HEALTHCARE REGULATORY CHECK-UP

IN THIS JANUARY 2025 ISSUE

MWE.COM

JANUARY REGULATORY UPDATE SUMMARY

This issue of McDermott's *Healthcare Regulatory Check-Up* highlights regulatory activity for January 2025. This month features long-awaited proposed and final rules regarding the Health Insurance Portability and Accountability Act (HIPAA) and controlled-substance prescribing via telemedicine. Active False Claims Act (FCA) cases include two hospitals defending against criminal and civil charges related to their alleged complicity in medically unnecessary surgeries. Settlements from this month include familiar themes such as lavish physician speaker programs, a dental pay-per-referral marketing arrangement, and fraudulent durable medical equipment (DME) prescribing via telemedicine. The Office of Inspector General (OIG) issued a favorable advisory opinion on a pharmaceutical manufacturer's program to provide free infusion drugs to patients with financial need. Finally, the change of presidential administration has resulted in a flurry of executive actions and regulatory freezes.

NOTABLE CASES, SETTLEMENTS, AND RELATED AGENCY ACTIVITY

FOURTH CIRCUIT UPHOLDS DISTRICT COURT RULING AGAINST PCPA, ADOPTS BROAD INTERPRETATIONS OF KEY AKS TERMS

On January 23, 2025, the US Court of Appeals for the Fourth Circuit ruled against Pharmaceutical Coalition for Patient Access's (PCPA) challenge to an unfavorable OIG advisory opinion concerning a charitable patient assistance program. The ruling, which upheld the underlying district court decision, is notable for its broad interpretations of two key Anti-Kickback Statute (AKS) terms: "induce" and "remuneration." The Fourth Circuit declined to adopt a narrower read of "induce" that would require inclusion of a criminal element, opting to construe the word under its "ordinary meaning" rather than applying a specialized criminal law meaning (despite the AKS being a criminal law). The Fourth Circuit also adopted a broad definition of the term "remuneration," declining to require that the meaning include a "corrupt payment that distorts the medical decision-making process." Rather, it again adopted its ordinary meaning of "payment or compensation." However, the Fourth Circuit sidestepped the issue of whether an AKS violation

McDermott Will & Emery

requires a *quid pro quo*. The ruling is a potential setback for PCPA and manufacturers seeking ways to ease patient financial burden. Whether PCPA will continue to pursue its positions in a subsequent appeal remains to be seen.

PHARMACEUTICAL COMPANY AGREES TO PAY $59.7 MILLION TO RESOLVE AKS, FCA ALLEGATIONS RELATED TO MIGRAINE DRUG

A pharmaceutical company has agreed to pay $59.7 million to resolve allegations that its subsidiary violated the AKS by providing kickbacks to healthcare providers to induce prescriptions of its migraine drug, resulting in false claims to Medicare. According to the US Department of Justice (DOJ), from March 2020 through September 2022, the company allegedly provided improper remuneration to healthcare providers in the form of expensive restaurant meals, speaker honoraria, and other perks. The company allegedly selected providers for its speaker program and provided paid speaking opportunities with the intent to induce the providers to prescribe the drug. Some prescribers allegedly attended multiple programs on the same topic without educational benefit while other programs were attended by speakers' family members, friends, or colleagues who had no legitimate need to attend. The case originated from a *qui tam* complaint filed in August 2021 by a former sales representative. Under the settlement terms, the company will pay $50.2 million to the federal government and $9.5 million to state Medicaid programs; beyond this $59.7 million total, the company will pay $8.4 million to the whistleblower.

HOSPICE PROVIDERS CHALLENGE CMS'S SPECIAL FOCUS PROGRAM METHODOLOGY IN FEDERAL COURT

A coalition of hospice providers filed suit in Texas federal court challenging the Biden administration's Hospice Special Focus Program, which identifies and publicly lists facilities failing to meet Medicare requirements. The lawsuit alleges that the implementing regulation of the US Centers for Medicare & Medicaid Services (CMS) uses a flawed algorithm that erroneously identifies high-performing hospice facilities as poor performers. According to the complaint, while the 2020 Social Security Act amendment directed CMS to identify hospice providers substantially failing to meet Medicare requirements, only two of CMS's four evaluation criteria – condition level deficiencies and substantiated complaints – actually relate to Medicare compliance. The plaintiffs argued that the other two criteria – Medicare claims data and consumer evaluations – fall outside the scope of compliance measurement. The complaint also alleges that the algorithm fails to adjust for facility size when counting substantiated complaints, disadvantaging larger providers. The providers contend that despite receiving numerous expert comments raising these concerns during rulemaking, the US Department of Health and Human Services (HHS) largely dismissed them in finalizing the rule. The plaintiffs, which includes hospice facilities from Texas, Indiana, North Carolina, and South Carolina, argue that the program's public list of "poor performers" unfairly damages provider reputations and may mislead the public about quality of care. The case is pending in federal district court.

