HEALTHCARE REGULATORY CHECK-UP

IN THIS DECEMBER 2023 RECAP ISSUE

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DECEMBER REGULATORY UPDATE SUMMARY

This issue of McDermott's Healthcare Regulatory Check-Up highlights significant regulatory activity for December 2023. We discuss several civil and criminal enforcement actions that involve alleged violations of the False Claims Act (FCA) and the Anti-Kickback Statute (AKS). We also review a recent advisory opinion issued by the Office of the Inspector General (OIG) pertaining to a medical-device manufacturer's proposal to subsidize certain Medicare cost-sharing obligations in the context of a clinical trial. Finally, we examine other notable healthcare regulatory and legislative updates.

NOTABLE ENFORCEMENT ACTIONS

CIVIL ENFORCEMENT CASES

TEXAS PHYSICIANS AND FORMER CAH EXECUTIVE RESOLVE FCA ALLEGATIONS

Three Texas physicians and a former Texas critical access hospital (CAH) executive agreed to pay a total of $880,199 to resolve False Claims Act (FCA) allegations involving illegal remuneration in violation of the federal Anti-Kickback Statute (AKS). The physicians agreed to pay a total of $555,199 to resolve allegations that they allegedly received thousands of dollars in payments from purported management services organizations (each, an MSO) in return for ordering clinical laboratory tests. The hospital executive agreed to pay $325,000 plus additional contingent payments to resolve allegations that she caused the submission of false claims to federal healthcare programs. The executive allegedly knew that her CAH paid commissions to recruiters who used MSOs to pay kickbacks to physicians to induce their laboratory testing referrals to the hospital. Under the terms of the settlement, the executive agreed to be excluded from participation in federal healthcare programs for five years.

PHARMACEUTICAL COMPANY TO PAY $6 MILLON TO SETTLE FCA DISPUTE

A pharmaceutical company agreed to pay $6 million to resolve allegations that it violated the FCA by paying for free genetic tests, as well as paying a separate fee to receive test result information for marketing purposes, to induce beneficiaries to obtain the drug and referrals of healthcare providers to the company for the furnishing or arranging of the drug.

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INDIANA HEALTH NETWORK PAYS $345 MILLION TO RESOLVE FCA AND STARK LAW VIOLATIONS

An Indiana health network agreed to pay $345 million to settle FCA allegations that it paid its physicians far above fair market value (FMV), including bonuses, to generate referrals in violation of the Stark Law. In addition, the health network will enter into a five-year corporate integrity agreement with the Office of Inspector General (OIG). The lawsuit originated as a *qui tam* action brought by the health network's former chief financial officer in 2014, to which the US Department of Justice (DOJ) intervened in 2019. The government alleged that, beginning in 2008 and continuing through at least 2017, the health network recruited physicians for employment for the purpose of capturing lucrative "downstream referrals" by offering salaries significantly higher than the physicians' private practice compensation—in some cases doubling their private practice salary.

URGENT CARE COMPANY WILL PAY MORE THAN $9.1 MILLION TO SETTLE FCA DISPUTE

An urgent care company agreed to pay more than $9.1 million to settle allegations that it had submitted false claims for medical services to Medicare, TRICARE, and the Health Resources and Services Administration's COVID-19 uninsured program. The purported violations involved COVID-19 testing, physician-performed office visits (when a non-physician practitioner had actually conducted the visits) and up-coded office visits. The settlement also resolved the company's self-disclosure made to the Centers for Medicare & Medicaid Services (CMS) in March 2021, in which the company reported that bonuses paid to certain physicians it employed were in part based on the volume or value of their referrals for designated health services, a prohibited practice.

TEXAS HOSPITAL SYSTEM SETTLES FCA ALLEGATIONS FOR MORE THAN $2 MILLION

On December 12, 2023, a Texas hospital system settled with the United States for $2 million plus additional contingent payments to resolve FCA allegations of double billing when it billed the federal government for COVID-19 tests and either the State of Texas or the City of Houston for those same tests. Additional allegations included submitting claims to Medicare for cost outlier payments by improperly increasing certain charges and failing to reimburse federal healthcare programs for excessive outlier payments received by its hospitals.

