# HEALTHCARE REGULATORY CHECK-UP

**IN THIS ISSUE**



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This issue of McDermott's *Healthcare Regulatory Check-Up* highlights significant enforcement activity between July 21 and August 20, 2022. Key updates include a case in which the US Court of Appeals for the Eighth Circuit decided that the phrase "resulting from" in the Anti-Kickback Statute (AKS) creates a but-for causal requirement between an antikickback violation and the items or services included in the claim to the government. This decision established a circuit split regarding the appropriate standard for establishing causation in False Claims Act (FCA) cases related to AKS violations. In another notable case, the US Court of Appeals for the Second Circuit upheld an unfavorable Office of Inspector General (OIG) advisory opinion and subsequent district court ruling related to a pharmaceutical manufacturer's proposed copay assistance program. The Second Circuit held that "corrupt" intent is not required to establish an AKS violation. This issue also reviews several criminal and civil enforcement actions related to AKS violations and false claims allegations.

In addition to examining a recent OIG advisory opinion, we provide a summary of key healthcare-related provisions of the Inflation Reduction Act, which allows the Centers for Medicare & Medicaid Services (CMS) to negotiate drug prices under Medicare for the first time, and the Joint Commission's new health equity standards for accreditations. Finally we take a look at recent CMS activity, including its 2023 proposed and final rules for its various prospective payment systems, along with a recent proposed rule updating CMS's interpretation of the nondiscrimination provisions of Section 1557 of the Affordable Care Act (ACA).

# NOTABLE ENFORCEMENT RESOLUTIONS AND ACTIVITY

## EIGHTH CIRCUIT CREATES CIRCUIT SPLIT ON CAUSATION STANDARD FOR FCA CASES ALLEGING AKS VIOLATIONS

In 2018, a Missouri neurosurgeon was found guilty and ordered to pay almost $5.5 million for violating the AKS by submitting claims for the use of spinal implants that were distributed by a company wholly owned by his fiancée, on the grounds that commissions on the purchase of particular devices and stock offers from the device manufacturer used by the neurosurgeon were unlawful kickbacks. On July 27, 2022, the US Court of Appeals for the Eighth Circuit remanded the case for a new trial because the jury was not properly instructed on the requirement of but-for causation. This ruling established a circuit split on the appropriate standard for establishing causation in FCA cases related to AKS violations.

As amended by the ACA in 2010, the AKS provides that "a claim that includes items or services *resulting from* a violation of [the AKS] constitutes a false or fraudulent claim for purposes of [the FCA]." In its 2018 ruling in *U.S. v. Medco Health Solutions Inc.*, the US Court of Appeals for the Third Circuit interpreted the "resulting from" requirement by applying a middle-ground approach between

requiring a direct causal link and no link at all that requires *some* evidence showing a link between the alleged kickbacks and subsequent reimbursement claims submitted by healthcare providers.

The Eighth Circuit rejected the Third Circuit's approach of relying on legislative history and the "drafters' intentions to interpret the statute," noting that it had previously rejected this interpretive approach in a different context. Instead, the Eighth Circuit took a more textual approach in *D.S. Medical*, holding that the "resulting from" language in the AKS creates a but-for causal requirement between an antikickback violation and the items or services included in the claim to the government.

*United States ex rel. Cairns v. D.S. Medical LLC*, No. 20-2445 (8th Cir., July 26, 2022)

## SECOND CIRCUIT RULES THAT PHARMACEUTICAL COMPANY MAY NOT PAY MEDICARE BENEFICIARIES' COPAYS FOR MEDICATIONS

The US Court of Appeals for the Second Circuit upheld a lower court's finding that the OIG's interpretation of the AKS was not contrary to law when it issued an advisory opinion finding that a pharmaceutical company's plan to give copay assistance to Medicare beneficiaries for an expensive heart medication would violate the AKS.

The drug in question costs $225,000 per year. Under Medicare's pricing formula, patients would be responsible for a copay of about $13,000 per year. In order to sell the treatment to Medicare Part D beneficiaries, the company planned to provide a copay assistance subsidy to reduce those costs, such that patients would only be responsible for paying $35 per month, with the company covering the remainder of the copay. On June 27, 2019, the company sought an advisory opinion from OIG to confirm that its program was in compliance with federal laws. OIG ultimately issued an unfavorable advisory opinion on September 18, 2020, concluding that the program "would present more than a minimal risk of fraud and abuse under the Federal anti-kickback statute," and was "highly suspect . . . because one purpose of the [program]—perhaps the primary purpose—would be to induce Medicare beneficiaries to purchase [the company's] federally reimbursable Medications."

