HEALTHCARE REGULATORY CHECK-UP

IN THIS MARCH 2025 ISSUE

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MARCH REGULATORY UPDATE SUMMARY

This issue of McDermott's *Healthcare Regulatory Check-Up* highlights key regulatory and enforcement activity for March 2025. This month features:

- Noteworthy enforcement actions demonstrating that the Anti-Kickback Statute (AKS) remains a significant source of compliance risk.
- A proposed rule from the Centers for Medicare & Medicaid Services (CMS) that would materially modify various components of the Affordable Care Act (ACA) implementing regulations.
- A revised statement of organization from the US Department of Health and Human Services (HHS) signaling potential changes in how the HHS Office of General Counsel (OGC) may engage in AKS and other enforcement and policymaking in the future.

NOTABLE CASES, SETTLEMENTS, AND RELATED AGENCY ACTIVITY

JURY FINDS NO LIABILITY IN "USUAL AND CUSTOMARY" PRICING CASE THAT SET SCOTUS *SCIENTER* STANDARD

Fourteen years after the False Claims Act (FCA) case against Supervalu, Inc., was filed in the US District Court for the Central District of Illinois, a jury found that the plaintiffs had not proved damages to either the federal or state government caused by Supervalu's pharmaceutical pricing system. Because no damages were sustained, Supervalu was found not liable for violations of the FCA. As a recap, Supervalu offered discounted pricing on pharmaceuticals to customers through loyalty programs and a price-match guarantee. Medicare and Medicaid programs were not offered these discounts. One of the questions in this case was whether these discounts impacted the "usual and customary" price that could be charged to federal healthcare programs. The case took on national prominence because of an appeal of the district court's determination that Supervalu did not have the *scienter* required to establish a violation of the FCA. The Supreme Court of the United States subsequently found that a defendant's subjective knowledge must satisfy the FCA's *scienter* requirements, and that establishing a *post hoc* objective rationale for the conduct is not sufficient to overcome the defendant's subjective view at the time of the conduct. Applying the new *scienter* standard, the jury

found that Supervalu had the requisite *scienter* but that no damages were suffered, and therefore there was no liability under the FCA.

CLINICAL RESEARCH FACILITY OWNERS PLEAD GUILTY TO CONSPIRACY TO COMMIT WIRE FRAUD

Two owners of a clinical research company in Florida that conducted clinical trials of prospective new drug treatments on behalf of drug sponsors seeking approval from the US Food and Drug Administration (FDA) pleaded guilty to conspiracy to commit wire fraud. The defendants admitted to making fraudulent representations to the asthma drug trial sponsor regarding subject eligibility and further admitted to falsifying and fabricating material documents and data, including case histories, spirometry readings, and echocardiogram data. The US Department of Justice (DOJ) alleged that the clinical research company reported data for subjects who did not participate in the trial and enrolled ineligible subjects who did not qualify. The defendants provided fraudulent clinical research data to the drug trial and an FDA investigator. The case was pursued by DOJ Consumer Protection Branch.

PROVIDERS, LAB MARKETERS AGREE TO PAY MORE THAN $1.9 MILLION TO SETTLE AKS ALLEGATIONS

Four medical practices and a marketing company agreed to pay more than $1.9 million to resolve alleged violations of the federal FCA and AKS. The physician owners of the medical practices allegedly received kickbacks in the form of office space rental or phlebotomy services payments in return for their referrals to a South Carolina laboratory from May 2016 through November 2021.

MEDICAL DEVICE COMPANY WILL PAY UP TO $14.25 MILLION TO RESOLVE ALLEGED FCA, STATE LAW VIOLATIONS RELATED TO VISION TESTING

A medical device company based in Pennsylvania agreed to pay up to $14.25 million to resolve allegations that it violated the federal FCA and various state laws by allegedly knowingly submitting, or causing others to submit, false claims for payment to Medicare and Medicaid in connection with certain vision testing services. The medical device company developed an FDA-approved electrophysiological device for visual evoked testing. Between January 1, 2015, and December 31, 2021, the medical device company allegedly caused healthcare providers to submit false claims to Medicare and Medicaid for services in which the device was used for medically unnecessary purposes, specifically electroretinography vision testing for which the device lacked FDA clearance. DOJ further contended that the company made substantial changes to the device that it never submitted to the FDA for clearance or approval, despite knowing that such a submission was required. The case originated from a *qui tam* complaint filed in October 2021 by an ophthalmologist. Under the settlement terms, the company will make guaranteed payments of $1.225 million and contingent payments of up to $13.025 million. The settlement is based on the company's financial condition. The company will pay $207,000 to the whistleblower.

