HEALTHCARE REGULATORY CHECK-UP

IN THIS MARCH 2024 RECAP ISSUE

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MARCH REGULATORY UPDATE SUMMARY

This issue of McDermott's *Healthcare Regulatory Check-Up* highlights regulatory activity for March 2024. We summarize a US Court of Appeals for the Second Circuit decision interpreting the intent standard under the federal Anti-Kickback Statute (AKS). We also discuss several criminal and civil enforcement actions pertaining to healthcare fraud, including alleged violations under the False Claims Act (FCA), AKS and Physician Self-Referral Law (Stark Law). We then review several US Department of Health and Human Services (HHS) agency actions, including several HHS Office of Inspector General (OIG) audits regarding Provider Relief Fund spending and diabetes drug and opioid prescriptions, as well as an upcoming OIG study of vertical integration of prescription drug pharmacy benefits managers. We also cover other government activities, including a multi-agency request for information about the involvement of private equity in the healthcare system and a proposed rule concerning compounding drugs.

NOTABLE ENFORCEMENT RESOLUTIONS AND ACTIVITY

SECOND CIRCUIT ENDORSES "WILLFULNESS" STANDARD FOR FCA CLAIMS BASED ON THE FEDERAL AKS

On March 12, 2024, the Second Circuit issued its opinion in *United States ex. rel. Hart v. McKesson Corp, No. 23-726*. The Second Circuit opined on the "willfulness" standard under the AKS for FCA claims. The Second Circuit endorsed the US Court of Appeals for the Eleventh Circuit's interpretation that to "act willfully, a defendant need not be aware of the AKS or have a specific intent to violate that statute, but she must act knowing that her conduct is in some way unlawful." Upon this interpretation, the Second Circuit affirmed dismissal of a federal AKS claim against McKesson Corp.

The case involved a relator's allegation that a wholesale distributor of medical supplies and drugs, McKesson Corp., allegedly provided certain free business management tools to healthcare practices as an incentive to induce the practices to purchase drugs from the distributor. In alleging willful action, the relator pointed to several regular internal trainings on the AKS that stated that providing anything of value to induce the sale of pharmaceuticals violates federal law.

The Second Circuit rejected the relator's arguments that the distributor knew that the offering of certain free business management tools was unlawful and determined that the destruction of documents after receiving notice of potential unlawfulness was insufficient grounds to proving knowledge. The appellate court further rejected the relator's proposed two-factor test whereby willfulness could

be satisfied through evidence that the defendant intentionally provided something of value in connection with a medical purchase reimbursed by the government while knowing that it is illegal to provide things of value with such purchases. The Second Circuit affirmed the dismissal of the federal AKS claim, vacated the dismissal of the state claims, and remanded for further proceedings.

DEPARTMENT OF JUSTICE SUES SIX HEALTH PLANS AND THEIR ALLIANCE FOR OVERPAYMENTS RECEIVED FROM THE US FAMILY HEALTH PLAN

The Department of Justice (DOJ) intervened in a *qui tam* action alleging that more than $300 million in overpayments were made to six private health plans between 2008 and 2012 by the Department of Defense (DOD) under the US Family Health Plan (USFHP), a health plan for active and former military personnel and their families. The six health plans had entered into USFHP contracts, which contracts incorporated contract terms from the Federal Acquisition Regulation (FAR). One of these incorporated FAR terms required the private health plans to immediately notify the responsible government officer in the event that they became aware of government overpayments. The complaint alleges that the six health plans became aware of the DOD overpayments in June 2012 but never reported the overpayments to the government. The alleged overpayments stemmed from two errors made by an actuarial firm retained by the DOD, which resulted in the calculated statutory payment limitations for certain USFHP beneficiaries being inflated. The complaint further alleges that the six plans continued to file claims under the faulty higher rates for six months after discovering the errors.

