HEALTHCARE REGULATORY CHECK-UP

IN THIS FEBRUARY 2025 ISSUE

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FEBRUARY REGULATORY UPDATE SUMMARY

This issue of McDermott's *Healthcare Regulatory Check-Up* highlights regulatory activity for February 2025, including 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 allegations related to the Anti-Kickback Statute (AKS), such as a dental pay-per-referral marketing arrangement, and allegations concerning 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, and the new Trump administration issued a flurry of executive orders and regulatory freezes.

NOTABLE CASES AND SETTLEMENTS

HEALTH SYSTEM AGREES TO $29 MILLION SETTLEMENT RELATED TO MILITARY CARE OVERPAYMENTS

On February 18, 2025, a healthcare system and the US Department of Justice agreed to a $29 million settlement to resolve allegations that the system retained erroneous overpayments for medical services provided to retired military members by a healthcare plan participating in the US Family Health Plan. The whistleblowers who brought the *qui tam* action include an interim CFO and a consultant to the CEO of another health plan participating in the US Family Health Plan. The government alleged that the health system was aware of errors in the calculation of the capitated rate for services provided to military personnel, retirees, and families, but instead of notifying the government of the overpayment, the health system concealed it and continued to submit invoices at the inflated payment rates.

DME EXECUTIVE PLEADS GUILTY IN CONSPIRACY SCHEME RELATED TO $1 BILLION IN FALSE CHARGES

McDermott Will & Emery

On February 20, 2025, a vice president of a DME company pleaded guilty to operating an internet-based platform that generated false doctors' orders for orthotic braces, pain cream, and other DME supplies. These fake orders resulted in more than $1 billion in total charges and $360 million in payments from Medicare and other federal healthcare programs. The defendant admitted that he and his coconspirators targeted hundreds of thousands of Medicare beneficiaries, convincing them to agree to accept medically unnecessary DME and other reimbursable items and services through misleading mailers, television advertisements, and calls from offshore call centers. The defendant also offered to connect pharmacies, DME suppliers, and marketers with telemedicine companies that would accept illegal kickbacks and bribes in exchange for signed doctors' orders transmitted using the DME company's internet-based ordering platform. The falsified orders generated by the defendant's company falsely represented that a doctor had examined and treated the Medicare beneficiaries when in reality telemedicine companies paid doctors to sign the orders without regard to medical necessity and based on only a brief telephone call with the beneficiary – and in some cases, no interaction with the beneficiary at all. A sentencing hearing will be forthcoming.

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SNF FRAUDULENT BILLING SUIT ALLEGES UPCODING COMPLEXITY OF SERVICES RENDERED

On February 19, 2025, the US Attorney's Office filed a complaint with the Massachusetts Attorney General's Office under the federal and Massachusetts FCA against 19 skilled nursing facilities (SNFs) in Massachusetts and Connecticut and their present and former managers. The complaint alleged that between 2017 and 2023, the SNFs and their managers fraudulently caused the submission of claims to Medicare and Medicaid, through Mass Health and its managed care organizations, for medically unreasonable and unnecessary services, such as the highest level of skilled rehabilitation therapy services.

OIG REGULATORY UPDATES

OIG MODIFIES ADVISORY OPINION 21-13

OIG issued a modification to Advisory Opinion No. 21-13 regarding a proposal to subsidize Medicare cost-sharing obligations for a clinical study involving positron emission tomography (PET) scans of patients with mild cognitive impairment or dementia for the presence of beta amyloid plaque – a core feature of patients diagnosed with Alzheimer's disease.