HEALTH SYSTEM TO PAY $135 MILLION TO RESOLVE ADDITIONAL FCA CLAIMS IN WHISTLEBLOWER SUIT

A health system has agreed to pay $135 million to resolve remaining FCA allegations brought by its former chief financial officer (CFO) and chief operating officer in a *qui tam* action. The settlement follows a previous $345 million settlement with the federal government in the same case and a $20.3 million settlement in 2015, bringing the system's total FCA-related payments to more than half a billion dollars in the past decade. The latest settlement resolves allegations that the health system violated the Stark Law by overpaying employed physicians and an independent oncology group that contracted exclusively with the organization. The settlement also addresses claims that the health system violated the AKS by paying above fair-market-value rent to a physician-owned real estate partnership to induce patient referrals to a health-system-owned ambulatory surgical center. The health system settled the claims with no admission of wrongdoing. The case originated from a *qui tam* complaint filed in 2014 by the former CFO, who was granted permission in 2020 to file an amended complaint asserting FCA claims separate from those pursued by the government.

> **A health system has agreed to pay $135 million to resolve remaining FCA allegations brought by its former chief financial officer and chief operating officer in a *qui tam* action.**

MEDICAL CENTER INDICTED FOR HEALTHCARE FRAUD RELATED TO UNNECESSARY SURGICAL PROCEDURES

A federal grand jury has indicted a medical center on criminal charges of healthcare fraud and conspiracy to defraud the United States for allegedly enabling and profiting from unnecessary surgeries performed by a surgeon. Charges against healthcare facilities are typically brought under civil statutes; this case represents a rare indictment of a hospital on criminal charges. According to the indictment, the medical center granted privileges to the surgeon from 1984 until his 2019 arrest, despite knowing his privileges had been terminated at another hospital for performing unnecessary surgeries and knowing of his 1996 federal felony convictions. The indictment alleges that the medical center and the surgeon conspired to defraud Medicare, Medicaid, TRICARE, and various private insurers by performing and billing for medically unnecessary procedures, including early elective deliveries and sterilizations without proper consent. Prosecutors claim the medical center allowed the surgeon to deviate from scheduling policies and continue practicing despite red flags, including altered medical records and inappropriate outpatient classifications of inpatient procedures. The charges follow the surgeon's November 2020 conviction on 52 counts of healthcare fraud and false statements, for which he was sentenced to 59 years in prison.

CMS WILL NOT PURSUE AN APPEAL IN MEDICARE ADVANTAGE RATINGS CASE

CMS abandoned plans to appeal a health plan's Medicare Advantage star ratings win. In September 2024, the health plan sued CMS in the US District Court for the Eastern District of Texas alleging that CMS violated the Administrative Procedure Act by not following the statute's requirements when reviewing the health plan's foreign language call center services for determining star ratings. When CMS issued industry ratings during the next month, the health plan had one of the largest score drops among large insurers. The district court ordered CMS to revise the health plan's score, and in December 2024, CMS gave higher ratings in 12 contracts to the health plan. This decision not to appeal was a reversal by the new acting US attorney on his first day in office.

THE SUPREME COURT WILL HEAR ARGUMENTS REGARDING THE CONSTITUTIONALITY OF THE US PREVENTIVE SERVICES TASK FORCE

> **"The Supreme Court of the United States will hear arguments in a case that could significantly impact health insurance coverage of preventative care.**

The Supreme Court of the United States will hear arguments in *Braidwood v. Becerra*, a case that could significantly impact health insurance coverage of preventive care. The suit challenges provisions in the Affordable Care Act requiring insurers to cover interventions that the US Preventive Services Task Force recommends without cost sharing. The US Preventive Services Task Force is an independent panel in HHS, and plaintiffs and two courts have said that it exercises enough power that the US Senate needs to confirm its participants. The Supreme Court will address this Senate confirmation issue, along with the related question of whether any unconstitutional provision should be severed from the statute.

