# HEALTHCARE REGULATORY CHECK-UP

**IN THIS MAY 2024 ISSUE**



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# MAY REGULATORY UPDATE SUMMARY

This issue of McDermott's *Healthcare Regulatory Check-Up* highlights regulatory activity for May 2024. We discuss several notable cases and enforcement resolutions, including the US Court of Appeals for the District of Columbia Circuit's (DC Circuit) favorable decision for drug manufacturers in the ongoing Section 340B dispute and the resolution of several enforcement actions, including some that alleged violations under the False Claims Act (FCA) and federal Anti-Kickback Statute (AKS). We also review several US Department of Health and Human Services (HHS) agency actions, such as a final rule that provides robust civil rights protections for individuals with disabilities, and a new process for submitting independent dispute resolution (IDR) requests under the No Surprises Act that are improperly batched or bundled. We also preview the telehealth extension and remote monitoring legislation that is currently working its way through the House of Representatives. Additionally, we discuss a recently issued Office of Inspector General (OIG) report pertaining to continued fraud and abuse risks with off-the-shelf orthotic braces.

# NOTABLE CASES, ENFORCEMENT RESOLUTIONS AND RELATED AGENCY ACTIVITY

## DC CIRCUIT SIDES WITH DRUG MAKERS IN 340B DISPUTE OVER CONTRACT PHARMACIES

On May 21, 2024, the DC Circuit issued a unanimous decision in favor of drug manufacturers, finding that Section 340B of the Public Health Service Act does not categorically prohibit manufacturers from imposing certain conditions on the distribution of covered drugs to covered entities, such as imposing obligations to provide claims data for contract pharmacy orders. The Court concluded that, although Section 340B requires drug manufacturers to "offer" each covered entity covered outpatient drugs for purchase at or below a specified ceiling price, the section is silent with regard to delivery conditions. In the Court's opinion, this silence "preserves—rather than abrogates—the ability of the sellers to impose at least some delivery conditions." The Court added the important caveat that "other, more onerous" conditions might violate the statute, and it did not foreclose the possibility that the same conditions set forth in the case may violate Section 340B as applied in particular circumstances.

The DC Circuit is the second of three federal appellate courts to assess the scope of the contract pharmacy requirements. The US Court of Appeals for the Third Circuit recently decided in favor of manufacturers on similar grounds, while the US Court of Appeals for the Seventh Circuit has yet to issue a final opinion.

### ELEVENTH CIRCUIT HOLDS HEALTH PLAN'S BLANKET EXCLUSION OF GENDER-AFFIRMING SURGERY VIOLATES TITLE VII

Relying on the Supreme Court of the United States' decision in *Bostock*, a divided US Court of Appeals for the Eleventh Circuit held that a Georgia county's health plan violated Title VII of the Civil Rights Act of 1964. The plan imposed a blanket exclusion for gender-affirming surgery. The Court found that discrimination on the basis of transgender status necessarily implicates discrimination on the basis of sex, while the dissent concluded that the exclusion did not fit *Bostock*'s rubric because the exclusion did not turn on the plaintiff's sex. While the case law regarding gender-affirming care and group health plan coverage continues to evolve, insurers and employers should be mindful of their plan exclusions moving forward and take potential litigation risks into account. The full Eleventh Circuit opinion is available here.

### FLORIDA BUSINESSMAN TO PAY MORE THAN $27 MILLION FOR MEDICARE FRAUD

A Florida businessman has agreed to pay more than $27 million to resolve civil allegations that he and his companies conspired to violate the FCA by submitting false claims to Medicare for cancer genomic tests that were not medically necessary, and further conspired to violate the AKS by illegally procuring the tests through an elaborate scheme. Specifically, the alleged scheme involved use of telemarketing agents and "health fairs" to provide Medicare beneficiaries with free test kits. Completed test kits were funneled through a hospital, repackaged and sent to a third-party lab for testing, and the co-conspirators obtained telemedicine prescriptions from doctors who did not conduct proper telemedicine visits or otherwise have a treating relationship with the patient. Each test was reimbursed by Medicare for approximately $12,000. The scheme also allegedly included sham marketing and consulting arrangements that compensated marketers based on the volume of tests and the resulting Medicare reimbursement. The defendant had previously pled guilty to related criminal charges in 2022, resulting in restitution and penalties of more than $97 million.