TELEHEALTH AND CARDIOLOGY DEVICE COMPANIES AGREE TO PAY NEARLY $15 TO SETTLE FCA ALLEGATIONS

On December 18, 2023, a Pennsylvania-based telehealth company and its Illinois-based cardiology monitoring device subsidiary entered into a settlement agreement with the United States. The companies agreed to pay almost $15 million to resolve FCA allegations that the companies enrolled patients in more expensive cardiac monitoring device services than necessary.

CRIMINAL ENFORCEMENT CASES

CALIFORNIA DEFENDANT RECEIVES 180-MONTH PRISON SENTENCE FOR FRAUDULENT MEDICARE CLAIMS

A California woman was sentenced to 180 months in federal prison for billing Medicare more than $24 million by submitting fraudulent claims for medically unnecessary durable medical equipment (DME)—mostly powered wheelchairs (PWCs)—and PWC repairs, most of which were never performed. The woman was the *de facto* owner of two equipment and supply companies, both of which were enrolled in Medicare in the name of the woman's out-of-state relatives. The scheme involved paying marketers for

referring patients to physicians, who in turn prescribed medically unnecessary DME, including PWCs, after which the companies then submitted fraudulent claims to Medicare. In 2011, when a change to reimbursement for PWCs made upfront payments less lucrative to suppliers, the woman pivoted to having the companies instead bill Medicare for PWC repairs. The repairs were not medically necessary, not only because the patients did not need the PWCs in the first place, but also because those repairs were not needed to make the PWCs serviceable—and often, the repairs were not performed at all.

FLORIDA NURSE PRACTITIONER SENTENCED TO 20 YEARS IN PRISON FOR SUBMITTING MORE THAN $192 MILLION IN FALSE CLAIMS

A Florida nurse practitioner was sentenced to 20 years in prison for her role in a scheme to defraud Medicare by submitting more than $192 million in claims for genetic tests and DME that patients did not need and telemedicine visits that never occurred. The nurse practitioner signed thousands of orders for medically unnecessary orthotic braces and genetic testing for Medicare beneficiaries she never spoke to, examined or treated. As part of the scheme, telemarketing companies would contact Medicare beneficiaries to convince them to accept orthotic braces and genetic tests and would then send pre-filled orders for these products to the nurse practitioner, who signed them, attesting that she had examined or treated the patients. However, she had never spoken with many of the patients and often had others, including non-licensed individuals, sign her name to fraudulent orders. She also falsified information in the orders about beneficiaries' symptoms and injuries. During the period of the conspiracy, the nurse practitioner ordered more cancer genetic tests for Medicare beneficiaries than any other provider in the nation. In 2020, when Medicare expanded its telemedicine coverage in response to the COVID-19 pandemic, the nurse practitioner also billed Medicare for thousands of telemedicine visits she never performed, routinely billing more than 24 hours of telemedicine in a single day.

OHIO BUSINESS OWNER IS LATEST TO PLEAD GUILTY TO CHARGES OF HEALTHCARE FRAUD AND ILLEGAL KICKBACK SCHEME

An Ohio man and owner of several marketing companies pled guilty to conspiracies to commit healthcare fraud and to pay and receive illegal kickbacks. The man participated in a scheme with pharmacies, telemedicine companies and doctors to submit false claims to healthcare benefit programs, including Medicare and TRICARE, based on a circular scheme of kickbacks and bribes. The man controlled several marketing companies that identified Medicare and TRICARE beneficiaries to target for expensive drugs, speaking to the beneficiaries by phone and pressuring them to agree to try the expensive medications, regardless of medical necessity. The man and his companies then paid kickbacks to telemedicine companies, which in turn paid kickbacks to doctors, to obtain prescriptions for the medications. The man transmitted to the telemedicine companies the beneficiaries' medical information, the telephone call recordings and pre-marked prescription pads for particular drugs, which were chosen largely based on the reimbursement amount and not medical need. The doctors paid by the telemedicine companies signed the prescriptions regardless of medical necessity, often without ever speaking to the patient. The man and his conspirators then directed the prescriptions to pharmacies with which the man and his business partner had additional kickback arrangements. The pharmacies submitted claims for reimbursement to healthcare benefit programs including Medicare and TRICARE, and thereafter sent a portion of the proceeds to the man and his companies as payment for the prescriptions generated through the conspiracy. In total, the man and his conspirators caused the submission of false and fraudulent prescription-drug claims to healthcare benefit programs totaling more than $24 million. Several other individuals have pled guilty to conspiracy charges as a result of the scheme.