PENNSYLVANIA-BASED PHARMACEUTICAL MANUFACTURER AGREES TO PAY $2 MILLION FOR FCA CIVIL LIABILITY

A Pennsylvania-based generic drug manufacturer has agreed to pay the United States approximately $2 million to resolve allegations under the FCA that the manufacturer allegedly had, without receiving the consent of the US Food & Drug Administration (FDA), manufactured hydroxyzine tablets using an active pharmaceutical ingredient (API) that was produced at a foreign facility. Additionally, the manufacturer allegedly failed to comply with applicable regulations regarding its control of its computer and related manufacturing systems. In addition to the FCA settlement, the manufacturer also pled guilty to two misdemeanor counts of introducing adulterated drugs into interstate commerce in violation of the under the federal Food, Drug & Cosmetic Act (FDCA) and entered into a three-year deferred prosecution agreement and agreed to a $1.5 million fine.

MISSOURI-BASED LABORATORY CORPORATION AGREES TO PAY $13.6 MILLION TO RESOLVE NON-MEDICALLY NECESSARY LAB TEST ALLEGATIONS

A Missouri-based laboratory corporation and three of its owners have agreed to pay the United States approximately $13.6 million to resolve allegations under the FCA for automatically performing, and billing to Medicare, urinary tract infection (UTI) tests whenever a physician would order a urinalysis (UA) with culture and sensitivity (C&S) in 2020. The laboratory corporation's requisition forms allegedly did not permit physicians to opt out of ordering the UTI tests when a C&S test was ordered, and while Medicare only paid approximately $11 for a UA with C&S, Medicare paid an additional $573 for the UTI tests. The settlement arises from a *qui tam* case brought by a physician who owned a clinic that ordered tests from the lab. The owners also agreed to be excluded from federal healthcare programs for 15 years.

FEDERAL JURY CONVICTS TENNESSEE-BASED PODIATRIST WHO PRESCRIBED UNNECESSARY FOOT BATH MEDICATIONS

A Tennessee-based podiatrist was convicted by a federal jury of five counts of healthcare fraud arising from a scheme to submit nearly $4 million in claims to Medicare and TennCare (Tennessee's Medicaid program). The podiatrist operated a podiatry clinic and an in-house pharmacy. The podiatrist was found guilty of healthcare fraud for (1) prescribing medically unnecessary prescriptions for oral antibiotics and antifungal creams for use in footbaths; and (2) regularly waiving or reducing patient Medicare copayments without taking patients' ability to pay the copayments into consideration. After the podiatrist's in-house pharmacy was audited by Medicare Part D plans and pharmacy benefit managers, the podiatrist formed a new in-house pharmacy, allegedly to conceal his fraudulent practices. In submitting the Medicare enrollment for this new in-house pharmacy, the podiatrist concealed his interest in the original

in-house pharmacy. The podiatrist faces a maximum sentence of 10 years in prison on each of the five counts for which he was convicted.

CMS REGULATORY UPDATES

GOVERNMENT ACCOUNTABILITY OFFICE RECOMMENDS CMS INCREASE OVERSIGHT ACTIVITIES OVER MEDICAID MANAGED CARE PROGRAMS

The US Government Accountability Office (GAO) released its recommendations to the US Centers for Medicare & Medicaid Services (CMS) on request of the Senate Committee on Finance and the House Committee on Energy and Commerce, based on an examination of the appeals and grievances data that states were required to report beginning in 2022 for their respective managed care programs. GAO analyzed data across 35 states and released its reports and recommendations on March 14, 2024. GAO found that the rates of appeals and grievances varied dramatically across states, ranging from 0.4 to 38.0 grievances per 1,000 enrollees. GAO also noted that there was significant plan-level variation in the data as, in one state, the grievance rates varied from 2.8 to 89.5 grievances per 1,000 enrollees across the managed care plans. Interviews with state officials from South Carolina, New Jersey and Ohio suggest that the variance is related to subjectivity in how plans define a "grievance."

The data contained two major limitations: (1) gaps and inconsistencies in the submitted data and (2) state non-reporting. GAO found that CMS had begun taking steps to address limitations in the data as of December 2023, including hosting a webinar, sharing technical assistance resources and making minor revisions to the reporting template to clarify instructions. Despite these steps, GAO found that CMS has made limited progress in implementing its stated draft plan from April 2023, including: (1) launching an analytic dashboard, (2) publishing summary reports and state-level data, and (3) developing and implementing an oversight plan. GAO further found that CMS does not collect outcomes data on enrollee appeals or denials. GAO recommended that CMS require states to report such outcomes data and implement plans to analyze, utilize and publicize the collected data.