DC DISTRICT COURT REJECTS PHARMACEUTICAL COMPANY'S ATTEMPT TO LIMIT AKS SCOPE

A pharmaceutical company lost at summary judgment in its challenge to an HHS Office of Inspector General (OIG) advisory opinion in the US District Court for the District of Columbia. The pharmaceutical company had requested prospective immunity under the AKS for a program that would cover fertility treatments for patients who suffer from fertility-related side effects of its product, an innovative gene-editing therapy that treats sickle cell anemia and another blood disorder. Under the proposed program, eligible patients would receive up to $70,000 in fertility support. OIG determined that it could not offer prospective immunity under the AKS. The pharmaceutical company argued that the AKS should be restricted "corrupt quid-pro-quo transactions," but the District of Columbia rejected that argument and granted summary judgment to OIG.

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CMS REGULATORY UPDATES

CMS PUBLISHES MARKETPLACE INTEGRITY AND AFFORDABILITY PROPOSED RULE

On March 10, 2025, CMS released its first proposed rule under the Trump administration, the Marketplace Integrity and Affordability Proposed Rule. This rule is aimed at addressing improper enrollments in the ACA Health Insurance Marketplace resulting from consumers being enrolled in coverage without their knowledge or consent. Citing a report from the Paragon Institute, CMS stated that four to five million people were improperly enrolled in subsidized ACA coverage in 2024, which cost federal taxpayers up to $20 billion. To address improper enrollments and other policy concerns, the proposed rule would make several changes to ACA regulations.

For instance, the proposed rule would reverse the ACA's current policy restricting an issuer of health insurance coverage from attributing payment of a premium for new coverage to past-due premiums from prior coverage. The current policy, "in effect, restricts issuers from establishing premium payment policies that require enrollees to pay past-due premiums to effectuate new coverage," which allows consumers to "manipulat[e] guaranteed availability and grace periods to time coverage to when they need health care services." The proposed rule would allow issuers to add past-due premium amounts to the initial premium the enrollee must pay to effectuate new coverage and to not effectuate new coverage if the past-due and initial premium amounts are not paid in full, which CMS believes "would strengthen the risk pool and lower gross premiums."

To prevent fully subsidized enrollees from being automatically re-enrolled without taking action to confirm their eligibility, the proposed rule suggests three alternative solutions. The first option would be to decrease the amount of the advanced premium tax credit (APTC) applied to these policies, which would raise enrollees' premium to $5 per month (up from $0 per month) until they confirm or update their eligibility determination. The second option would be to require individuals who qualify for fully subsidized plans to re-confirm their plan and re-verify their income before they would be eligible to receive *any* APTC. Third, it would remove the option for health insurance exchanges to automatically re-enroll individuals who qualify for fully or partially subsidized plans, in order to force individuals to affirmatively choose their plan and verify their income during the open enrollment period. CMS seeks comments on these options.

For benefit years starting on or after January 1, 2026, the proposed rule would shorten the annual open enrollment period from November 1 through January 15 to November 1 through December 15 of the calendar year preceding the benefit year of enrollment. The proposed rule also would repeal the monthly special enrollment period for qualified individuals and their dependents who are eligible for the APTC and whose projected household income is at or below 150% of the federal poverty level (FPL). The rationale for this change is to discourage individuals from waiting until they are sick to seek coverage, which, in turn, would theoretically improve the risk pool and decrease the financial hardship on consumers who pay the full premium and federal cost of the APTC. Both proposed changes would come at the expense of coverage availability for low-income individuals.

> **"The proposed rule would amend the definition of "lawfully present" to exclude Deferred Action for Childhood Arrivals recipients.**

Of note, the proposed rule would amend the definition of "lawfully present" to exclude Deferred Action for Childhood Arrivals recipients, meaning these individuals would no longer be eligible to enroll in a qualified health plan through the Marketplace, for premium tax credits, for cost-sharing reductions, or for enrollment in a basic health program (BHP) where available. BHPs are programs in which states can provide coverage to individuals who are citizens or lawfully present noncitizens, who do not qualify for Medicaid, the Children's Health Insurance Program, or other minimum essential coverage, and have income between 133% and 200% of the FPL.

The changes discussed here do not cover the full scope of the proposed rule. For more information, please see the CMS fact sheet on the proposed rule and the full text of the proposed rule. Please also refer to our McDermott+ colleagues' summary.

