HEALTHCARE REGULATORY CHECK-UP

IN THIS APRIL 2025 ISSUE

MWE.COM

APRIL REGULATORY UPDATE SUMMARY

This issue of McDermott's *Healthcare Regulatory Check-Up* highlights regulatory activity for April 2025, including Centers for Medicare & Medicaid Services (CMS) updates to Medicare Advantage (MA) and other Medicare programs. This month features a landmark US Court of Appeals for the Seventh Circuit decision reversing a conviction in a marketing case under the Anti-Kickback Statute (AKS). We also discuss several enforcement actions focusing on allegations under the AKS, the False Claims Act (FCA), and other fraud and abuse laws, including familiar themes such as kickbacks related to durable medical equipment (DME) prescribing via telemedicine and billing federal healthcare programs for medically unnecessary services. This issue also examines a favorable advisory opinion issued by the Office of Inspector General (OIG) regarding a community health center's proposed arrangement to connect members of its community with primary care services. Finally, we discuss a new bill that proposes to repeal certain elements of the Affordable Care Act (ACA) that prohibit the expansion and creation of new physician-owned hospitals.

NOTABLE CASES, SETTLEMENTS, AND RELATED AGENCY ACTIVITY

SEVENTH CIRCUIT REVERSES DME DISTRIBUTOR CONVICTION IN AKS MARKETING CASE

On April 14, 2025, the US Court of Appeals for the Seventh Circuit in *United States v. Sorensen* reversed the conviction of Mark Sorensen, owner of a Medicare-registered distributor of DME, in an opinion that redefines the boundaries of permissible marketing practices under the AKS. In 2015, Sorensen, through his company SyMed, Inc., entered into a business arrangement with several entities, including a DME manufacturer, a marketing agency, and a billing agency. Under the arrangement, marketing firms published advertisements for orthopedic braces, and interested parties could respond by providing their personal information and contact information for a physician. After receiving a patient's information, marketing agencies would contact the patient to discuss ordering a brace and generating a prescription form, and would obtain the patient's consent to share the prescription form with the patient's physician. The marketer would then fax prefilled but unsigned prescription forms to the patient's physician. The forms included SyMed's branding and the DME to be ordered. Many physicians (about 80%) declined to sign the prescription forms, and many others ignored requests entirely. When a prescription form was signed, SyMed would direct the manufacturer to ship DME to patients, and the billing agency would bill Medicare for the DME on behalf of SyMed. Upon a successful conversion, SyMed would pay the manufacturer a portion of the reimbursement received and keep the remainder as a service fee, out of which SyMed would pay the billing agency for its role. Following a jury trial, Sorensen was convicted on one count of conspiracy and three counts of

substantive AKS violations, and the district court denied Sorensen's motion for judgment of acquittal. Sorensen was sentenced in 2024 to 42 months in prison and ordered to forfeit $1.8 million.

On appeal, the Seventh Circuit held that because Sorensen's payments were not made to physicians in a position to refer their patients nor to other decisionmakers in positions to "leverage fluid, informal power and influence" over healthcare decisions, the payments were not made for "referring" patients within the meaning of the AKS and thus did not violate the statute. The court observed that the AKS primarily targets payments to persons who are able to control or influence medical decision-making, such as payments made to a physician in exchange for referring patients to a particular specialist. On the other hand, where payments are made to non-physicians, whether the AKS has been violated requires scrutiny of the degree of control or influence that the recipient of the payments has over medical decision-making. While the Seventh Circuit did not set forth any bright-line rules for conducting this analysis, it examined a body of case law to distinguish legal versus illegal marketing practices, including three cases from the Fifth Circuit:

- *United States v. Miles* (5th Cir. 2004): The Fifth Circuit overturned the conviction of a home health provider who paid a public relations firm. The court explained that there are "certain situations where payments to non-doctors would fall within the scope of the [AKS]," but it distinguished between a payment to induce referrals from a payee in a position to make or influence healthcare decisions (which is illegal under the AKS) and a payment for advertising services (which is not). In this case, the public relations firm supplied promotional materials and occasionally plates of cookies to physicians, which the court found did not prevent the physicians from exercising independent medical judgment or deciding where to refer patients.
- *United States v. Polin* (5th Cir. 1999): The Fifth Circuit affirmed a conviction stemming from payments made to a sales representative for marketing pacemaker monitoring services, where the sales representative's recommendations "had never been overruled by a physician during his fourteen year career." The court found that the sales representative's "judgment was shown to have been improperly influenced by the payments he received" because he was the de facto decisionmaker, and the physicians' approval of his recommendations "seemed to be more of a formality or rubber stamping."
- *United States v. Marchetti* (5th Cir. 2024): The Fifth Circuit affirmed the conviction of a marketer who was paid a percentage of revenue by a medical laboratory for each Medicare patient attracted to the laboratory as a result of marketing efforts. The court observed that "percentage-based compensation structures are not per se unlawful," and that merely advertising the medical laboratory did not qualify as evidence that the marketer had impermissible influence over "those who make healthcare decisions on behalf of patients." However, when the marketer later took on a role that involved deciding which of two competing laboratories received patient samples, the court held that a rational trier of fact could find that the marketer crossed the line to become a "relevant decision maker" and payments made to him were intended to induce his referrals in violation of the AKS.