CMS concurred with the recommendations and noted plans to address them. In particular, the agency will include data fields on outcomes of appeals and denials in future reporting and reaffirmed its commitment to implementing the April 2023 draft plan.

OFFICE OF INSPECTOR GENERAL UPDATES

OIG ISSUES AUDIT REPORT ON PROVIDER RELIEF FUND PROGRAM OVERPAYMENTS

OIG audited a sample of 150 providers, reviewing funds disbursed under the Provider Relief Fund (PRF) Phase 2 General Distribution that was distributed to Medicaid, the Children's Health Insurance Program (CHIP), dental providers, and assisted living facilities. OIG found that the Health Resources and Services Administration (HRSA) improperly disbursed funds to 17 of the 150 sampled providers, amounting to $18.4 million in potential overpayments in the sample. Generalizing this result for all providers, OIG estimated that HRSA made $159.4 million in potential overpayments to providers. OIG recommended that HRSA continue to identify providers to review, and that HRSA better safeguard taxpayer funds.

OIG ANNOUNCES UPCOMING EVALUATION ABOUT VERTICAL INTEGRATION AND MEDICARE PART D SERVICES

OIG announced that it will be preparing a study of pricing, payment and rebate data relating to large prescription drug benefits plan sponsors, to analyze vertical integration in the field and the effect of such integration on costs for the Medicare program and its enrollees. The motivating factor for this study is that approximately three-quarters of Medicare Part D enrollees receive their prescription drug benefits through five companies. This study is part of a broader trend relating to the OIG's emphasis on Medicare Part D spending and federal focus on antitrust concerns in the healthcare industry.

OIG ISSUES AUDIT REPORT ON IMPROPER MEDICAID CLAIMS MADE BY PENNSYLVANIA FOR SCHOOL-BASED PROGRAMS

OIG audited a sample of claims submitted to Medicaid in Pennsylvania for school-based programs. The claims sampled were coded as either a "health service" or an "administrative activity." OIG found that Pennsylvania improperly claimed $551.4 million, noting that the state and its contractor had relied on difficult or impractical methods of computing and submitting claims. In light of this audit, OIG recommended that Pennsylvania refund the majority of the funds. Additionally, OIG made procedural recommendations to Pennsylvania to ensure accurate and supportable claims.

OIG ISSUES AUDITS OF STATES' MCO CONTRACTING PRACTICES

OIG conducted several audits relating to states' contracting with Medicaid managed care organizations (MCOs) and the provision of services to individuals seeking treatment for mental health and substance abuse disorders. In one audit, OIG sampled eight states and reviewed state contracts with MCOs to check whether they contained federally required parity provisions to ensure that individuals seeking care for mental health and substance use disorders receive treatment similar to that of any other individual seeking treatment. In all of the sampled states, the MCO contracts did not include the required provisions, and OIG recommended that CMS improve its oversight of states' compliance with the parity requirements. In a similar vein, OIG audited Delaware's contracting with MCOs and found that the state had been making unallowable capitation payments to MCOs on behalf of deceased Medicaid enrollees. OIG recommended the state refund the federal share of the unallowable funds disbursed.

OIG ANNOUNCES AUDITS ON DIABETES DRUGS WITH WEIGHT-LOSS SIDE EFFECTS

In light of increased Medicaid utilization of and gross spending on diabetes and weight-loss drugs, OIG has announced that it will select one or more states in which to audit that utilization and spending. The focus of the audit will be on drugs designed for individuals with type 2 diabetes that are covered by some states' Medicaid programs alternatively for diabetes and treatment and for weight loss. In a similar vein, noting that weight-loss drugs are excluded from Medicare Part D coverage and that billing for type 2 diabetes drugs with weight-loss side effects has risen steeply recently, OIG has announced that it will audit Medicare Part D data related to these billings.