The original proposed arrangement, which OIG approved, involved a clinical research study designed to evaluate PET scans and patient-centered outcomes, particularly in patients from diverse racial and ethnic backgrounds. At the time of the original request, a national coverage determination established limited coverage through a coverage with evidence development (CED) program for one beta amyloid plaque PET scan per patient in qualifying clinical studies that were Centers for Medicare & Medicaid (CMS)-approved, comparative, and longitudinal in nature. The study at issue here met all applicable criteria, and the requestors wished to cover the coinsurance amounts that Medicare beneficiaries otherwise would owe, to ensure that financial limitations did not present a barrier to participation for the target population, although all enrollees' coinsurance obligations would be subsidized regardless of financial need and without advertisement. OIG approved the proposed arrangement despite AKS and beneficiary inducements implications because:

- The clinical study was developed in consultation with CMS.
- The coinsurance subsidy was a reasonable means to facilitate enrollment.
- Inclusion criteria and institutional review board oversight limited the risk of overutilization.
- The nature of the study was limited to one PET scan and three reimbursable office visits without an expectation of subsequent use of reimbursable items or services.

Since the issuance of Advisory Opinion No. 21-13, changes in Medicare coverage for beta amyloid plaque PET scans led the requestors to seek continued assurance of the arrangement's propriety. Specifically, CMS stopped the CED program for beta amyloid PET scans, meaning that coverage would be determined by local Medicare Administrative Contractors. Noting that nothing else in the proposed arrangement had changed since 2021, OIG granted the modified advisory opinion, concluding that the risks of fraud and abuse and overutilization under the modified arrangement remained the same.

PROPOSED STATE BILLS

CALIFORNIA SB 351 PROPOSES CHANGES TO CORPORATE PRACTICE PROHIBITIONS

The California legislature introduced Senate Bill (SB) 351, which targets private equity groups and hedge funds managing physician or dental practices in California. This bill follows Assembly Bill (AB) 3129, passed in 2024 and vetoed by Governor Gavin Newsom. The bill seeks to ensure that healthcare providers control clinical decisions, limit private equity influence, and reinforce prohibitions on corporate practice of medicine and dentistry. It would prevent private equity groups from interfering in clinical decisions or controlling practice operations and would prohibit specific activities such as determining diagnostic tests and making hiring decisions. Under SB 351, private equity groups and hedge funds would not be permitted to restrict providers from engaging in competitive activities or commenting on quality of care and professional practices. The California attorney general would be able to enforce these provisions through injunctive relief and other remedies. While the bill includes some provisions from AB 3129, it does not require notice to or consent from the California attorney general for certain transactions and does not extend to psychiatric practices. For more information, please see our *On the Subject*.

ILLINOIS SB 1998 WOULD ADD NOTIFICATION REQUIREMENTS TO CERTAIN HEALTHCARE TRANSACTIONS

The Illinois state legislature introduced SB 1998, aiming to amend the Illinois Antitrust Act by adding a layer of scrutiny to covered transactions that are financed by private equity groups or hedge funds. The proposed amendment would add a requirement that if a hedge fund or private equity group provides any financing to a covered transaction, the Illinois attorney general (IL AG) must give written consent before the transaction can take effect. SB 1998 would also add definitions to clarify what would be considered a hedge fund and a private equity group under the Illinois Antitrust Act. The bill does not provide a clear timeframe for the IL AG to issue its consent, nor does it provide any criteria according to which consent would be issued or denied. Therefore, if this bill is passed, the IL AG's oversight on such transactions would likely cause delays and additional expenditures. For more information, please see our *On the Subject*.

HEALTHCARE TRANSACTION NOTIFICATION PROPOSED AS PART OF WISCONSIN APPROPRIATIONS BILL

> **"Entities that fail to submit required reports or that submit false information would face penalties, with fines up to $500,000 per violation.**

The Wisconsin state legislature introduced AB 50, a comprehensive 2,000-page budget bill for Wisconsin's 2025 – 2027 fiscal term. Among myriad other appropriations proposals, the bill would establish procedures for review, oversight, and transparency when healthcare entities propose to undergo material change transactions. The proposed bill also would require Wisconsin's Department of Health Services (DHS) to create rules to define what entities are considered healthcare entities and what constitutes a material change transaction. Other requirements proposed under the bill include requiring healthcare entities to provide written notice to DHS before making significant changes, and to report ownership and control details to DHS annually and after significant changes. DHS and the Wisconsin attorney general also would monitor compliance and enforce regulations, including via annual audits. Entities

that fail to submit required reports or that submit false information would face penalties, with fines up to $500,000 per violation. The bill would prohibit the corporate practice of medicine and would require DHS to define what constitutes such practice.