GEORGIA BUSINESS PLEADS GUILTY TO AKS VIOLATIONS AND CONSPIRACY TO COMMIT HEALTHCARE FRAUD

A Georgia man pleaded guilty to charges of conspiracy to violate the AKS and conspiracy to commit healthcare fraud. Through the marketing company he owned, the man targeted Medicare and TRICARE beneficiaries and pressured them to agree to accept DME such as back, shoulder and knee braces. The man paid bonuses to his company's employees to incentivize them to maximize the number of beneficiaries that would accept the DME. The man and his company paid kickbacks to telemedicine companies that then paid kickbacks to doctors in exchange for the doctors' improper orders for DME. The man then sent the doctors' orders to various DME suppliers. The DME companies submitted claims for reimbursement to Medicare and TRICARE, and thereafter, sent kickbacks to the man and his company. The company received more than $63 million from DME suppliers over the course of this two-year long scheme in exchange for the referrals. The false claims submitted to healthcare benefit programs totaled more than $127 million.

FLORIDA PAIR RECEIVE PRISON SENTENCES FOR $1.4 BILLION SCHEME TO DEFRAUD INSURANCE COMPANIES

Two Florida men were sentenced for participating in a scheme to defraud insurance companies. One of the men owned and managed hospitals and owned a billing company, while the other man managed that billing company. Together, the men obtained control over several financially distressed hospitals in rural Florida and Missouri. As part of the scheme, the men entered into arrangements with recruiters and substance-abuse treatment facilities in which they paid kickbacks in exchange for patient urine samples. The urine samples were sent to the hospitals but ultimately routed to independent laboratories to conduct the tests. The hospitals would then bill insurers for the testing, falsely mispresenting on claim forms that the testing was performed at the hospitals instead of at the laboratories, thus benefitting from the higher reimbursement rates afforded to rural hospitals. The scheme resulted in approximately $1.4 billion of fraudulent billing to insurers. The men were convicted in June 2022 for conspiracy to commit healthcare fraud and wire fraud, healthcare fraud, and conspiracy to commit money laundering, and were sentenced to prison in December 2023

TEXAS BUSINESS OWNER INDICTED ON NUMEROUS COUNTS OF HEALTHCARE FRAUD AND WIRE FRAUD

A federal grand jury indicted a Texas man with one count of conspiracy to commit healthcare fraud and wire fraud, four counts of healthcare fraud, one count of conspiracy to defraud the United States and to pay and receive healthcare kickbacks, and two counts of solicitation and receipt of healthcare kickbacks. The man owned and/or operated DME companies in several states that allegedly billed federal healthcare programs for medically unnecessary tests that were not reimbursable by Medicare. The man paid kickbacks to international call centers in exchange for Medicare beneficiary information and falsified physicians' orders. The call centers would pressure Medicare beneficiaries to accept medically unnecessary DME, tests and medications. The man would then refer doctors' orders for these medically unnecessary items to other DME suppliers, pharmacies and laboratories in exchange for bribes and kickbacks.

OIG ADVISORY OPINIONS

OIG ADVISORY OPINIONS 23-09 and 23-10, POSTED ON DECEMBER 19 AND 20, 2023, RESPECTIVELY

The US Department of Health and Human Services (HHS) OIG issued AO 23-10 and AO 23-09 (which are identical) in response to a request for an advisory opinion from a licensed issuer of Medicare Supplemental Health Insurance (Medigap) policies and a preferred hospital organization, as to a proposed arrangement between the entities. These two opinions are virtually identical to AO 22-12, which was issued by OIG on May 26, 2022. We analyzed AO 22-12 in depth in our *Healthcare Regulatory Check-Up* published in June 2022, available here.