The *Sorensen* court found that the conduct at issue was more like the conduct in *Miles* than in *Polin* or *Marchetti*. The marketers in *Sorensen* lacked any material influence over medical decision-makers, as evidenced by physicians' high rejection rate of SyMed's prefilled prescription forms. In *Sorensen*, the Seventh Circuit's analysis focused on whether payments made to a marketer show an intent to induce referrals versus an intent to merely advertise. In the court's view, this analysis hinges on whether the marketer is in a position to "leverage fluid, informal power and influence" over a medical decision-maker, which may be demonstrated by facts in the record – for example, a high success rate for marketing may indicate the ability to influence referrals, while a low success rate may suggest the opposite.

The Seventh Circuit's decision and pro-defense position in *Sorensen* represents a win for industry stakeholders. Marketing remains a dynamic area of the law, suggesting a need to continue monitoring the growing body of AKS marketing case law.

MEDICAL PRACTICE, PHYSICIAN OWNER AGREE TO PAY $152,000+ TO RESOLVE TELEHEALTH BILLING FCA ALLEGATIONS

A West Virginia-based medical practice and its physician owner agreed to pay the United States more than $152,000 to resolve civil allegations that they violated the FCA by submitting false claims to the Medicare and Medicaid programs and falsely certifying compliance with program requirements related in part to the practice's telehealth billing patterns. In addition to general internal medicine services, the medical practice provided medication assisted treatment for substance use disorder. According to the government, an analysis of the practice's Medicare and Medicaid claims revealed an unusual billing pattern for HCPCS procedure code Q3014 (telehealth originating site facility fee), which is intended to permit an enrolled facility where a patient is physically located to recoup costs associated with connecting the patient to an outside provider – such as a specialist – for telehealth services.

Under federal regulations, only the originating site may bill for the originating site facility fee; however, the government alleged that the medical practice routinely billed Q3014 for telehealth visits where the patient was at home.

REHABILITATION FACILITY WILL PAY $19.75M TO RESOLVE FCA ALLEGATIONS RELATED TO UNLICENSED CARE

A New Jersey drug and alcohol rehabilitation facility agreed to pay nearly $20 million to resolve allegations that it violated the FCA by allegedly submitting claims to the Community Care Program of Veterans Health Administration and New Jersey's Medicaid program for short-term residential treatment and partial hospitalization care. The United States alleged that from 2022 through 2024, the facility provided services for which it had no license, sought to conceal improperly performed services from state inspectors, failed to employ a sufficient number of properly credentialed caregivers, kept false and inadequate records of care provided, and provided the same care to veterans as it provided to other patients, despite claiming to provide specialized care.

FLORIDA MAN PLEADS GUILTY TO MEDICARE FRAUD SCHEME INVOLVING $8.4+M IN COVID-19 TEST KIT FALSE CLAIMS

A Florida man pleaded guilty to causing more than $8.4 million in false and fraudulent claims to be submitted to Medicare using Medicare identification numbers that the man had unlawfully purchased. According to court documents, the man and his codefendant conspired to unlawfully purchase Medicare beneficiary identification information, including Medicare identification numbers, and used that information to submit claims to Medicare for COVID-19 test kits that the beneficiaries did not need or want. From July 2022 through February 2023, the man, his codefendant, and others submitted more than $8.4 million in false claims to Medicare through companies that they owned or controlled, and Medicare reimbursed more than $2.6 million based on such false claims. The man and his codefendant each face a maximum penalty of up to five years in prison in connection with the scheme.