### MEDICAL DEVICE MANUFACTURER AND TWO TOP EXECUTIVES PAY $12 MILLION TO SETTLE FCA AND AKS ALLEGATIONS

A spinal device manufacturer and two of its top executives have agreed to pay $12 million to resolve FCA and AKS allegations involving improper payments to physicians. The allegations stem from payments made to 17 orthopedic surgeons and neurosurgeons, which were purportedly made to encourage the use of the manufacturer's spinal implants and other devices. The improper renumeration took the form of intellectual property acquisition and licensing fees, consulting fees, lavish dinners and parties for the surgeons, as well as travel to luxury resorts. For instance, the manufacturer allegedly paid the physicians exorbitant "consulting" rates far above fair-market value and, occasionally, paid the physicians for work that was never actually performed.

## CMS REGULATORY UPDATES

### TELEHEALTH EXTENSION, REMOTE MONITORING PASSES HOUSE SUBCOMMITTEE

The House Energy and Commerce Subcommittee on Health voted to send to the full committee the Telehealth Enhancement for Mental Health Act of 2024, the Telehealth Modernization Act of 2024 and the Expanding Remote Monitoring Access Act of 2024, which would preserve pandemic-era telehealth flexibilities and expand remote patient monitoring rules set to expire at the end of the year.

Although the bills were originally intended to establish permanent telehealth flexibilities, the amended versions extend the flexibilities through 2026. If passed, the Energy and Commerce bills would address a long-standing payment disparity by enabling rural health clinics and federally qualified health centers to bill the same amount for in-person outpatient services and telehealth services. Other key provisions in the telehealth bills include the extension of audio-only telehealth billing for two years, a five-year extension of the

Acute Hospital Care at Home program, and the elimination of geographic originating site restrictions for two years. The bills still need to pass the full committee before being presented to the House for a vote.

## HHS FINAL RULE: NONDISCRIMINATION ON THE BASIS OF DISABILITY IN PROGRAMS OR ACTIVITIES

On May 9, 2024, HHS implemented a final rule entitled Nondiscrimination on the Basis of Disability in Programs or Activities Receiving Federal Financial Assistance, which repromulgates and expands upon Section 504 of the Rehabilitation Act of 1973 and provides robust civil rights protections for a broad array of individuals with disabilities who seek services from more than 100 federally funded programs (*e.g.*, services at hospitals participating in Medicare and Medicaid). The final rule expressly prohibits the denial of medical treatment based on bias or stereotypes, sets forth additional prohibitions specific to child welfare programs/services, and implements accessibility standards for all newly acquired diagnostic medical equipment.

The rule will take effect on July 8, 2024. For more details regarding the final rule and the requirements that affected parties will need to prepare for, see our OTS here.

## CMS PROPOSES MANDATORY PAYMENT MODEL AND OTHER INNOVATIONS TO IMPROVE ACCESS TO KIDNEY TRANSPLANTS

The Centers for Medicare & Medicaid Services (CMS) has proposed the Increasing Organ Transplant Access (IOTA) Model, a new mandatory Medicare payment model intended to test whether performance-based incentive payments to kidney transplant hospitals can increase access to kidney transplants. The proposed model will be implemented by the CMS Innovation Center. Under the proposed model, hospitals would be incentivized to increase the number of transplants, increase organ acceptance rates and improve post-transplant outcomes for patients. The program would award payments of up to $8,000 per Medicare transplant for meeting certain positive criteria and make hospitals responsible for a maximum downside risk payment of $2,000. CMS proposed other financial incentives for increasing equity and access to kidney transplants and has indicated that hospitals in the model would be provided greater flexibility to address health-related social needs and donation processes for kidney donors and recipients.

CMS will run the model by selecting approximately half of all eligible kidney transplant hospitals as participants, with the other half serving as a control group. The model has a proposed start date of January 1, 2025, and will run for six years. CMS is accepting comments on the proposed model until July 16, 2024. The public can submit comments here.

