

HEALTHCARE REGULATORY CHECK-UP



JANUARY REGULATORY UPDATE

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JANUARY REGULATORY UPDATE SUMMARY

This issue of McDermott's *Healthcare Regulatory Check-Up* highlights significant regulatory activity and developments occurring in January 2023, including several criminal and civil enforcement actions related to the federal Anti-Kickback Statute (AKS), physician self-referral law (Stark Law) and False Claims Act (FCA). This issue also discusses recent regulatory developments more broadly.

NOTABLE ENFORCEMENT ACTIONS

SUPREME COURT DENIES CERTIORARI IN FCA CASE

On January 9, 2023, the Supreme Court of the United States [denied](#) a [petition for a writ of certiorari](#) filed by a pharmaceutical manufacturer seeking to establish that liability in AKS cases requires proof of corrupt intent. This case arose from the manufacturer's challenge to a negative US Department of Health and Human Services (HHS) Office of Inspector General advisory opinion on the manufacturer's patient assistance program. The manufacturer previously lost its challenge at the federal district court and the US Court of Appeals for the Second Circuit.

PHARMACEUTICAL COMPANY ALLEGES DOJ IGNORED, CONCEALED EVIDENCE

A pharmaceutical manufacturer [alleged](#) that the US Department of Justice (DOJ) concealed and ignored evidence in an FCA claim in which the DOJ alleged that the pharmaceutical company provided illegal kickbacks under the guise of charitable contributions. The pharmaceutical manufacturer argued that before filing suit in 2020, the government was aware that a charity had contacted the manufacturer about the charity's funding needs, which were allegedly not limited to patients who were prescribed the manufacturer's drugs. The manufacturer argued that the DOJ concealed and disregarded this evidence when it filed the FCA suit, and filed a motion for summary judgment on January 31, 2023.

MEDICAL DEVICE COMPANY PAYS \$700,000+ TO SETTLE MISBRANDING CLAIMS

A Pennsylvania medical device company agreed to pay \$200,000 in criminal fines and another \$545,000 in a [civil settlement](#) regarding misbranded devices under the Federal Food, Drug and Cosmetic Act. The case arose from a qui tam complaint filed in the Southern District of Illinois. The device company allegedly distributed a nerve block catheter, a device intended to help with

migraines, without approval or clearance from the US Food and Drug Administration. The company also allegedly did not conduct an investigational study regarding the product's safety and effectiveness.

LAB OWNERS, EXECUTIVES INDICATED FOR \$107M KICKBACK SCHEME

Genetic testing laboratory owners and executives were indicted in an [AKS-based case](#) alleging that more than \$107 million in false and fraudulent claims were submitted to the government for genetic testing services. The government alleged that the defendants paid kickbacks and bribes in exchange for thousands of Medicare beneficiaries' DNA specimens and corresponding prescriptions using sham contracts for purported marketing and other payments. The case was brought as part of Operation Double Helix, a coordinated federal law enforcement action led by the DOJ Criminal Division's Health Care Fraud Unit.

DOCTORS CONVICTED FOR SCHEME TO DEFRAUD MEDICARE

A federal jury convicted two Florida doctors for their roles in a [scheme](#) to defraud Medicare by submitting more than \$31 million in claims for medically unnecessary durable medical equipment procured through kickbacks. According to court documents and evidence presented at trial, the doctors, who owned interests in certain durable medical equipment companies, paid kickbacks to marketers who used overseas call centers to solicit patients and telemedicine companies to procure prescriptions for medically unnecessary braces for patients.

FLORIDA INDIVIDUALS CHARGED FOR SELLING 7,600+ FAKE NURSING DIPLOMAS

More than two dozen people in Southern Florida were charged in a [wire fraud scheme](#) to sell fake nursing diplomas and transcripts. The individuals allegedly engaged in a scheme in which they would sell fraudulent nursing diplomas and transcripts from Florida-based nursing schools to those seeking to become nurses. Once the fraudulent documents were obtained, recipients could sit for the national nursing board exam and obtain jobs as registered, licensed practical or vocational nurses upon passage. In total, the scheme allegedly resulted in the distribution of more than 7,600 fake diplomas.

OTHER NOTABLE DEVELOPMENTS

ADMINISTRATION ANNOUNCES INTENTION TO END COVID-19 PHE

On January 30, 2023, the Biden administration announced the end of the COVID-19 national emergency and public health emergency (PHE), which were declared by the Trump administration in 2020 and are currently set to expire on March 1 and April 11, respectively. The Biden administration stated that it plans to extend the emergency declarations to May 11, then end both emergencies on that date. This wind-down is consistent with the administration's previous commitments to give at least 60 days' notice prior to termination of the PHE.