OIG ADVISORY OPINION 23-11, POSTED ON DECEMBER 27, 2023

On December 21, 2023, OIG issued a favorable opinion regarding a medical-device manufacturer's proposal to subsidize certain Medicare cost-sharing obligations in the context of a clinical trial. The requestor manufactures a medical device-based therapy that is designed to modulate the strength of cardiac muscle contractions in patients experiencing heart failure (the system). The system is currently approved by the US Food and Drug Administration (FDA) for use in heart-failure patients who meet certain criteria, including a left ventricular ejection fraction ranging from 25% to 45%. The requestor is also the sponsor of a clinical trial designed to determine the efficacy of the system in a population of patients with a higher ejection fraction of between 40% and 60% (the study). For this population, the system does not have full FDA approval but rather is available only for clinical use pursuant to a Category B investigational device exemption (IDE) approved by the FDA. Although patients—including federal healthcare program beneficiaries—may continue to receive follow-up services related to the system, the system itself is designed as a one-time treatment.

The requestor intends to enroll up to 1,500 participants in the study. For all participants, a physician will implant the system via a surgical procedure. The participants will then be randomized in a 2:1 ratio into two groups: for participants in the treatment group, the system will be activated immediately; and for participants in the control group, the system will remain inactive for a period of 18

months. The requestor certified that the study will comply with all relevant federal regulations and will include oversight and monitoring by an institutional review board (IRB). The study has also been approved by CMS as a Category B IDE study, for which Medicare pays for the Category B IDE device and routine care items and services furnished by the study.

Under the proposed arrangement, the requestor will pay cost-sharing obligations for which participants—including Medicare beneficiaries—are personally responsible, up to a maximum of $2,000 per participant. The cost-sharing subsidies will not be advertised to prospective participants, and the requestor will pay the subsidies directly to the site and investigator to which the participant would otherwise owe the amount. The requestor offers several reasons for providing the cost-sharing subsidies: (i) to reduce financial barriers to initial and continued enrollment in the study, (ii) to facilitate socioeconomic diversity of the participant pool, and (iii) to preserve blinding of participants by obscuring that participants in the control group are not charged for cost-sharing.

OIG Analysis

First, OIG noted that the proposed arrangement would implicate the AKS) because the subsidies paid by the requestor could induce Medicare (and potentially other federal healthcare program beneficiaries) to participate in the study, during which they would receive healthcare items and services that are reimbursable by a federal healthcare program. Additionally, under the proposed arrangement, the requestor would provide two forms of remuneration to investigators and sites participating in the study:

(i) the opportunity to bill federal healthcare programs for items and services related to the study, and (ii) guaranteed payment of beneficiary cost-sharing amounts (up to $2,000), which an investigator or site may not otherwise be able to collect. OIG found that the proposed arrangement would not be protected by any safe harbor.

Second, OIG found that the proposed arrangement would implicate the Beneficiary Inducements Civil Monetary Penalty Law (CMP) because the remuneration provided by the requestor would be likely to influence a beneficiary to receive Medicare-billable items and services from a particular provider, practitioner or supplier, and no exception would apply. Specifically, the proposed arrangement would not satisfy the exception for waivers of beneficiary cost-sharing obligations because, among other reasons, the exception applies only to a "waiver" of cost-sharing obligations, but the remuneration to be provided by the requestor would be in the form of a subsidy paid on behalf of a beneficiary.