The company challenged OIG's interpretation of the AKS, arguing that it would only be liable under the AKS if there was some "corrupt" intent in the copay program. The company pointed to various phrases in the statute to back up its argument. For example, the company argued that the phrase "any remuneration . . . to induce" implied a quid pro quo that "improperly or corruptly" skews the patient's decision-making. The district court, however, found nothing in the text of the AKS that suggested that there must be "corrupt" intent involved for a violation. The Second Circuit agreed and affirmed the district's court conclusion that OIG's interpretation was not contrary to law.

*Pfizer, Inc. v. United States Department of Health and Human Services et al.*, No. 21-2764 (2nd Cir, July 25, 2022)

## DENTAL PROVIDER SETTLES FCA ALLEGATIONS FOR $1.5M

A Tennessee-based dental provider and his affiliated companies agreed to pay $1.5 million to settle allegations that they knowingly and improperly submitted false claims for dental services to TennCare, Tennessee's Medicaid program, in violation of the federal FCA and the Tennessee Medicaid False Claims Act. The settlement resolved allegations that from January 2015 through February 2019, the companies knowingly submitted or caused to be submitted to TennCare claims for payment that falsely identified the dental provider as the rendering provider for services that were actually rendered by uncredentialled dentists who were ineligible to bill TennCare.

## MEDICAL PRACTICE PAYS $850,000 TO RESOLVE ALLEGATIONS OF IMPROPER INCIDENT-TO BILLING

A New York-based medical practice agreed to pay $850,000 for what it admitted was "improper" and "reckless" billing to Medicare on an "incident-to" basis for services rendered by a non-physician practitioner (NPP) without the requisite direct supervision of the billing physician.

The medical practice admitted that on 120 occasions it "submitted or caused to be submitted claims for payment to Medicare that improperly listed a physician as the rendering provider for services rendered by a physician assistant when no physician was physically present in the office and immediately available to furnish assistance and direction throughout the performance of the procedure." The

practice further admitted that it "knew or should have known the requirements of incident-to billing and that it was improper to submit claims to Medicare in a physician's name for services rendered by an NPP when no physician was in the office," because, among other reasons, its billing company had informed the practice's owner of separate incident-to billing violations several years earlier.

The settlement also addressed instances in which the medical practice improperly billed Medicare for administration of the drug Botox even though other insurers had already paid for the drug. The practice admitted that on approximately 761 occasions from March 2015 through February 2021, its providers administered and the practice billed Medicare for Botox that was paid for by another insurer "in reckless disregard to the fact that Medicare reimbursement for the administration of Botox included reimbursement for the cost of the drug being administered."

## PHYSICIAN PAYS ALMOST $2M TO RESOLVE FALSE CLAIMS ALLEGATIONS REGARDING STIVAX DEVICE REIMBURSEMENT

A California-based physician and his medical corporation agreed to pay almost $2 million to resolve allegations that they violated the FCA by submitting millions of dollars of false claims to Medicare for surgically implanted neurostimulators and paying kickbacks to sales marketers. According to the settlement, the physician and the medical corporation admitted that claims were submitted to Medicare for surgically implanted neurostimulator devices even though they did not perform surgery or implant neurostimulators. Instead, they taped a disposable electroacupuncture device called Stivax to their patients' ears. Stivax devices do not require surgical implantation and are not reimbursable by Medicare. The physician and his medical corporation also admitted that they paid a marketing company a percentage of the reimbursements they received from Medicare for billing implantable neurostimulators in return for the marketing company arranging for and recommending that patients order Stivax from them. In addition to the settlement, both parties agreed to enter into an integrity agreement with the OIG.

## BIOTECH COMPANY SETTLES KICKBACK CLAIMS FOR $900M DAYS BEFORE TRIAL

A biotech company settled a whistleblower lawsuit for $900 million just days before the decade-long case was set to go to trial. The relator accused the company of directing millions of dollars in kickbacks via "sham" consulting deals and speaker programs, lavish dinners and entertainment for physicians and other healthcare professionals to prescribe its drugs for treatment of multiple sclerosis from 2009 to 2014. The lawsuit alleged that these kickback schemes caused the submission of hundreds of millions of dollars in false reimbursement claims for the multiple sclerosis drugs to government healthcare programs, including Medicare and Medicaid, in violation of the federal FCA and 11 states' false claims acts. The US Department of Justice (DOJ) had declined to intervene in the case in 2015, leaving the relator to litigate the case on his own.