HEALTH PLAN SETTLES FCA ALLEGATIONS INVOLVING THE AKS

On January 17, 2025, a health plan reached a settlement resolving FCA allegations against a health maintenance organization (HMO) that the health plan acquired in 2022. After the HMO began operating a Medicare Advantage plan in 2019, the HMO allegedly paid healthcare professionals and staff in doctors' practices to provide the HMO with contact information for patients who consented to the HMO contacting them about its Medicare Advantage plan. Additionally, the HMO allegedly made payments to four physicians that it described as advances on "coordination of care" services that physicians would provide beneficiaries once the HMO's plan was active in 2020. The government alleged the cash payments violated the AKS. Significantly, the health plan self-disclosed its conduct to the government, which earned it cooperation credit.

LABORATORY GRANTED SUMMARY JUDGMENT ON INDEPENDENT CONTRACTOR MARKETING ALLEGATIONS

A laboratory that uses the services of independent contractor marketing agents successfully defended against allegations that its commission-based compensation structure violated the AKS and FCA. In the complaint, the relator alleged that the laboratory violated

the AKS and FCA by paying independent contractors commissions that were based on the revenue generated from their accounts. The US District Court for the District of Massachusetts found that no reasonable jury could conclude that the submission of claims for lab testing resulted from the defendant's commission-based payments to independent contractors. The case offers a useful analysis of independent contractor compensation structures that do not strictly satisfy an AKS safe harbor, but nonetheless do not present material risk under the AKS.

CONNECTICUT DENTIST AND PRACTICES PAY $608,296 TO RESOLVE FCA, AKS ALLEGATIONS INVOLVING PATIENT REFERRAL KICKBACKS

A Connecticut dentist and her former dental practices have agreed to pay $608,296 to resolve allegations that they violated the federal and state FCA and AKS. The settlement resolves allegations that the practices paid $110 per patient to a third-party recruiting company for patient referrals, including referrals of Connecticut Medicaid patients, when patients received services beyond routine preventative care. The conduct allegedly occurred from January 2019 through April 2023. In a related criminal case, the dentist pleaded guilty to conspiracy to violate the AKS, admitting that between 2016 and 2023, she paid patient recruiters more than $360,000 in kickbacks, resulting in approximately $2.2 million in Medicaid reimbursements. On December 18, 2024, she was sentenced to two years of probation and ordered to forfeit $500,000. The investigation is part of a broader probe into healthcare providers allegedly submitting kickback-tainted claims to Connecticut Medicaid for services to Medicaid patients referred by third-party recruiting companies.

> **"The investigation is part of a broader probe into healthcare providers allegedly submitting kickback-tainted claims to Connecticut Medicaid for services to Medicaid patients referred by third-party recruiting companies.**

IOWA HEALTHCARE PRACTITIONERS PAY $164,326 TO RESOLVE DME TELEMEDICINE SCHEME ALLEGATIONS

Two Iowa healthcare practitioners have agreed to pay a combined $164,326 to resolve FCA allegations involving fraudulent Medicare billing through a telemedicine scheme. The individuals were alleged to have billed Medicare for false claims for office visits and medical discussions that never occurred, in addition to signing thousands of orders for medically unnecessary DME. According to prosecutors, both practitioners participated in a scheme where they ordered orthotic braces based solely on recorded cold calls to Medicare beneficiaries discussing common aches and pains, without any direct patient contact. Medicare beneficiaries reportedly received braces they neither wanted nor used. The investigation and settlement are evidence of continued enforcement focus on fraudulent DME and telemedicine arrangements.

CMS REGULATORY UPDATES

CMS ADDS NEW PRODUCT CATEGORY FOR RESPIRATORY DEVICES TO DMEPOS ENROLLMENT FORM

As of January 27, 2025, CMS has announced that it will now permit suppliers of durable medical equipment, prosthetics, orthotics, and supplies (DMEPOS) to bill Medicare for supplying multifunction respiratory devices (excluding ventilators). Existing DMEPOS suppliers may add these products to their enrollments through the Provider Enrollment, Chain, and Ownership System.

NEW PAYMENT BUNDLE FOR ADVANCED PRIMARY CARE MANAGEMENT SERVICES AVAILABLE JANUARY 1, 2025

Starting January 1, 2025, primary care providers enrolled in Medicare may utilize a new payment bundle for advanced primary care management (ACPM) services. The payment bundle combines several existing care management and technology-based communication services, such as disease-specific services, to help manage patient care for a single, complex chronic condition, transitional care management services, and chronic care management services. Eligible providers include physicians and non-

physician providers engaged in providing primary care services to patients. ACPM services may be billed once per patient per calendar month.

PHYSICIAN NONMONETARY COMPENSATION LIMITS UPDATED FOR 2025

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, 2025, the nonmonetary compensation limit is $519 (up from $507); the medical staff incidental benefit limit is set at "[l]ess than $45" (up from $44); and the maximum limited remuneration amount is $6,055 (up from $5,913).