OTHER NOTABLE DEVELOPMENTS

LITIGATION OVER EXECUTIVE ORDERS 14168 AND 14187

In January 2025, US President Donald Trump signed executive orders (EOs) directing federal agencies to define "sex" as an immutable binary biological classification and remove recognition of the concept of gender identity (EO 14168) and targeting the provision of gender-affirming care to minors (EO 14187).

To date, numerous complaints have been filed in federal court in response to EO 14168. In one such case, *Doctors for America v. Office of Personnel Management*, the US District Court for the District of Columbia granted a temporary restraining order on February 11, 2025, prohibiting the government from removing or modifying health-related webpages and datasets from federal websites and databases and directing the government to restore any information removed because of the EO. In another case, *National Council of Nonprofits v. Office of Management and Budget*, the same district court issued a preliminary injunction on February 25, 2025, that prohibits defendants from restricting the disbursement of federal funds under any open awards.

To date, two complaints have been filed in federal court in response to EO 14187. *PFLAG v. Trump*, filed in the US District Court for the District of Maryland, led to a nationwide preliminary injunction prohibiting the Trump administration from conditioning federal education and research grant funds on medical institutions ceasing to provide gender-affirming care services to patients under age 19. *PFLAG v. Trump* is currently under appeal before the Fourth Circuit Court of Appeals. *Washington v. Trump*, filed in the US District Court for the Western District of Washington, led to an identical injunction that applies only in Washington, Oregon, Colorado, and Minnesota. *Washington v. Trump* is currently under appeal before the Ninth Circuit Court of Appeals. For a deeper dive into EO 14187, please refer to our FAQs.

EO 14192: UNLEASHING PROSPERITY THROUGH DEREGULATION

EO 14192 was signed by President Trump on January 31, 2025, and published in the *Federal Register* on February 6, 2025. This EO establishes an executive branch policy to be prudent and financially responsible in the expenditure of public and private funds and to alleviate unnecessary regulatory burdens. To achieve this policy, executive branch agencies will be required to identify at least 10 existing regulations to be repealed whenever they propose a new regulation for notice and comment. The EO instructs agency heads to ensure that the total incremental cost of all new regulations, factoring in repealed regulations, is less than $0.

No challenges to EO 14192 have been filed to date.

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EO 14212: ESTABLISHING THE PRESIDENT'S MAKE AMERICA HEALTHY AGAIN COMMISSION

EO 14212 was signed by President Trump on February 13, 2025, and published in the *Federal Register* on February 13, 2025. This order establishes as federal policy an obligation to combat chronic disease challenges facing US citizens, including mental health disorders, obesity, and diabetes. The EO directs that federally funded health research should be transparent, include open-source data, and avoid or eliminate conflicts of interest. Executive branch agencies are also directed to work with farmers to ensure that healthy, abundant, and affordable food is available. The EO specifies that expanded treatment options and flexible health insurance coverage should support beneficial lifestyle changes and disease preventions.

The new Make American Healthy Again Commission will be chaired by the secretary of HHS, with the assistant to the president for domestic policy serving as executive director. Several Cabinet members and other members of the Trump administration are also designated commission members. In addition to a general focus on chronic diseases, the commission's initial mission is to evaluate and advise on childhood chronic diseases and any potential contributing causes, such as diet, toxic materials, medical treatments, lifestyle, environment, governmental policy, food production, electromagnetic radiation, corporate influence, and cronyism. The commission's first report is expected within 100 days of the EO's signing.

No challenges to EO 14212 have been filed to date.

EO 14214: KEEPING EDUCATION ACCESSIBLE AND ENDING COVID-19 VACCINE MANDATES IN SCHOOLS

EO 14214 was signed by President Trump on February 14, 2025, and published in the *Federal Register* on February 20, 2025. This order states that discretionary federal funds should not be used to directly or indirectly support or subsidize educational institutions that require students to have received a COVID-19 vaccine in order to attend in-person programs.