Although the proposed arrangement implicates both the AKS and the Beneficiary Inducements CMP, OIG stated that it would exercise its discretion to forgo imposing sanctions against the requestor with respect to the proposed arrangement. First, OIG noted that the proposed arrangement appears to be a reasonable means of promoting equitable initial and continued enrollment in the study. Second, OIG found the proposed arrangement would pose a low risk of overutilization or inappropriate utilization of items and services payable by a federal healthcare program—although utilization may increase, nothing suggests to OIG that such increase would be inappropriate. In support, OIG noted that the study will contain certain guardrails, including the following: that the requestor will not advertise the cost-sharing subsidies; participants must satisfy enrollment criteria and execute informed consent documents; the study is subject to oversight and monitoring by an IRB; the study is capped at 1,500 participants; and—most importantly—CMS approved the study as a Category B IDE study, which indicates that CMS has ensured that the study contains appropriate patient protections and is designed to answer questions of importance to the Medicare program and its beneficiaries. Finally, OIG distinguished the proposed arrangement from problematic arrangements, such as those in which manufacturers offer subsidies to secure future utilization of a reimbursable item or service, because the system is intended as a one-time treatment and the requestor does not anticipate use of the system will prompt future utilization by participants of any other products manufactured by the requestor.

OTHER NOTABLE DEVELOPMENTS

HHS AGREES TO SETTLEMENT WITH LOUISIANA MEDICAL GROUP IN FIRST-EVER PHISHING CYBERATTACK INVESTIGATION UNDER HIPAA

The HHS Office for Civil Rights (OCR) entered into a settlement with a Louisiana medical group, marking OCR's first ever phishing cyberattack investigation under Health Insurance Portability and Accountability Act of 1996 (HIPAA) rules. The settlement resolves an investigation launched after a phishing attack that affected the electronic protected health information (ePHI)

of approximately 34,862 individuals. On May 28, 2021, the medical group filed a breach report with HHS stating that a hacker, through a successful phishing attack on March 30, 2021, gained access to an email account that contained ePHI. OCR's investigation revealed that, prior to the 2021 reported breach, the medical group failed to conduct a risk analysis to identify potential threats or vulnerabilities to ePHI across the organization as required by HIPAA. OCR also discovered that the medical group had no policies or procedures in place to regularly review information system activity to safeguard ePHI against cyberattacks. As a result, the medical group agreed to pay $480,000 to OCR and to implement a corrective action plan that will be monitored by OCR for two years.

NEW JERSEY PHYSICIAN GROUP SETTLES WITH HHS OCR TO RESOLVE ALLEGED VIOLATIONS OF HIPAA PRIVACY RULE

A New Jersey physician group entered into a settlement with HHS OCR to resolve multiple complaints filed with OCR concerning violations of the HIPAA Privacy Rule's right of access provision. The right of access provision requires that individuals or their personal representatives have timely access to their health information for a reasonable cost. OCR's investigation revealed that the physician group failed to provide access within 30 calendar days. The physician group has agreed to pay $160,000 and to implement a corrective action plan that requires workforce training, reporting record requests to OCR, and reviewing and revising as necessary its right of access policies and procedures to provide timely responses to requests. Under the plan, OCR will monitor the physician group for one year.