## DERMATOLOGIST SETTLES FCA VIOLATION ALLEGATIONS FOR $1.66M

An Iowa-based dermatologist and his practice agreed to pay $1.66 million and enter into an integrity agreement with ongoing monitoring to settle allegations that he violated the FCA by submitting "up-coded" claims related to dermatology office visits and the destruction or removal of skin tags and lesions (*i.e.*, billing for services at a higher level than provided).

## HOME HEALTH COMPANY OWNER SENTENCED TO PRISON FOR 18 MONTHS

The owner of a home health company pleaded guilty to one count of conspiracy to commit healthcare fraud and one count of conspiracy to pay and receive healthcare kickbacks, and was sentenced to 18 months in prison by the US District Court for the Eastern District of California. Despite the owner's billing certifications, from at least July 2015 through April 2019 the owner paid and directed others to pay kickbacks to multiple individuals for beneficiary referrals, including employees of healthcare facilities and employees' spouses. Of the $31 million that Medicare paid to the home health company for more than 8,000 claims during that period, more than $2 million was for services purportedly provided to beneficiaries referred in exchange for kickbacks paid. Several recipients of the kickbacks also pleaded guilty for their roles in the kickback scheme and await sentencing.

## MEDICAL DEVICE MANUFACTURER SETTLES ALLEGATIONS OF PHYSICIAN KICKBACKS FOR $12.95M

An Oregon-based medical device manufacturer agreed to pay $12.95 million to resolve allegations that it violated the FCA by causing the submission of false claims to Medicare and Medicaid by paying kickbacks to physicians to induce their use of the manufacturer's

implantable cardiac devices, such as pacemakers and defibrillators. The manufacturer allegedly used a new employee training program to pay physicians for an excessive number of trainings and, in some cases, for training events that either never occurred or were of little or no value to trainees. The settlement also resolves allegations that the manufacturer violated the AKS when it paid for physicians' holiday parties, winery tours, lavish meals with no legitimate business purpose, and international business class airfare and honoraria in exchange for making brief appearances at international conferences. The civil settlement includes the resolution of certain *qui tam* claims brought under the FCA by independent sales representatives previously employed by the manufacturer.

## CLINICAL LAB OWNERS SETTLE FCA VIOLATION ALLEGATIONS FOR $5.7M

The owners of clinical laboratories in Mississippi and Texas agreed to pay $5.7 million to resolve allegations that they violated the FCA by paying kickbacks in return for genetic testing samples. The owners allegedly participated in a scheme with various marketers who solicited genetic testing samples from Medicare beneficiaries. The marketers allegedly arranged to have a physician fraudulently attest that the genetic testing was medically necessary, and the owners allegedly caused the clinical laboratories to process the tests, receive reimbursement from Medicare and pay a portion of that reimbursement to the marketers. In an attempt to conceal the nature of the kickback arrangement, the clinical laboratories entered into allegedly sham agreements with marketers to provide various consulting, marketing and other services at an hourly rate. However, the owners allegedly caused the clinical laboratories to pay the marketers a percentage of revenue, including Medicare reimbursement, in return for the samples, and the marketers then allegedly generated sham invoices for hourly services that matched the agreed-upon kickback amount.

The owners of the clinical laboratories have each previously pled guilty to one count of conspiracy to defraud the United States in connection with this scheme and are awaiting sentencing. *See United States v. Kennerson*, No. 20-cr-00448 (BRM), and *United States v. Madison*, No. 20-cr-00449 (BRM) (D.N.J.)

## PHARMACY ADMITS TO ILLEGAL DISTRIBUTION OF PRESCRIPTION OPIOIDS, KICKBACK SCHEME

A New Jersey licensed retail pharmacy admitted to a conspiracy to illegally distribute prescription opioids and give kickbacks to healthcare providers. The pharmacy and its parent company also signed a civil settlement with the United States for alleged violations of the FCA and the Controlled Substances Act. From 2015 through 2019, the pharmacy dispensed prescription transmucosal immediate release fentanyl (TIRF) medications and other controlled substances while knowing that the prescriptions were not written for a legitimate medical purpose. The pharmacy also knowingly filled prescriptions for controlled substances, including TIRF medications, for patients exhibiting suspicious and drug-seeking behavior, including patients who repeatedly requested early refills, paid thousands of dollars in cash for their prescriptions, or requested that prescriptions be sent to suspicious or inappropriate locations, including hotels, casinos and elementary schools. Despite warnings from third parties, including some of its suppliers, the pharmacy continued to fill prescriptions for TIRF medications and other opioids written by doctors with suspicious and problematic prescribing habits, sometimes without receiving an original prescription.