> **A Florida man pleaded guilty to causing more than $8.4 million in false and fraudulent claims to be submitted to Medicare using Medicare identification numbers that the man had unlawfully purchased.**

SALES DIRECTOR PLEADS GUILTY IN TRANSCRANIAL DOPPLER KICKBACK SCHEME

A New York-based national sales director pleaded guilty to conspiring to offer and pay kickbacks to doctors in exchange for ordering medically unnecessary brain scans. From 2013 through 2020, the sales director conspired with others, including two mobile medical diagnostics company managers that performed transcranial doppler (TCD) scans, to pay physicians kickbacks based on the number of TCD ultrasounds ordered, and entered into sham rental and administrative service agreements that concealed the arrangements' true nature. The scheme resulted in fraudulent bills of more than $70 million to Medicare. The sales director faces a sentence of up to five years in prison, three years of supervised release, and a fine of up to $250,000.

MARKETING COMPANY OPERATORS SENTENCED FOR ROLES IN TELEMEDICINE DME KICKBACK SCHEME

Two operators of a New Jersey marketing company were sentenced to 51 months and 80 months in prison, respectively, and ordered to pay more than $127 million in restitution for their roles in a fraud and kickback scheme. According to the court documents, the operators submitted false claims to healthcare benefit programs, including TRICARE and Medicare, as part of a circular kickback scheme with DME companies, telemedicine companies, and physicians. Through their marketing company, the operators targeted beneficiaries and pressured them to agree to accept back, shoulder, and knee braces, regardless of medical necessity. The operators compensated company employees with commissions, incentives, and bonuses to convince beneficiaries to accept DME. The operators also paid kickbacks to telemedicine companies, which in turn paid kickbacks to doctors in exchange for DME prescriptions. As part of the conspiracy, the doctors would sign the prescription orders regardless of medical necessity and often without speaking to the patient. The operators then distributed the DME prescriptions to DME suppliers, which submitted claims for the DME to federal healthcare programs and remitted a portion of the proceeds to the operators. In total, the operators' company received more than $63 million from DME suppliers in exchange for the referrals. In addition to the prison terms, each defendant

was sentenced to three years of supervised release, one defendant was ordered to forfeit more than $63 million, and the other was ordered to forfeit more than $5.5 million.

CMS REGULATORY UPDATES

CMS RELEASES FINAL RULE REGARDING CONTRACT YEAR 2026 POLICY AND TECHNICAL CHANGES TO THE MA PROGRAM, MEDICARE PRESCRIPTION DRUG BENEFIT PROGRAM, MEDICARE COST PLAN PROGRAM, PACE

On April 15, 2025, CMS issued a final rule revising the MA, Medicare Prescription Drug Benefit (Part D), Medicare cost plan, and Programs of All-Inclusive Care for the Elderly (PACE) regulations. The rule codifies the vaccine and insulin cost-sharing requirements of the Inflation Reduction Act of 2022 (IRA), mandating that the Medicare Part D deductibles shall not apply to covered Part D vaccines and covered insulin products. The rule also states that cost sharing cannot apply to vaccines, and, in 2026 and each subsequent year, the covered insulin applicable cost-sharing amount must be the lesser of:

- $35;
- An amount equal to 25% of the maximum fair price established for covered insulin product; or
- An amount equal to 25% of the negotiated price.

With respect to payment plans, the rule codifies Section 11202 of the IRA to establish the Medicare Prescription Payment Plan and requires certain sponsors and MA organizations to provide enrollees with the option pay cost sharing in capped monthly installments. The rule also addresses fragmentation for dually eligible individuals through policies that mitigate cost-shifting incentives between Medicaid and Medicare, maximize person-centered coordination of services, create integrated member identification cards for individuals enrolled in Medicare and Medicaid, and conduct an integrated health risk assessment for Medicare and Medicaid rather than separate assessments for each program. The rule revises several risk adjustment terms, such as Hierarchical Condition Categories, and codifies the longstanding practice of requiring collection and mandatory submission of risk adjustment data by PACE organizations and cost plans. The regulations go into effect on June 3, 2025.

CMS ANNOUNCES CY 2026 MA CAPITATION RATES, PART C AND PART D PAYMENT POLICIES

On April 7, 2025, CMS released its Announcement of Calendar Year (CY) 2026 MA Capitation Rates and Part C and Part D Payment Policies. CMS projects that the final policies in the CY 2026 rate announcement will result in an increase of 5.06%, or more than $25 billion, in MA payments to plans in CY 2026.