## CMS ISSUES MEMO REGARDING SOCIAL WORKERS, MENTAL HEALTH COUNSELORS, AND MARRIAGE AND FAMILY THERAPISTS AS PART OF HOSPICE TEAMS

In a memo to state survey directors, CMS drew attention to requirements that were made effective January 1, 2024. Under the updated Conditions of Participation (CoPs), hospice facilities are required to include at least one social worker, marriage and family therapist (MFT), or mental health counselor (MHC) as part of the hospice interdisciplinary group. Further, MFTs and MHCs can now be owners or employees of rural health clinics and federally qualified health centers. CMS notes that the CoPs for each of these facility types were updated to recognize MFTs and MHCs as recognized staff, but facilities offering the services of MFTs and MHCs must update their patient-care policies to reflect these additions. Further, the CoP definition of "nurse practitioner" was updated to align with current professional practice standards for nurse practitioners.

## NO SURPRISES ACT: NEW PROCESS FOR RESUBMITTING IDR DISPUTES

HHS, along with the US Departments of Labor and the Treasury, released a new process for submitting IDR disputes that were improperly batched or bundled. Entities that have submitted IDR requests will receive an email notification that their dispute is eligible to be resubmitted and such resubmission will be processed through the user's federal IDR portal. Parties have four business days from the date of the email to resubmit their dispute. While this update is a relatively minor procedural update, federal regulators have commented that they plan to issue final regulations this year to improve other efficiencies in the arbitration process. Providers subject to the No Surprises Act should be on the lookout for the resubmission emails.

# OFFICE OF INSPECTOR GENERAL UPDATES

## OIG ISSUES REPORT ON CONTINUED FRAUD AND ABUSE RISKS WITH OFF-THE-SHELF ORTHOTIC BRACES

Off-the-shelf (OTS) orthotic braces have long been an area of concern for OIG and CMS, as regulators believe that OTS braces have certain factors that make them more vulnerable to fraud, waste and abuse. Suppliers of OTS braces are not required to be licensed or certified, braces may be shipped directly to Medicare beneficiaries, and minimal clinical criteria means, according to OIG, that OTS braces can readily be overprescribed to Medicare beneficiaries. In its new report, OIG reviewed vulnerabilities identified in prior audits and evaluations and found that (1) providers without a treating relationship with a beneficiary frequently ordered braces for such beneficiaries, (2) new suppliers were located in geographic areas with known Medicare fraud, (3) Medicare paid more than private payors for OTS braces and (4) suppliers used prohibited solicitation methods to contact beneficiaries.

OIG recommended that CMS strengthen its oversight of Medicare billing for OTS braces. Primarily, it recommended that CMS (1) ensure claims include required modifiers, (2) proactively identify providers who order OTS braces for beneficiaries with whom there is no treating relationship, (3) proactively analyze supplier billing patterns, (4) compare Medicare OTS allowable amounts to amounts allowable by non-Medicare payors, (5) educate suppliers on permitted telemarketing practices and (6) use predictive data analysis to identify emerging fraud schemes related to OTS braces.

# OTHER NOTABLE DEVELOPMENTS

## NURSING HOME GROUP SUES TO BLOCK CMS FINAL RULE ON MINIMUM STAFFING

The American Health Care Association (AHCA) recently filed a lawsuit in the US District Court for the Northern District of Texas alleging that CMS has exceeded its statutory authority and acted arbitrarily in promulgating its controversial final rule implementing minimum nurse staffing requirements for Medicare- and Medicaid-participating long-term care facilities. By AHCA's estimation, the final rule will cost facilities approximately $6.5 billion annually, which surpasses CMS's $5 billion estimate. The complaint also alleges that CMS's decision to impose an unfunded mandate at a time when nursing homes are already financially constrained will likely force hundreds of homes to close. For additional details, see commentary here from Partner Gregory Fosheim.

## WHITE HOUSE TO PUSH CYBERSECURITY STANDARDS FOR HOSPITALS

In light of the February 2024 hack against Change Healthcare, the Biden administration announced that it intends to require hospitals to meet minimum cybersecurity standards. The administration will also offer free cybersecurity trainings to 1,400 small, rural hospitals across the country in the coming weeks.

# AUTHORS & CONTACT


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

**EMILY COOK**
PARTNER
ecook@mwe.com
Tel +1 310 284 6113

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

**JAMES CANNATTI**
PARTNER
jcannatti@mwe.com
Tel +1 202 756 866

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

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


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