The pharmacy also admitted that it conspired to offer kickbacks to healthcare providers and pharmaceutical company sales representatives in violation of the federal AKS, in the form of lunches, dinners and happy hours to induce them to send TIRF prescriptions to the pharmacy. The pharmacy admitted that its violations of the AKS caused a loss to federally funded healthcare programs of more than $4.5 million. While the pharmacy's criminal restitution payment will be applied to the civil resolution, the pharmacy has also agreed to pay up to $50 million over the next five years to resolve its civil liability if it generates future revenue.

## PHYSICIAN AND PAIN MANAGEMENT GROUP SETTLE FCA VIOLATION ALLEGATIONS FOR $980K

A Maryland physician and his pain management practice group agreed to pay $980,000 to resolve allegations that they violated the FCA by submitting false claims for medically unnecessary urine drug tests (UDTs) to Medicare, Medicaid and the Railroad Retirement Board. This settlement resolves allegations that the UDTs billed to the government were not ordered based on an individualized determination of medical necessity for each patient. Instead, the physician and the practice group allegedly used blanket orders that tested all patients for the same 22+ drug classes. The practice group's patients were allegedly required to provide a UDT sample upon entry into the clinic and before being seen by a provider and discussing the results from any prior UDT the patient received. According to the government's allegations, UDTs showing unexpected positive or negative results were ignored, or not checked at all, while the practice group's providers continued to prescribe the patients opioids and other controlled substances despite obvious warning signs that the patients were abusing drugs.

### NURSE PRACTITIONER SENTENCED TO PRISON, ORDERED TO PAY $1.6+M IN RESTITUTION

A Georgia nurse practitioner was sentenced to 87 months in prison with three years of supervised release and ordered to pay $1.6 million in restitution after a jury convicted her of participating in an illegal kickback conspiracy and five counts each of healthcare fraud, false statements related to healthcare, and aggravated identity theft. According to court documents and testimony, the nurse practitioner facilitated orders for more than 3,000 orthotic braces that generated more than $3 million in fraudulent or excessive charges to Medicare for senior citizens, whose identities were captured by co-conspirators through a telemarketing scheme. The nurse practitioner signed her name to fake medical records in which she falsely claimed to have provided examinations to those patients, and created orders for orthotic braces and other durable medical equipment that were sold to several DME companies in order to generate reimbursement from Medicare for the companies.

### SKILLED NURSING AND LONG-TERM CARE PROVIDER SETTLES FCA VIOLATION ALLEGATIONS FOR $5.5+M

An Indiana-based skilled nursing and long-term care provider agreed to pay more than $5.5 million to resolve allegations that it violated the FCA by submitting false claims to the Medicare program. In 2017, a former employee of a hospice services company doing business with the provider filed a whistleblower lawsuit in the US District Court for the Southern District of Indiana alleging that the provider had engaged in conduct to defraud the Medicare program. The complaint alleged that the provider charged Medicare directly for various therapy services provided to beneficiaries who had been placed on hospice, when those services should have already been covered by the beneficiaries' Medicare hospice coverage.

### CLINICAL LAB SETTLES FCA VIOLATION ALLEGATIONS FOR $16M

A clinical laboratory headquartered in Texas that provides anatomic pathology services to physician practices agreed to pay $16 million to resolve *qui tam* allegations that it submitted false claims for payment to Medicare and other federal healthcare programs. In the settlement, the company admitted that between 2013 and 2018, it routinely and automatically conducted additional tests on biopsy specimens prior to a pathologist's review and without an individualized determination regarding whether the additional tests were medically necessary. The United States contended that this policy of conducting routine additional tests caused the laboratory to perform many tests that were medically unnecessary.

