal healthcare program enrollee, there was a low risk that the manufacturer would violate the AKS, provided that:

- The prescription drug is not billed to a federal healthcare program.
- The sale of the prescription drug is not conditioned on the current or future order or purchase of any other item or service that is or could become billable to a federal healthcare program.
- The arrangement aligns with the other risk-minimizing characteristics, including that the individual has a valid prescription, no drug claims are submitted to any insurer (including federal healthcare programs), and the pharmaceutical manufacturer does not use the DTC program for one product as a vehicle to market other federally reimbursable products it manufactures or services it provides.

The bulletin recommends that pharmaceutical manufacturers operating DTC programs establish mechanisms to communicate with the federal healthcare program enrollee's plan (*e.g.*, Medicare Part D, MA, Medicaid) to facilitate appropriate drug utilization review and medication therapy management.

The bulletin does not address the application of the AKS to any arrangements that the pharmaceutical manufacturer may have with physicians, pharmacies, pharmacy benefit managers (PBMs), telemedicine vendors, marketers, or other individuals or entities, nor does it address any arrangements that those individuals or entities may have among themselves or with federal healthcare program enrollees. OIG acknowledges that "because DTC programs have only recently begun to proliferate, it is impossible to predict the ways in which abuse may occur in such programs and how best to minimize the risk of such abuse. Consequently, this Bulletin cannot, and is not intended to, be an exhaustive or definitive discussion of relevant risks of DTC programs."

OIG also issued a request for information on whether any additions or modifications are necessary to the safe harbor regulations under the AKS or Beneficiary Inducements CMP for emerging DTC sales programs established by pharmaceutical manufacturers, including those that will be available through TrumpRx. Stakeholders, including telehealth companies and drug manufacturers, should consider submitting comments by the March 30, 2026, deadline.

OIG ISSUES FALL 2025 SEMIANNUAL REPORT TO CONGRESS

On January 21, 2026, OIG released its Fall 2025 Semiannual Report to Congress, which highlights OIG's fraud detection and enforcement activities from April 2025 to September 2025:

- OIG noted that by using advanced data analytics, it detected potentially concerning trends warranting follow-up from HHS or other investigators, including a 640% increase in Medicare Part B expenditures for skin substitutes provided in noninstitutional settings over the last two years.
- OIG noted that its investigations led to 352 criminal actions and 481 civil actions. The fraudulent schemes most often related to durable medical equipment, diagnostic testing, telemedicine, wound care, and drug diversion.
- OIG recommended that Wisconsin refund $12.2 million in improper payments for services provided to children diagnosed with autism that did not comply with federal and state requirements.
- OIG prioritized oversight of managed care and expressed concern that high-risk diagnosis codes were not being submitted in compliance with federal requirements.

DOJ updates

DOJ RELEASES 2025 REPORT ON FCA SETTLEMENTS

The DOJ issued a press release announcing that settlements and judgments under the FCA exceeded $6.8 billion in the fiscal year ending September 30, 2025, representing the highest amount in a single year in the history of the FCA. Of the $6.8 billion recovered, $5.7 billion related to matters involving healthcare fraud. In 2025, whistleblowers filed 1,297 *qui tam* lawsuits, the most in a single year, and the government opened 401 investigations. FCA settlements and judgments since 1986, when Congress substantially strengthened the civil FCA, now total more than $85 billion.

DOJ ISSUES 2025 YEAR-IN-REVIEW REPORT

The DOJ Criminal Division Fraud Section published a year-in-review report summarizing notable accomplishments and developments in 2025. The Fraud Section comprises four units, including the Health Care Fraud (HCF) Unit, which works in tandem with US and state attorneys' offices, the OIG, the Federal Bureau of Investigation, the US Drug Enforcement Administration, and other federal and state law enforcement agencies to prosecute healthcare fraud schemes nationwide, including large-scale fraud involving Medicare, Medicaid, TRICARE, and other benefit programs.

Per the report, the HCF Unit had a record-setting year in 2025. It lead the largest national healthcare fraud takedown in DOJ history, charged more than $15 billion in alleged loss, forfeited and returned to the public fisc more than $560 million, and brought four corporate matters.

The national healthcare fraud takedown represented a coordinated, nationwide effort to combat and deter healthcare fraud. The HCF Unit, US attorneys' office partners, and state attorneys' general offices charged 324 individuals, including 96 licensed medical professionals, in 50 federal districts and 12 state jurisdictions. These cases involved alleged participation in healthcare fraud schemes with an intended loss exceeding $14.6 billion. Law enforcement seized more than $245 million in cash, luxury vehicles, cryptocurrency, and other assets. CMS prevented more than $4 billion in fraudulent payments, and suspended or revoked the billing privileges of 205 providers. Civil charges were also filed against 20 defendants for $14.2 million in alleged fraud, and civil settlements totaled $34.3 million from 106 defendants.