OIG ISSUES AND ANNOUNCES AUDITS RELATED TO THE OPIOID CRISIS

OIG recently audited New Jersey's implementation of the HHS Substance Abuse and Mental Health Services Administration's (SAMHSA) award and grant program for reducing opioid overdose-related deaths. OIG found that the state complied with federal requirements, but that it did not meet program goals. OIG recommended that New Jersey delay funding upon receiving grant applications until SAMHSA's goals were met. OIG also announced that it will select nursing facilities to be audited for compliance with quality-of-care requirements and reported, investigated and implemented corrective actions for potential illegal drug usage and pain medication errors involving opioid overdoses. These completed and upcoming audits are part of a broader and ongoing OIG effort to examine drug abuse and overdose deaths throughout the United States.

OTHER NOTABLE DEVELOPMENTS

OCR ISSUES UPDATE ON ITS BULLETIN REGARDING THE USE OF ONLINE TRACKING TECHNOLOGIES BY HIPAA COVERED ENTITIES AND BUSINESS ASSOCIATES

On March 18, 2024, the HHS Office for Civil Rights (OCR) issued an update to its December 1, 2022, bulletin on HIPAA requirements for online tracking technologies. OCR stated that the update, titled "Use of Online Tracking Technologies by HIPAA Covered Entities and Business Associates," was issued to "increase clarity for regulated entities and the public." The update largely reconfirms prior guidance in the 2022 bulletin while responding to criticisms that the bulletin was overbroad. The update appears to narrow the scope of what OCR considers to be HIPAA-protected health information (PHI) in the context of online tracking technologies. For more information, please see our On the Subject, *OCR Update on Tracking Technologies Provides Little Relief for HIPAA-Regulated Entities*.

PRESIDENT BIDEN ISSUES EXECUTIVE ORDER ADVANCING WOMEN'S HEALTH RESEARCH AND INNOVATION

On March 18, 2024, President Biden issued Executive Order #14120, titled "Advancing Women's Health Research and Innovation." The executive order issues directives to several constituent agencies, including HHS, DOD, the Department of Veterans Affairs, the Department of Agriculture, the Environmental Protection Agency and the National Science Foundation. The directives focus on the following goals: (1) integrating women's health across the federal research portfolio by directing the constituent agencies to develop and strengthen research and data standards on women's health across all relevant research and funding opportunities; (2) prioritizing investments in women's health research through the Advanced Research Projects Agency for Health (ARPA-H), the Small Business Innovation Research Program and the Small Business Technology Transfer Program; (3) launching a National Institutes of Health (NIH)-wide effort supported by $200 million from NIH beginning in FY 2025 to catalyze interdisciplinary research on multi-faceted projects such as research on the impact of perimenopause and menopause on heart health, brain health and bone health; (4) spurring new research on women's midlife health via expanded data collection and developing a comprehensive research agenda to narrow research gaps on diseases and conditions associated with women's midlife health or that are more likely to occur after menopause; and (5) assessing unmet needs to support women's health research by directing the Office of Management and Budget (OMB) and the Gender Policy Council, a White House policy council established in 2021, to advance gender equity and equality in domestic and foreign policy development and implementation.

FTC, DOJ AND HHS ISSUE JOINT REQUEST FOR INFORMATION ON THE EFFECTS OF TRANSACTIONS IN THE HEALTHCARE INDUSTRY

On March 5, 2024, the Federal Trade Commission (FTC), DOJ and HHS issued a joint Request for Information (RFI) asking for public comment regarding transactions conducted by private equity funds, health systems and private payers. The cross-agency inquiry seeks to understand the effects of consolidation, the claimed business objectives for the transactions, notable transactions, the need for government action and any other impacts. In issuing the RFI, the agencies raised concerns regarding competition in healthcare markets. The public may submit comments through May 6, 2024. The agencies stated that they intend to use the responses to inform future enforcement priorities and regulatory actions.

SENATOR CHARLES E. GRASSLEY PROBES DOJ REGARDING THE DISMISSALS OF *QUI TAM* ACTIONS

On March 6, 2024, Senator Charles E. Grassley (R-Iowa), Ranking Member of the Senate Budget Committee, sent a letter to US Attorney General Merrick Garland inquiring about the DOJ's policies on intervening in FCA *qui tam* cases. In particular, Senator Grassley raised concerns over the DOJ's practice of declining to intervene in cases early on, only to intervene later for the sole purpose of dismissing the case and after many years of litigation by the relator. Specifically, Senator Grassley requested information regarding the DOJ's policies and position on the practice post-*United States ex. Rel. Polansky v. Executive Health.* In *Polansky*, the US Supreme Court held that the DOJ may move to dismiss an FCA action whenever it decides to intervene, whether during the seal period or later.