### DOJ COORDINATED ENFORCEMENT ACTION TARGETS $1.2B OF ALLEGED TELEMEDICINE, LAB AND DME FRAUD

The DOJ announced criminal charges against 36 people in 13 federal districts for $1.2 billion in alleged healthcare fraud. More than $1 billion of the total alleged losses stem from telehealth schemes, indicating increased regulatory scrutiny in these areas. The nationwide coordinated law enforcement action included criminal charges against a telemedicine company executive, owners and executives of clinical laboratories, durable medical equipment companies, marketing organizations and medical professionals. In connection with the enforcement action, the department seized more than $8 million in cash, luxury vehicles and other fraud proceeds. The CMS Center for Program Integrity also announced administrative actions against 52 providers involved in similar schemes.

# OIG ADVISORY OPINIONS

### ADVISORY OPINION 22-16, POSTED ON AUGUST 19, 2022

The requester operates a shared-decision-making online learning tool that educates patients on potential risks, benefits and expectations related to surgeries. The program consists of two modules, each with three components. The first module aims to help patients understand their diagnosis (or diagnoses) and explain their symptoms, educate patients on how to discuss their diagnosis (or diagnoses) with their primary care providers, and educate patients on non-surgical treatment options. The second module is for patients who choose a surgical treatment option and is designed to educate patients on the various types of surgical facilities that exist (*e.g.*, hospitals and ambulatory surgery centers); help patients prepare for surgery by, for example, creating a pre-operation "to-do" list; and reduce the chance of complications and facilitate recovery by providing information on post-operative care. The program's content is

customized to the individual user. The program does not contain any information about particular providers, practitioners, suppliers or services. Instead, the program directs patients to contact their primary care provider for additional information.

The requestor contracts with certain Medicare Advantage Organizations (MAOs) to offer the program to enrollees in their Medicare Advantage (MA) plans, and charges each MAO on a per-member, per-month basis for its services. Enrollees who complete the first module of the program, along with a survey, receive a $25 gift card to a retailer. The gift cards may be for a big-box store or an online retail vendor that sells a wide variety of items. While enrollees may use the program multiple times during their period of enrollment, each enrollee may only receive one $25 gift card annually. The requestor conducts regular audits to ensure that each eligible enrollee receives only one gift card in a single year period. The gift card is not contingent on the enrollee undergoing surgery, pursuing a non-surgical treatment option, receiving any additional treatment or demonstrating surgery literacy on the survey, and the program does not refer to or recommend any provider, practitioner, supplier or service. Use of the program by enrollees is voluntary, and any enrollee may use the program and earn a gift card under the arrangement.

The requestor certified that it does not advertise, market or promote the program or the arrangement to individuals who are not enrollees. The standard contract governing the arrangement between requestor and each MAO prohibits the MAO from including information about the gift cards offered under the arrangement in the MAO's marketing communications to prospective enrollees.

## OIG Analysis

The OIG concluded that the arrangement implicates the AKS because the $25 gift card that requestor provides to enrollees, each of whom is a federal healthcare program beneficiary, is remuneration that could induce the enrollees to self-refer to a particular MA plan offered by an MAO that arranges for the provision of federally reimbursable items or services. The gift cards are also a cash equivalent because they are for a big-box store or an online retail vendor that sells a wide variety of items. However, OIG concluded the arrangement presented a low risk of fraud and abuse under the AKS for the following reasons:

- The arrangement is unlikely to increase costs to federal healthcare programs or result in inappropriate utilization, and could potentially have the opposite effect.

- The likelihood that the arrangement would meaningfully influence a beneficiary's selection of a particular MA plan is low because requestor does not advertise the program or the arrangement to beneficiaries who are not enrollees, and the requestor's standard contract with MAOs prohibits the MAO from including information about the gift cards offered under the arrangement in the MAO's marketing communications to prospective enrollees.

- The arrangement is unlikely to impact competition among healthcare providers, practitioners or suppliers.

For these reasons, OIG stated that it would not impose administrative sanctions on the requestor under the AKS in connection with the arrangement.

OIG also concluded that although the arrangement is clearly remuneration to a Medicare program beneficiary, the arrangement does not implicate the Social Security Act civil monetary penalty provision prohibiting inducements to beneficiaries (beneficiary inducements CMP). OIG noted that, in evaluating an arrangement under the beneficiary inducements CMP, it considers whether the requestor would know or have reason to know that the remuneration it provides to beneficiaries is likely to influence their selection of a particular provider, practitioner or supplier for the order or receipt of any item or service for which payment may be made, in whole or in part, by Medicare or a state healthcare program. The remuneration to enrollees under the arrangement (*i.e.*, the gift card) is provided upon completion of the first module of the program. OIG reasoned that because the program does not refer to or recommend any provider, practitioner, supplier or service, the remuneration provided to enrollees is not likely to influence an enrollee's selection of a particular provider, practitioner or supplier. To the extent that the program has the potential to influence a beneficiary's selection of a particular MA plan, OIG noted that an MA plan is not a provider, practitioner or supplier for purposes of the beneficiary inducements CMP.