NONPROFIT'S REQUEST FOR PRELIMINARY INJUNCTION AGAINST GOVERNMENT ENFORCEMENT OF STARK LAW FAQS

On December 21, 2023, the US District Court for the District of Columbia denied the request of Community Oncology Associates (COA)—a nonprofit advocacy group representing community oncology practices across the United States—for a preliminary injunction to enjoin the government from enforcing the Stark Law FAQs published by CMS, specifically with respect to the prohibition against physicians' mailing of prescription drugs to patients' homes, as provided in the FAQs. Under the Stark Law, a physician's referrals for outpatient prescription drugs are generally protected under the In-Office Ancillary Services Exception (IOASE) if the physician dispenses the drugs in the physician's office (provided that other conditions of the IOASE are satisfied). During the COVID-19 pandemic, the Secretary of HHS issued certain waivers to the Stark Law, including one waiver that expressly permitted physicians to furnish medically necessary drugs and devices to patients outside of a physician's office, including by mail to a patient's home. When the pandemic was winding down, CMS and HHS published a series of FAQs that explicitly stated that the "location" requirement of the IOASE would no longer be satisfied if a physician furnished drugs or devices to a patient by mail. COA filed for a preliminary injunction to enjoin the government from enforcing the guidance in the FAQs, prompting the court to consider the issue of whether a physician may mail drugs to such physicians' patients without violating the Stark Law. In denying the preliminary injunction, the district court found that COA (i) would not suffer irreparable harm, (ii) would be unlikely to succeed on the merits and (iii) failed to prove that an injunction would be in the public interest. First, the court found that COA lacked standing to argue irreparable harm on behalf of its members' patients and failed to show irreparable harm to its members, since any harm suffered would not rise to the level of "extreme hardship" or threaten the "very existence" of such members' practices. Second, the court applied a statutory interpretation analysis to reject COA's assertion that the FAQs substantively expanded the scope of the Stark Law by narrowing the application of the IOASE. The court reasoned that the most natural reading of the IOASE is that the office location requirement is a mandatory perquisite for qualifying for the IOASE, and thus the court concluded that COA was unlikely to succeed on the merits. Finally, the court found that COA failed to prove an overriding public interest that would be grounds for overriding the regulatory scheme developed by Congress and HHS.

(*Community Oncology Alliance v. Becerra*, Civ. Action No. 23-cv-2168 (D.D.C.) – Order denying plaintiff's motion for preliminary injunction (December 21, 2023))

WHITE HOUSE RELEASES FACT SHEET ANNOUNCING HEIGHTENED ENFORCEMENT OF FEDERAL ANTITRUST LAWS IN THE HEALTHCARE INDUSTRY

On December 7, 2023, the White House released a fact sheet announcing new actions to enforce federal antitrust laws in various subsectors of the healthcare industry, including physician practices, nursing homes, hospices, home care, autism treatment and travel nursing. First, the Biden administration directed the DOJ, Federal Trade Commission (FTC) and HHS to issue a joint request for information to examine how private equity and other corporate transactions involving healthcare companies affect competition in

the healthcare industry. Second, the White House directed these agencies to identify "anticompetitive 'roll ups'" that currently "evade" antitrust review. The White House also encouraged agencies to make certain data related to ownership of hospitals, nursing homes, hospice providers, and home health agencies publicly available. Finally, the Biden administration directed CMS to improve Medicare Advantage price transparency data.

CMS ISSUES REVISED INFLATION REDUCTION ACT GUIDANCE ON CALCULATION OF DRUG-MANUFACTURER REBATES AND INVOICES

On December 14, 2023, CMS issued revised guidance outlining the procedures that CMS will follow in calculating rebates and invoices to drug manufacturers pursuant to the Inflation Reduction Act, signed into law by President Biden. Under the Inflation Reduction Act, drug companies must pay rebates to Medicare when prices for certain prescription drugs covered by Medicare increase more quickly than the rate of inflation. Pursuant to this law, CMS established the Medicare Prescription Drug Inflation Rebate Program which details procedures and requirements for calculating rebates for Medicare Parts B and D, and further clarified these requirements in its revised guidance in December 2023.

CMS ISSUES REVISED INFLATION REDUCTION ACT GUIDANCE ON CALCULATION OF DRUG-MANUFACTURER REBATES AND INVOICES

On December 13, 2023, HHS finalized a rule titled "Health Data, Technology, and Interoperability: Certification Program Updates, Algorithm Transparency, and Information Sharing" (the HTI-1 Rule"). The HTI-1 Rule aims to safeguard patient data when that data is used in AI-enabled devices to aid with medical diagnoses and treatments. More specifically, the HTI-1 Rule establishes new conditions and maintenance of certification requirements for developers of health information technology (health IT) under the ONC Health IT Certification Program.