FDA ISSUES A PROPOSED RULE ON COMPOUNDING OF DRUGS THAT ARE DEMONSTRABLY DIFFICULT TO COMPOUND

On March 20, 2024, the FDA issued a proposed rule on "Drug Products or Categories of Drug Products that Present Demonstrable Difficulties for Compounding Under Sections 503A or 503B of the Federal Food, Drug, and Cosmetic Act." The proposed rule continues the trend of increased FDA oversight over the compounding of pharmaceutical products. The FDA proposes the formation of two lists: one for Section 503A compounding pharmacies and one for Section 503B outsourcing facilities. The proposed rule would also establish the criteria for listing drug products or categories of drug products that present demonstrable difficulties for compounding. The proposed criteria include the following: (1) formulation complexity, (2) drug delivery mechanism complexity, (3) dosage form complexity, (4) bioavailability achievement complexity, (5) compounding process complexity, and (6) physicochemical or analytical testing complexity. The FDA is also proposing to add the following three categories of drug products to both lists: (1) oral solid modified-release drug products that employ coated systems, (2) liposome drug products and (3) drug products produced using hot melt extrusion. The development of these lists may impede the compounding of pharmaceutical products as drug products or categories of drug products that appear on the respective demonstrable difficulties for compounding (DDC) lists may not be compounded under Section 503A or 503B of the Federal Food, Drug, and Cosmetic Act. The comment period closes on June 18, 2024.

FDA PROPOSES RULE TO BAN ELECTRICAL STIMULATION DEVICES INTENDED FOR SELF-INJURIOUS OR AGGRESSIVE BEHAVIOR

The FDA issued a proposed rule that would ban electrical stimulation devices (ESDs) intended for self-injurious or aggressive behavior due to these devices presenting an "unreasonable and substantial risk of illness or injury that cannot be corrected or eliminated by labeling." The FDA had previously issued a similar proposed rule in 2016 and final rule in 2020. However, in 2021, the US Circuit Court of Appeals for the District of Columbia vacated the rule, finding that the FDA did not have the authority to ban products for some but not all their intended uses. Following the ruling, Congress amended the FDCA to clarify that the FDA may issue selective purpose bans. The FDA rarely issues bans on medical devices, having issued only two such bans in its history. If finalized, this proposed rule would ban the use of ESDs for the treatment of patients with self-injurious or aggressive tendencies as the FDA determined that such patients tend to have difficulty communicating their experiences and may lack the ability to consent to its use. The comment period ends on May 28, 2024.

FDA ISSUES GUIDANCE ON HANDLING AND RETENTION OF BIOAVAILABILITY AND BIOEQUIVALENCE TESTING SAMPLES

The FDA issued part final and part draft guidance, titled "Handling and Retention of BA and BE Testing Samples," to revise its previous 2004 guidance of the same name. The guidance is meant to clarify the FDA's policy on the quantity and quality of samples to ensure comparability to reference-listed drugs and to deter fraud in testing. The FDA stated that this guidance comes as the result of observing a number of concerning practices in its inspections of clinical and analytical sites performing bioavailability and bioequivalence studies. The guidance outlines (1) how the test articles and reference standards should be distributed to testing sites, (2) how samples for testing and maintained for reserves should be randomly selected, and (3) how the samples should be reserved. The comment period ends on May 28, 2024.

AUTHORS & CONTACT

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

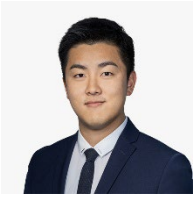
EMILY COOK
PARTNER
ecook@mwe.com
Tel +1 310 284 6113

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

STEVEN SCHNELLE
PARTNER
sschnelle@mwe.com
Tel +1 212 547 5403

MAX LUBIN
ASSOCIATE
mlubin@mwe.com
Tel +1 212 547 5501

BENJAMIN GLASS
ASSOCIATE
bglass@mwe.com
Tel +1 212 547 5612



JAE HYUN LEE
LAW CLERK
jhlee@mwe.com
Tel +1 212 547 5348

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