The FDA also posted [guidance](#) on its website explaining the linkage between the end of the PHE and emergency use authorizations (EUAs) for medical products such as drugs, tests and vaccines. The guidance explains that an EUA declaration is distinct from, and not dependent on, an HHS PHE declaration, and therefore an EUA may remain in effect beyond the duration of the PHE declaration if all other applicable statutory conditions under the Public Health Service Act are met.

CAA 2023 EXTENDS CERTAIN TELEHEALTH FLEXIBILITIES

While many telehealth flexibilities will end with the COVID-19 PHE, the Consolidated Appropriations Act, 2023 (CAA 2023) decoupled the extension of certain telehealth flexibilities from the PHE and will permit certain telehealth flexibilities to continue long after the end of the PHE. [Click here](#) for further details and a chart explaining the flexibilities extended by the CAA 2023.

FTC PROPOSED RULE WOULD BAN NONCOMPETE AGREEMENTS

On January 5, 2023, the Federal Trade Commission (FTC) issued a proposed rule that, if adopted, would make it illegal for employers—including certain healthcare employers—to enter into noncompete agreements with their employees or independent

contractors, maintain a noncompete with an employee or represent to an employee that the worker is subject to a noncompete. The proposed rule would permit the use of confidentiality agreements, but it states that other agreements (*e.g.*, nonsolicitation clauses) would be permitted only if they do not operate as a *de facto* noncompete. The proposed rule further states that noncompetes would only be permitted in connection with the sale of a business for those who own at least 25% of the business. It likely will take at least six months before any final rule is adopted, followed by a 180-day delay in enforcement. When the final proposed rule goes into effect, there will likely be immediate legal challenges accompanied by a request for injunctive relief to stay the rule. In the meantime, the FTC seeks public comments on the proposed rule by March 20, 2023. This is an opportunity to make a factual record and present specific and unique data and information relating to the importance and benefits of noncompete agreements. For more information on the potential impact of the proposed rule, [click here](#).

DOJ CONCLUDES THAT USPS MAY MAIL ABORTION DRUGS

On January 3, 2023, DOJ Office of Legal Counsel released an [opinion](#) that the US Postal Service (USPS) is not prohibited from mailing prescription drugs used for abortions. The DOJ's opinion concluded that USPS is not prohibited from sending mifepristone and misoprostol, which are commonly used for abortions, where the sender does not intend that the recipient of the drugs will use them unlawfully. Additional post-*Roe* resources can be found [here](#).

CMS UPDATES ASC PAYMENT SYSTEM

On January 17, 2023, the Centers for Medicare and Medicaid Services (CMS) [issued](#) new HCPCS C-codes for ambulatory surgical center (ASC) covered procedures and new HCPCS codes for certain drugs and biologicals. CMS also made changes to the cost assignment for skin substitute products.

CMS ISSUES INFORMATIONAL BULLETIN ON MEDICAID CONTINUOUS ENROLLMENT CONDITION

CMS released an [informational bulletin](#) providing more details and key dates related to the Medicaid continuous enrollment requirement. The CAA 2023 includes several changes to the Children's Health Insurance Program (CHIP) and Medicaid programs. This includes a change to the prohibition on certain states disenrolling individuals if the states are taking a higher 6.2% reimbursement rate. Once the increased reimbursement ends, states will have 12 months to initiate, and 14 months to complete, renewals for enrollees in returning to normal enrollment and eligibility for the programs. The CAA 2023 does not tie the end of continuous enrollment condition to the COVID-19 PHE, but instead provides an end date of March 31, 2023. Beginning on April 1, 2023, states will be able to disenroll individuals that are no longer eligible for program participation. HHS [estimates](#) as many as 6.8 million people may lose Medicaid coverage when continuous enrollment requirements are reinstated.

CMS ISSUES NEW ENROLLMENT UPDATES FOR PROVIDERS AND SUPPLIERS

In late January 2023, CMS issued two updates relevant for providers and suppliers enrolled in Medicare: the Provider Enrollment, Chain and Ownership System is undergoing a major redesign, and ownership information across all enrollment records under a single tax identification number is being reviewed for consistency. CMS also added revised standardized nondiscrimination language to three newly renewed and required hospital notices to beneficiaries. These developments align with CMS's priorities of modernizing its enrollment processes, increasing transparency and streamlining processes for Medicare beneficiaries. Read more about these updates [here](#).

TJC ADDS NATIONAL PATIENT SAFETY GOAL FOR HEALTH EQUITY

Effective July 1, 2023, The Joint Commission (TJC) will include a National Patient Safety Goal for health equity for certain TJC-accredited organizations. This change will apply to all critical access hospitals and hospitals, certain ambulatory healthcare organizations, and certain behavioral healthcare and human services organizations. Read more about this update [here](#).



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