CMS ANNOUNCES SECOND ROUND OF MEDICARE DRUG PRICE NEGOTIATION PROGRAM

Beginning March 1, 2025, CMS will begin the second round of the Medicare Drug Price Negotiation Program, which gives Medicare the ability to directly negotiate the prices of certain drugs with manufacturers. In the first round of negotiations, CMS selected 10 drugs covered under Medicare Part D and negotiated maximum fair prices with the drugs' manufacturers. For the second round of the program, CMS selected the top 15 drugs by gross prescription cost and number of Medicare enrollees who used the drug from November 2023 through October 2024. The drugs selected treat type 2 diabetes (*e.g.*, Ozempic and Wegovy), asthma, prostate cancer, breast cancer, and certain types of leukemia. The negotiated prices from round one of the program will go into effect on January 1, 2026, and CMS estimates that the program will lower out-of-pocket costs for Medicare enrollees by $1.5 billion in 2026. The negotiation process for round two will conclude in November 2025, with any agreed-upon maximum fair prices going into effect on January 1, 2027.

OIG UPDATES

OIG ISSUES FY 2024 MEDICAID FRAUD CONTROL UNIT REPORT

The annual report highlights OIG recovery actions in 2024. Highlights include 1,151 convictions for patient abuse and neglect and fraud; 1,042 individuals or entities excluded from federally funded programs; 493 civil settlements or judgments; and $1.4 billion recovered. Of that amount, $407 million was civil recoveries, and $961 million was criminal recoveries.

OIG REPORT: MACS DID NOT CONSISTENTLY MEET MEDICARE COST REPORT OVERSIGHT REQUIREMENTS

On March 18, 2025, CMS published the results of an audit that reviewed individual Medicare Administrative Contractors' (MACs) compliance with the Medicare cost report oversight requirements for fiscal years 2019 through 2021. CMS concluded that MACs did not consistently meet the Medicare cost report requirements, and that each of the 12 MAC jurisdictions failed to comply with the contract requirements for audit and reimbursement desk review and audit quality in at least one of the three years reviewed. CMS's other key findings include that MACs inadequately reviewed graduate medical education and indirect medical education reimbursement, and improperly calculated reimbursement for nursing and allied health programs. In response, the MACs pointed to limited feedback from CMS on cost report reviews and inadequate training as reasons for noncompliance.

OIG REPORT: MEDICARE, MEDICAID PAYMENTS ARE AT RISK OF DIVERSION THROUGH ELECTRONIC FUNDS TRANSFER FRAUD SCHEMES

On March 6, 2025, OIG published a report that found that Medicare and Medicaid payments are at risk of diversion through a scheme in which fraudulent actors pretend to be hospital providers and submit incorrect electronic funds transfer (EFT) information to MACs and state Medicaid programs. These agencies then update the hospital providers' bank account information to reflect the accounts specified in the fraudulent requests, causing claims payments intended for providers to be diverted to fraudulent accounts. As of the date of the report, such fraud schemes targeting hospital providers have resulted in reported diversion of about $26.5 million from the Medicare and Medicaid programs. OIG recommends that CMS engage with MACs on improving security measures, share information with Medicaid agencies to help improve security measures at the state level, and support periodic information sharing to mitigate evolving threats of EFT fraud schemes.

HHS OFFICE OF GENERAL COUNSEL ISSUES REVISED STATEMENT OF ORGANIZATION SIGNALING EXPANSION OF AUTHORITY

On March 14, 2025, HHS issued a revised Statement of Organization for the HHS Office of the General Counsel (OGC). The revised Statement announced a plan to consolidate the number of regional OGC offices from 10 to four, resulting in the closure of six regional offices. OGC's regional offices provide legal counsel and support enforcement, compliance, and administrative functions across Medicare, Medicaid, and other federal healthcare programs, including provider surveys and inspections. Historically, OGC and regional offices have served the same geographic area to provide coordinated regulatory and legal oversight. OGC has not announced an official timeline for the consolidation. The revised Statement provides that the four remaining regional

OGC offices "will provide the same geographic support for CMS regional offices" but does not indicate how OGC support will be redirected or redistributed to providers and suppliers in regions affected by the closures. Medicare, Medicaid, and other federal healthcare program providers and suppliers may experience delays in regulatory processes, including compliance actions, provider enrollment reviews, and appeals of adverse determinations.

The Statement also may signal shifts in the relationship between OGC and the Office of Counsel to the Inspector General (OCIG). OCIG's scope includes traditional OIG responsibilities, as well as work that HHS has historically delegated to the OIG, such as interpretation and enforcement of the AKS. The revised Statement provides that OIG is authorized to have its own counsel "with respect to matters solely within the OIG's jurisdiction," and states that OGC will supervise all HHS legal activities "except with respect to certain matters within the jurisdiction of the OIG." It is unclear whether or how these changes might impact enforcement and compliance guidance activities historically handled by OCIG.