No challenges to EO 14214 have been filed to date.

EO 14221: MAKING AMERICA HEALTHY AGAIN BY EMPOWERING PATIENTS WITH CLEAR, ACCURATE, AND ACTIONABLE HEALTHCARE PRICING INFORMATION

EO 14221 was signed by President Trump on February 25, 2025, and published in the *Federal Register* on February 28, 2025. This order establishes a US policy to put patients first and ensure that they have the information necessary to make well-informed healthcare decisions. The government is instructed to promote universal access to clear and accurate healthcare processes, improve existing transparency requirements, increase enforcement of price transparency requirements, and identify opportunities to empower patients with meaningful price information. The EO instructs the US Departments of Health and Human Services (HHS), Labor, and the Treasury to require actual prices of healthcare items and services to be disclosed rather than estimates and to issue guidance or regulation that standardizes pricing information into an easily comparable format across hospitals and health plans. Agencies are also instructed to issue guidance or regulation describing enforcement policies.

No challenges to EO 14221 have been filed to date.

POLICY STATEMENT FROM HHS REGARDING RICHARDSON WAIVER

In 1971, the US Department of Health, Education and Welfare (now HHS) issued a notice stating that any rulemaking issued by the agency would go through the notice-and-comment process. Under the Administrative Procedure Act (APA), certain rules and regulations pertaining to public property, loans, grants, benefits, and contracts were exempt from public comment. At the time, legislation had been proposed to repeal the exemption, but rather than wait for the new laws (which never came to fruition), the department opted to follow the recommendation of the Administrative Conference of the United States that government agencies should not wait for the statute to be amended before inviting public participation when formulating rules in the exempt categories. The department's notice stated that "[t]he public benefit from such participation should outweigh any administrative inconvenience or delay which may result from use of the APA procedures in the five exempt categories" (36 Fed. Reg. 2532 (Feb. 5, 1971)).

On February 28, 2025, HHS issued a policy statement that issued a policy statement that rescinded this long-standing agency policy. Effective immediately, HHS will adhere to APA exemption criteria. Matters related to agency management or personnel, or to public property, loans, grants, benefits, or contracts, are now exempt from notice-and-comment procedures unless otherwise required by law, although HHS has direction to apply notice-and-comment procedures if it wishes. The scope of the rules that could be impacted by this change is not easily defined, even under caselaw, and will need to be reconciled against other statutes and legal requirements that may still require notice-and-comment rulemaking.

DISTRICT COURT ENJOINS NIH 15% INDIRECT COST RATE

On February 7, 2025, the National Institutes of Health (NIH) circulated an official notice (NOT-OD-25-068) titled Supplemental Guidance to the 2024 NIH Grants Policy Statement: Indirect Cost Rates. NIH announced that effective February 10, 2025, all new

and some existing grants would be subject to a 15% uniform indirect cost rate rather than a negotiated rate. The notice identified negotiated rates as averaging between 27% and 28% over time, with some grant-receiving organizations charging indirect rates in excess of 60%. In establishing the blanket 15% indirect cost rate, NIH found that many of the indirect cost rates offered by private foundations ranged from a maximum indirect rate of 0% to 15%, suggesting that many researchers are willing to accept research grants that do not fully allow for recovery of indirect institutional costs.

Three complaints filed in the US District Court for the District of Massachusetts resulted in temporary restraining orders that enjoined NIH on a nationwide basis from implementing the blanket rate change. HHS and NIH likely will appeal the injunction while also exploring different avenues to cut the indirect cost rate for NIH grants, such as through a congressional appropriations bill, amendments to regulations governing federal awards, or disregarding judicial orders. For an in-depth look at this topic, please see our *On the Subject*.

For more insight into healthcare policies under the Trump administration, visit the McDermott+ First 100 Days Resource Center.

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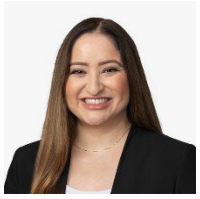

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