CMS regulatory updates

CMS WITHDRAWS LOCAL COVERAGE DETERMINATIONS FOR SKIN SUBSTITUTES

Medicare Administrative Contractors withdrew Local Coverage Determinations (LCDs) for skin substitute grafts and cellular and tissue-based products for the treatment of diabetic foot ulcers and venous leg ulcers. These LCDs were set to become effective on January 1, 2026, and would have significantly reduced the number of skin substitute products eligible for Medicare coverage and reimbursement.

CMS RELEASES OPPS DRUG ACQUISITION COST SURVEY

The Outpatient Prospective Payment System (OPPS) Drug Acquisition Cost Survey is available for submission until March 31, 2026. CMS implemented this survey in November 2025 when it published the CY 2026 Hospital OPPS and Ambulatory Surgical Center Payment System final rule. The survey's goal is to gather data regarding hospital acquisition costs for covered outpatient drugs at hospital outpatient departments. CMS indicated that rulemaking will occur before it uses the survey data to alter payment rates under Medicare, but suggested that the data could be used to set CY 2027 OPPS payment rates.

CMS INTRODUCES WISER MODEL TO IMPROVE CLAIM REVIEW PROCESS

CMS created the Wasteful and Inappropriate Service Reduction (WISeR) model to expedite the claims review process for services that are susceptible to fraud and abuse. The model leverages artificial intelligence and machine learning (in addition to human review) to apply commercial payer processes faster and more accurately. WISeR was implemented on January 1, 2026, in New Jersey, Ohio, Oklahoma, Texas, Arizona, and Washington and will run until December 31, 2031. The model is particularly focused on claims for skin and tissue substitutes, electrical nerve stimulator implants, and knee arthroscopy. Model participants will receive a portion of the costs saved by preventing unnecessary services and fraud in exchange for their reviews.

CMS RELEASES ADVANCE NOTICE OF CHANGES TO CY 2027 MA AND PART D RATES

CMS announced proposed changes to the CY 2027 MA and Medicare Part D capitation rates. The net payment increase is projected to be 2.54%. To account for differences in coding between MA and fee-for-service, CMS plans to reduce MA risk scores by 5.9%. To align with the Inflation Reduction Act of 2022's changes to Medicare Part D benefit design, CMS will change the RxHCC risk adjustment model by applying the new benefit design to historical spending. CMS will announce the final rates by April 6, 2026.

Notable cases, settlements, and related agency activity

HEALTH PLANS SUE PHARMACEUTICAL MANUFACTURER OVER ALLEGED ANTICOMPETITIVE PRACTICES

After health plans filed an amended complaint, a federal judge in Illinois allowed a class action to proceed against a pharmaceutical manufacturer. The health plans allege that the pharmaceutical company bribed PBMs to suppress generic competition for its drug. According to the amended complaint, the PBMs designated the generic a specialty drug and had it placed at higher tiers than the manufacturer's drug in exchange for rebates. The health plans assert that this conduct aims to preserve the manufacturer's market dominance in violation of the Sherman Act, Robinson-Patman Act, and the Racketeer Influenced and Corrupt Organization Act.

DOJ, LAB SETTLE ALLEGATIONS OF INFLATED BILLS

A Seattle-based medical testing laboratory resolved allegations that it improperly billed Medicare when it requested permission to bill a series of urinary tract infection tests as a panel, had its request denied, and then billed the tests under multiple billing codes instead of a single code. The company agreed to pay $2 million to resolve the matter without admitting fault.

HOME HEALTH COMPANY WILL PAY $34M TO RESOLVE FCA LIABILITY

A home healthcare company agreed to pay $34 million to resolve allegations under the FCA that it billed medically unnecessary home health claims to Medicare and provided financial benefits to physicians in exchange for referrals. The home healthcare company self-disclosed the matter to the government. The government credited the company for its extensive cooperation with the investigation, including the provision of detailed and thorough written disclosures to the government and the prompt implementation of remedial actions, including removing individuals identified as responsible for the misconduct, improving its compliance program, and providing additional training to employees.

LAB OWNER PLEADS GUILTY TO $52M FRAUD SCHEME INVOLVING GENETIC TESTS

A Florida man pleaded guilty for his role in a scheme to defraud Medicare by submitting more than $52 million in false and fraudulent claims for medically unnecessary genetic testing ordered for Medicare beneficiaries based on prescriptions purchased through illegal kickbacks and bribes. The man owned and operated two laboratories through which he purchased doctors' orders for expensive genetic testing from patient recruiters who ran deceptive

telemarketing campaigns that targeted Medicare beneficiaries and persuaded them to agree to take the tests to justify the fraudulent billing. The man pleaded guilty to conspiracy to commit healthcare fraud and conspiracy to offer and pay kickbacks. He is scheduled to be sentenced on April 16, 2026, and faces a maximum penalty of 15 years in prison.