OTHER NOTABLE DEVELOPMENTS

PROPOSED MASSACHUSETTS LAWS WOULD IMPACT HEALTHCARE TRANSACTION NOTICE REQUIREMENTS, PPM STRUCTURES

Three proposed laws would impact health transaction notice requirements in Massachusetts. All three of these laws were referred to the Senate and House committees for further consideration on February 27, 2025. We will monitor for developments.

House Bill 1355 (An Act Strengthening Oversight of Health Care Facility Spending) would expand the definition of "material change" to include applications for the issuance of new freestanding ambulatory surgery centers or clinic licenses, or new satellite facilities under existing licenses. It would also mandate that the Health Policy Commission (HPC) conduct annual reviews of approved material changes in healthcare facilities to assess whether anticipated benefits have been realized. Healthcare entities that exceed cost benchmarks or have high relative prices would be required to file performance improvement plans. H. 1355 also stipulates that a public hearing for a determination of need (DON) application may be required at the request of *either* the attorney general or the HPC. Before a DON can be approved, the HPC must file a report on the application's impact on healthcare costs and the cost growth benchmark. The bill also would introduce new licensing requirements for secondary healthcare facilities, requiring them to obtain separate NPI numbers and negotiate contracts independently from their primary licensed facilities, subject to certain exceptions.

Senate Bill 868 (An Act Enhancing Health Care Market Oversight and Pharmaceutical Access) would effectuate changes to the Massachusetts healthcare landscape. As with H. 1355, this law would amend Massachusetts' existing health transaction notice law by requiring the HPC to determine whether a material change is likely to result in a significant negative impact on Massachusetts healthcare consumers, in addition to the HPC's existing obligation to examine the material change for its impact on the Commonwealth's ability to meet the healthcare cost growth benchmark and on the competitive market. This law also would place restrictions on private equity companies and healthcare real estate investment trusts engaging in transactions with providers and provider organizations, with the aim of protecting these providers from financial distress.

A pair of companion bills, House Bill 2486 and Senate Bill 1628 (together, An Act to Protect the Independence of Clinical Decision Making), would implement a statutory prohibition on the corporate practice of medicine (CPOM) with some narrow exceptions and provide guardrails around management services organization (MSO) relationships with physician practices to protect clinical decision making authority. With respect to CPOM, Massachusetts has historically relied on a prohibition established by case law (*McMurdo v. Getter*, 298 Mass. 363 (1937)). H. 2486 and S. 1628 would formalize this prohibition, in accordance with certain requirements: A "clinician" with "independent practice authority" may practice at a "health care practice" if the healthcare practice is wholly owned or controlled by one or more Massachusetts-licensed physicians or nurses, or the healthcare practice is formed in Massachusetts as a professional corporation, nonprofit organization, nonprofit hospital services corporation, nonprofit medical services corporation, or limited liability company or partnership, or under comparable law of any other state, provided that all shares of the organization are be owned by a Massachusetts-licensed clinician. H. 2486 and S. 1628 also propose limitations on healthcare practices' relationships with MSO entities. In particular, MSOs would not be allowed to own patient medical records, hire or fire any owner or clinician based on clinical competency, set parameters under which a practice enters into contractual relationships with clinicians for the delivery of care, make final decisions regarding coding and billing procedures for patient care services, or approve the selection of medical equipment and medical supplies for the practice.

McDermott is carefully tracking transaction notice law developments in all jurisdictions, with more information available here.

HEALTH PLAN WINS RULING ON $2 BILLION IN ALLEGED MEDICARE OVERPAYMENTS

A health plan claimed a major victory on March 4, 2025, when a court-appointed special master found that DOJ did not have sufficient evidence to support a billion-dollar fraud case against the plan regarding overpayments for patients on Medicare Advantage plans. The special master's recommendation is not a final ruling, but if adopted by the court, it would end DOJ's claims. DOJ claimed in its 2016 lawsuit that the plan submitted false diagnoses for patients on government funded, privately administered Medicare Advantage plans to get higher payments. Medicare reimbursements to insurers that administer Medicare Advantage plans are tied to patients' diagnosis codes, with sicker patients receiving higher reimbursement. Medicare paid more than $7.2 billion from 2009 through 2016 for services provided to Medicare Advantage patients, and DOJ alleged that these payments were inflated by the plan's practice of reviewing patient records to find additional diagnoses and adding medical billing codes to their files. According to DOJ, Medicare would have paid $2.1 billion less if the unsupported billing codes were deleted.

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