GAO ISSUES REPORT ON INDEPENDENT DISPUTE RESOLUTION PROCESS FOR OUT-OF-NETWORK CLAIMS

On December 12, 2023, the US Government Accountability Office (GAO) released a report titled "Roll Out of Independent Dispute Resolution Process for Out-of-Network Claims Has Been Challenging" (the report). The report details the administrative difficulties faced by the three departments charged with administering the independent dispute resolution (IDR) process under the No Surprises Act (the NSA), which went into effect on January 1, 2022. The NSA prohibits out-of-network providers from "balance billing" patients in excess of their in-network cost-sharing amounts, and also sets forth a formula by which insurance companies compensate out-of-network providers. The NSA charged CMS with administration of the federal IDR process, which is intended to serve as a voluntary forum for healthcare providers and health insurers to resolve disputes about bills for out-of-network care. Certified dispute resolution entities then serve as arbiters that make the payment determination. The GAO, directed to review the IDR process under the Consolidated Appropriations Act of 2021, reported the following key findings: (i) the dispute volume between April 15, 2022, and June 30, 2023, was higher than expected, (ii) there were backlogs resulting in delays in payment determinations and (iii) the departments reported limited ability to increase enforcement because of budgetary constraints. Appendix I of the report includes data examining the percentage of major initiating parties in the IDR process that are private-equity owned. The report found that the top 10 initiating parties were responsible for submitting 67% of disputes involving out-of-network emergency and non-emergency services. The report also found that six of the top 10 initiating parties submitting emergency and non-emergency disputes were owned, at least in part, by private equity firms. Private equity firms accounted for 46% percent of all out-of-network emergency and non-emergency disputes submitted in calendar year 2022.

FTC AND DOJ ISSUE REVISED MERGER GUIDELINES

On December 18, 2023, the FTC and DOJ issued revised merger guidelines. For the most part, the changes are subtle language revisions and largely reflect feedback from comments and experts that the language in the previous guidelines was too broad. Read more in our *On the Subject*.

LEGISLATIVE DEVELOPMENTS

HOUSE OF REPRESENTATIVES PASSES BILL REQUIRING POSTING OF PUBLICLY AVAILABLE PRICING DATA FOR CERTAIN HEALTHCARE SERVICES

The US House of Representatives passed a bill on December 11, 2023, titled "Lower Costs, More Transparency Act" (H.R. 5378) which requires hospitals, insurers and pharmacy benefit managers to post publicly available pricing data for certain healthcare services performed and reimbursed by hospitals, insurers, imaging services, diagnostic laboratories and pharmacy benefit managers (PBMs). The bill would codify and expand the reach of a rule promulgated by HHS in 2019. The bill also bans PBMs from "spread pricing" in Medicaid. PBMs would get paid an administrative fee and pass on savings resulting from negotiations with drug companies. Moreover, the bill includes site neutrality provisions barring hospitals that participate in the Medicare program from charging more for certain services when those services are performed in locations such as hospitals, as compared to when those services are performed at sites such as physician offices. Read more in a report from the McDermott+Consulting team.

US SENATORS LAUNCH INVESTIGATION INTO THE EFFECTS OF PRIVATE EQUITY OWNERSHIP ON HOSPITALS

On December 6, 2023, US Senators Sheldon Whitehouse (D-R.I.) and Chuck Grassley (R-Iowa) announced an investigation examining the impact of private equity ownership on hospitals. Sens. Whitehouse and Grassley sent letters to several private equity firms; the letters requested information about transactions involving sellers of rural healthcare facility.

MEMBERS OF CONGRESS URGE HHS SECRETARY TO BAN WARRANTLESS PROVISION OF PATIENT DATA TO LAW ENFORCEMENT

On December 12, 2023, three members of Congress sent a letter to HHS Secretary Xavier Becerra, urging him to ban pharmacies from providing patient data to law enforcement agencies without a warrant. The letter was drafted in response to the US Supreme Court's ruling in *Dobbs v. Jackson Women's Health Organization*, and reflects widespread concerns over the possibility that law enforcement in states with strict abortion laws will be able to access sensitive health data directly from healthcare providers or pharmacies in order to gather evidence to prosecute women obtaining abortions. The letter specifically asks HHS to add a warrant requirement to its HIPAA rules, and to update its HIPAA rules to require pharmacies to notify patients of law enforcement requests for their records.

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