LAB AGREES TO PAY AT LEAST $6.8M TO SETTLE KICKBACK ALLEGATIONS

A South Carolina laboratory company and its founder and CEO agreed to pay at least $6.8 million to resolve FCA allegations involving payment of illegal kickbacks to physicians. From August 2018 to November 2021, the company and its CEO allegedly paid physicians kickbacks to induce them to order the company's laboratory tests. In an attempt to cover up the kickbacks, the company and its CEO allegedly hand-delivered money orders for some payments, entered into contracts that falsely described the payments as being made for office space rental or phlebotomy or toxicology services, and falsified square footage and hours in "fraud and abuse" certification forms. The settlement also resolves allegations that from September to December 2016, the company and its CEO arranged to pay a North Carolina-based physician practice an inflated amount for used laboratory equipment to induce the practice to order the company's testing. With this settlement, the DOJ secured more than $11.5 million in civil FCA settlements related to the company, including recoveries from nine doctors. In addition to the civil settlement, the company agreed to plead guilty to five counts of offering and paying kickbacks in violation of the AKS.

Other notable developments

HHS ANNOUNCES 2026 FEDERAL CIVIL PENALTIES ADJUSTMENTS

Pursuant to the Federal Civil Penalties Inflation Adjustment Act Improvements Act of 2015, on January 28, 2026, HHS updated its regulations to reflect required annual inflation-related increases to the CMP amounts in its statutes and regulations. The annual inflation adjustment for each applicable CMP is determined using the percentage increase in the Consumer Price Index for all Urban Consumers (CPI-U) for October of the year in which the amount of each CMP was most recently established or modified.

DEPARTMENT OF LABOR PROPOSES PBM FEE DISCLOSURE RULE

The US Department of Labor proposed disclosure requirements for PBMs to fiduciaries of employer-sponsored self-insured health plans. The proposal's intent is to provide fiduciaries with tools to address rising drug costs. The disclosures would include payments from drug manufacturers, price protection arrangements, spread compensation, and payments recouped from pharmacies in relation to prescription drugs dispensed to the plans. The proposed rule would implement an executive order issued by the Trump administration in April 2025 that was intended to create a more competitive drug market with lower costs and greater accountability. Under the proposed rule, disclosures by PBMs would also be subject to audits by the fiduciaries to ensure accuracy.

FDA RELEASES 2026 PRIORITY DELIVERABLES FOR HUMAN FOODS PROGRAM

On January 23, 2026, the FDA announced its 2026 priority deliverables for the Human Foods Program (HFP) in furtherance of the Trump administration and HHS Secretary Robert F. Kennedy, Jr.'s Make America Healthy Again initiative. The HFP was created to improve the FDA's regulation of the US food supply. To achieve greater food chemical safety, the FDA will prioritize using natural color additives, reducing the contaminants in food for children, researching methods to detect microplastics in food, and requiring notice for new "generally recognized as safe" substances. To reduce the occurrence of chronic illness, the FDA intends to further define ultra-processed foods, increase access to safe infant formula, encourage the food industry to use less sodium and added sugar, and limit marketing of certain foods to children. To promote microbiological food safety, the FDA will modernize recall process,

release an updated food code reflecting best practices and data on outbreaks, and collaborate with states to conduct more routine safety inspections.

TRUMP ADMINISTRATION RELEASES "GREAT HEALTHCARE PLAN"

On January 15, 2026, US President Donald Trump unveiled the "Great Healthcare Plan," a policy framework intended to lower prices and maximize transparency. One of the plan's goals is to codify the administration's most favored nations deal to reduce drug prices and make more drugs available for over-the-counter purchase. To lower insurance premiums, the plan seeks to fund a cost-sharing reduction program for health insurance plans that would save taxpayers $36 million, in addition to ending kickbacks paid by PBMs to middlemen that raise insurance costs. The plan will require insurance companies to publish rate and coverage comparisons in easy-to-understand language so consumers can make informed coverage decisions. The plan will also mandate certain data reporting, including the percentage of insurance companies' revenue paid out to claims versus profits and overhead costs, and average wait times for routine care. Healthcare providers or insurers that accept Medicare or Medicaid will be required to prominently post their pricing and fees inside of their businesses.

EXECUTIVE ORDER CALLS FOR INITIATIVES TO ADDRESS ADDICTION CRISIS

On January 29, 2026, President Trump issued an executive order to create the White House Great American Recovery Initiative to address the US addiction crisis. The initiative will be led by HHS Secretary Kennedy and the senior advisor for addiction recovery. The executive order states that addiction is contributing to family instability, increased healthcare costs, and a decrease in workforce participation. It directs the initiative to increase awareness of addiction as a disease; set clear objectives for the federal government's response to the addiction crisis; and advise agencies on how to implement programs and grants that will support prevention, treatment, and early intervention.

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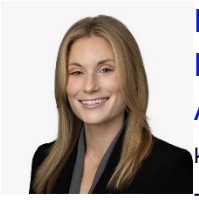

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