OFFICE OF INSPECTOR GENERAL UPDATES

OIG ISSUES FAVORABLE ADVISORY OPINION REGARDING MANUFACTURER'S FREE MEDICATION PROGRAM

OIG issued a favorable advisory opinion regarding a pharmaceutical manufacturer's program to provide free access to an infusion drug for patients with demonstrated financial needs. The drug in question targets dementia and cognitive impairment. The drug is administered as an infusion every two weeks and is covered under Medicare Part B, meaning recipients of the drug are subject to a standard 20% coinsurance once they have met their Medicare Part B deductible. State Medicaid programs also cover the drug, with varying cost-sharing requirements.

The manufacturer's program provides the drug to patients at no cost if they have a household income below 500% of the federal poverty level and are uninsured, underinsured, or otherwise cannot afford Medicare out-of-pocket costs associated with the drug. Under the program, vials of the drug labeled with the patient's name are shipped to their infusion provider. The infusion provider may bill insurance programs for the administration of the drug but not the drug itself. Program enrollees who qualify receive the free drug for the remainder of the year, even if their insurance coverage changes, and must reapply at the end of each year to ensure they meet the eligibility criteria. Further, the infusions provider must make certain certifications as a condition of participating in the program.

> **"Because the program is available to all patients at all providers, OIG concluded there is low risk that the program would steer patients to a particular provider.**

OIG concluded that the arrangement does not satisfy an AKS safe harbor, but otherwise does not present material risk under the AKS. The arrangement is not likely to inappropriately increase costs to federal healthcare programs as the only billed cost to federal healthcare programs is the administration fee, which is billable regardless of whether the medically necessary drug is provided for free or reimbursed by Medicare. The arrangement is not likely to interfere with clinical decision-making, as prescribers and infusion providers do not have a financial incentive to order the drug when the drug is covered by the program because the prescriber and the infusion provider agree to not bill payors for the free drug. Finally, because the program is available to all patients at all providers, OIG concluded there is low risk that the program would steer patients to a particular provider. OIG also favorably noted that the program is administered based on reasonable, uniform, and consistent assessments of patient financial needs and without regard to the provider or insurance plan selected by the patients.

OIG also concluded that the program does not present material risk under the Beneficiary Inducements Civil Monetary Penalty Law as it is not likely to influence patient selection of a particular provider, practitioner, or supplier. Pharmaceutical manufacturers are not "providers, practitioners, or suppliers" unless they also own or operate, directly or indirectly, pharmacies, pharmacy benefits management companies, or other entities that file claims for payment under the Medicare or Medicaid programs. The requestor in this

opinion certified that it does not operate any such entities, and that its vendor is a noncommercial pharmacy that administers free product programs.

OTHER NOTABLE DEVELOPMENTS

NEW MASSACHUSETTS LAW IMPACTS HEALTHCARE PRIVATE EQUITY INVESTORS

Healthcare private equity investors will now encounter increased oversight under a new Massachusetts law. The law expands the definition of "material change" to encompass additional transactions that require pre-closing notice to the Massachusetts Health Policy Commission, such as transactions involving a "significant equity investor" that result in a change of ownership or control of a provider or provider organization. Further, the law will require private equity investors, among other types of entities, to follow financial reporting requirements from Massachusetts' Center for Health Information and Analysis, and there will be increased fines for noncompliance. The law also increases the Massachusetts Health Policy Commission's authority and allows the Commission to seek testimony from "significant equity investors" at its annual public hearing. For more information, please see our *On the Subject* on this new law.

HHS CHOOSES 15 DRUGS FOR MEDICARE DRUG PRICE NEGOTIATIONS

On January 17, 2025, HHS announced price negotiations for 15 drugs that are covered under Medicare Part D. The drugs treat a wide range of conditions ranging from cancer to diabetes to asthma. These negotiations occur in accordance with the Inflation Reduction Act of 2022, and any negotiated prices will go into effect in 2027. Drug companies with one of the chosen drugs must decide if they will engage in the negotiations by February 28, 2025.

OCR PROPOSES EXTENSIVE CHANGES TO HIPAA SECURITY RULE

The HHS Office for Civil Rights (OCR) published a proposed rule on January 6, 2025, proposing extensive changes to the HIPAA Security Rule. If finalized, the changes would be the first modifications to the Security Rule since 2013. Covered entities and business associates could face significant new compliance costs and obligations as a result of the proposals. For more information, see our *Special Report*.