OFFICE OF INSPECTOR GENERAL UPDATES

OIG ISSUES FAVORABLE ADVISORY OPINION ON COMMUNITY HEALTH CENTER'S PRIMARY CARE PROPOSAL

OIG issued a favorable advisory opinion regarding a community health center's proposal to connect individuals in the community with primary care services. Under Section 330 of the Public Health Service Act, community health centers are required to provide certain healthcare and other services to community members (*i.e.*, outreach services) and may provide supplemental health services that promote and facilitate optimal use of primary health services. Community health centers also provide primary healthcare services to underserved populations, regardless of their ability to pay. According the center, while individuals in its community frequently access the center's additional services, they typically do not seek healthcare services from the center because they do not believe they have the financial means to do so or do not understand how to do so.

Under its proposed arrangement, in connection with the provision of certain social services to individuals in the community, the center would identify individuals in need of primary care services, inform such individuals of the availability of primary care

services, and schedule appointments for such individuals to receive primary care services from the center or another local primary care provider. The center would ask each individual receiving additional services whether they have seen a primary care provider within the last year; if not, the center would provide the individual with a list of primary care providers. The list would be organized alphabetically, and while it would include the center, the center would not be emphasized or prioritized in any way. If an individual elected to receive primary care services from the center, the center would schedule an appointment for the individual. Otherwise, the center would make a referral to the individual's requested primary care provider. Regardless of whether an individual elected to receive primary care services from the center, the center would continue to provide additional services to such individual.

OIG concluded that while the proposed arrangement does not satisfy an AKS safe harbor, it does not present material risk under the AKS. OIG concluded that the arrangement is unlikely to result in patient steering because of several safeguards, including the following:

- Individuals in need of primary care services would be identified using an objective criterion (*i.e.*, whether the patient has seen a primary care provider within the last year) that does not promote the center.
- The list of primary care providers would be organized alphabetically and in a manner that does not emphasize the center, and the list would include any community provider that requests to be included in the list.
- Individuals could continue to receive additional services from the center regardless of whether they choose to receive primary care services from the center.

The arrangement is also consistent with the center's designation as a health center under Section 330 of the Public Health Service Act, since it would align with the Center's statutory obligation to increase community access to healthcare services.

For the same reasons, OIG concluded that while the proposed arrangement would implicate the beneficiary inducements civil monetary penalty law, OIG would exercise its enforcement discretion to not impose sanctions under the law.

OTHER NOTABLE DEVELOPMENTS

TEXAS DISTRICT COURT STRIKES DOWN CMS NURSING HOME STAFFING RULE

On April 7, 2025, the US District Court for the Northern District of Texas struck down a CMS rule mandating certain staffing requirements for nursing homes participating in Medicare and Medicaid. The rule would have mandated nursing homes to staff sufficient registered nurses to provide 24/7 coverage and maintain certain other minimum staffing requirements. The court found that because Congress had already passed legislation addressing minimum staffing requirements for nursing homes, promulgation of the rule exceeded CMS's rulemaking authority.

SENATE REPUBLICANS INTRODUCE PHYSICIAN LED AND RURAL ACCESS TO QUALITY CARE ACT

On April 9, 2025, Senator James Lankford (R-OK) and eight other Republican senators introduced S. 1390 to enact the Physician Led and Rural Access to Quality Care Act, which would repeal certain elements of the ACA's prohibition on the expansion and creation of new physician-owned hospitals. More specifically, the legislation would revise certain self-referral exemptions by permitting physician ownership in rural hospitals located further than a 35-mile drive from a critical access hospital or main patient campus. The legislation also would enable grandfathered physician-led hospitals to expand and meet community needs.

The proposed legislation follows a similar bill, H.R. 2191, which was introduced in the US House of Representatives last month and has garnered bipartisan support. While similar proposed amendments to lift the ACA's ban on new physician-owned hospitals have failed in the past, these recent legislative efforts appear to make more modest amendments to the ACA's ban on physician hospital ownership and may attract more bipartisan support. With a new administration and Congress, it is unclear if we will see this or similar legislation liberalizing physician ownership in hospitals moving forward.

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

NICHOLAS ALARIF
PARTNER
nalarif@mwe.com
Tel +1 202 756 8041

ASSERET FRAUSTO
ASSOCIATE
afrausto@mwe.com
Tel +1 617 535 4067

VINCENT LEAHEY
ASSOCIATE
vleahey@mwe.com
Tel +1 305 507 2316

LAUREN ELLISON
ASSOCIATE
lellison@mwe.com
Tel +1 202 886 8563

Stay current on the latest healthcare regulatory developments.

SUBSCRIBE TO HEALTH LAW UPDATES

FOR MORE INFORMATION, VISIT MWE.COM.

McDermott Will & Emery