DEA, HHS RELEASE FINAL RULES EXPANDING CONTROLLED SUBSTANCE PRESCRIBING VIA TELEMEDICINE

On January 17, 2025, the Drug Enforcement Administration (DEA) and HHS issued a final rule that allows practitioners to prescribe schedule III-V controlled substances for the treatment of opioid use disorder, including buprenorphine, via telemedicine (including audio-only encounters). An initial six-month supply can be prescribed by a practitioner after reviewing the patient's prescription drug monitoring data. Subsequent prescriptions can be issued via other forms of telemedicine permitted under the Controlled Substances Act or after an in-person evaluation. The final rule also required pharmacists to verify patient identity before filling prescriptions. DEA and HHS state that the final rule aims to prevent care lapses while maintaining existing telemedicine flexibilities for opioid use disorder treatment. On the same day, the DEA and HHS issued another final rule that permits the US Department of Veteran Affairs (VA) practitioners to prescribe controlled substances, including prescriptions for purposes other than opioid use disorder treatment, to a VA patient via telemedicine if another VA practitioner has, at any time, conducted an in-person medical evaluation of the patient. Both final rules went into effect February 18, 2025.

> **"The DEA and HHS issued a final rule that allows practitioners to prescribe schedule III-V controlled substances for the treatment of opioid use disorder, including buprenorphine, via telemedicine.**

DEA ANNOUNCES LONG-AWAITED PROPOSED RULE ON TELEHEALTH SPECIAL REGISTRATIONS

DEA published a proposed rule on January 17, 2025, that would establish three special registrations that create a pathway for certain healthcare professionals to prescribe certain controlled substances via telemedicine once current telehealth flexibilities expire on December 31, 2025. The special registration would only apply where the prescribing practitioner has never conducted an in-person medical evaluation of the patient prior to the issuance of the prescription. For more information on the proposed rule, see our *On the Subject*.

TRUMP ADMINISTRATION HALTS PUBLISHING OF REGULATIONS AND POSTPONES EFFECTIVE DATES

On January 20, 2025, US President Donald Trump issued an executive memorandum implementing a regulatory freeze. The memorandum halts the proposal, publication, or issuance of any new rules or regulatory actions, pending review by a Trump administration appointee, instructs agencies to withdraw any rules sent to the Office of the Federal Register but not yet published, and directs agency staff to consider postponing for 60 days the effective date for any rules that have been published or issued but that have not yet taken effect for purposes of reviewing questions of fact, law, and policy that a rule may raise. During the 60-day period, agencies are instructed to consider opening a comment period on the rule for interested parties to provide comments on such issues.

TRUMP ADMINISTRATION ISSUES A FLURRY OF EXECUTIVE ORDERS IMPACTING HEALTHCARE

President Trump has released several executive orders impacting healthcare. These include orders withdrawing the US from the World Health Organization (EO 14155), directing federal agencies to define "sex" as a binary immutable biological classification and remove recognition of the concept of gender identity (EO 14168), and targeting the provision of gender-affirming care for minors (EO 14187).

President Trump has also issued an executive order (EO 14148) rescinding a number of Biden-era executive orders on healthcare. These include executive orders addressing access to care for LGBTQ+ individuals (EO 14075), efforts to improve access to care through Medicaid and the ACA (EO 14009; EO 14070), and actions to reduce lower prescription drug costs (EO 14087). For more insight into healthcare policies under the Trump administration, visit the McDermott+ First 100 Days Resource Center.

AUTHORS & CONTACT

TONY MAIDA
PARTNER
tmaida@mwe.com
Tel +1 212 547 5492

MONICA WALLACE
PARTNER
mwallace@mwe.com
Tel +1 312 984 7757

SARAH KITCHELL
PARTNER
skitchell@mwe.com
Tel +1 617 535 3929

JAMES A. CANNATTI III
PARTNER
jcannatti@mwe.com
Tel +1 202 756 8866

EVIE ATWATER
ASSOCIATE
eatwater@mwe.com
Tel +1 312 984 6472

MAX DOHERTY
ASSOCIATE
mdoherty@mwe.com
Tel +1 617 535 4073

NATHAN GRAY
ASSOCIATE
ngray@mwe.com
Tel +1 202 756 8971

WILLIAM W. HAMELINE
ASSOCIATE
whameline@mwe.com
Tel +1 312 984 2036

Stay current on the latest healthcare regulatory developments.

SUBSCRIBE TO HEALTH LAW UPDATES

FOR MORE INFORMATION, VISIT MWE.COM.

McDermott Will & Emery