# CMS REGULATORY UPDATES

## NONDISCRIMINATION IN HEALTH PROGRAMS AND ACTIVITIES

On August 4, 2022, CMS issued a proposed rule on Section 1557 of the ACA, which prohibits discrimination on the basis of race, color, national origin, sex, age or disability in certain health programs and activities. CMS proposes to revise its interpretation regarding whether Medicare Part B constitutes federal financial assistance for purposes of civil rights enforcement, and to revise nondiscrimination provisions to prohibit discrimination on the basis of sexual orientation and gender identity in regulations issued by CMS. The proposed rule would also reinstate the rule clarifying that Section 1557 generally applies to many health insurance issuers and also prohibits discrimination in health insurance and other health-related coverage. In the preamble to the proposed rule, CMS noted that the reinstatement would further a central goal of the ACA to increase access to health-related coverage. The proposed rule also seeks to create consistent procedural requirements for covered health programs and activities by requiring grievance procedures (for employers with 15 or more employees), the designation of a responsible employee (for employers with 15 or more employees) and the affirmative provision of civil rights notices. The absence of such consistency leaves individuals with different procedural protections in covered programs and activities depending on whether their complaint is based on race, color, national origin, sex, age and/or disability. For more information, see our *On the Subject* on this proposed rule.

## 2023 OPPS AND ASC PAYMENT SYSTEM PROPOSED RULE

On July 15, 2022, the CMS released the CY 2023 Hospital Outpatient Prospective Payment and Ambulatory Surgical Center Payment Systems Proposed Rule, which was published in the *Federal Register* on July 26, 2022. The proposed rule includes proposals to update payment rates, policies and regulations affecting Medicare services furnished in hospital outpatient and ambulatory surgical center (ASC) settings beginning in CY 2023.

For CY 2023, CMS proposes to increase payment rates for the outpatient prospective payment system (OPPS) and ASC payment system by 2.7%. CMS also proposes to expand the categories of services subject to prior authorization, outlines proposals to ensure continued access to mental health services via telehealth following the end of the COVID-19 public health emergency (PHE), and proposes numerous changes for hospital outpatient departments, including maintenance of the site neutrality process for exempt rural sole community hospitals and quality reporting policies for rural emergency hospitals (a new provider type that will be introduced in CY 2023). For additional information and analysis on rural emergency hospitals, see our *On the Subject*.

In the CY 2023 proposed rule, CMS proposes a payment rate of average sales price minus 22.5% for drugs and biologicals acquired through the 340B program. However, CMS notes that it plans to apply a rate of average sales price plus 6% to such drugs and biologicals in the final rule for CY 2023 and make a corresponding adjustment to the conversion factor to preserve budget neutrality, in light of the Supreme Court's June 15, 2022, decision in *American Hospital Association v. Becerra*, which held that US Department of Health and Human Services (HHS) may not vary payment rates for drugs and biologicals among groups of hospitals without conducting a survey of hospitals' acquisition costs. CMS notes that it did not have time to adjust payment in the proposed rule. CMS also states that it is evaluating how to apply the Supreme Court's recent decision to prior calendar years, including CYs 2020–2022,

which were not subject to the Supreme Court decision. This means that CMS is determining whether additional dollars need to be provided back to hospitals that lost reimbursement because of the CY 2018 OPPS rule.

For additional analysis on the CY 2023 OPPS and ASC proposed rule, see McDermott+Consulting's article on the topic. Comments on the proposed rule are due September 13, 2022.

## CY 2023 IPPS FINAL RULE

On August 1, 2022, CMS released the FY 2023 Inpatient Prospective Payment System (IPPS) Final Rule updating Medicare payment policies and quality reporting programs relevant for hospital inpatient services, and building on key priorities to address health disparities and improve the safety and quality of maternity care.

For additional analysis on the CY 2023 IPPS final rule, see McDermott+Consulting's article on the topic.

## 2023 SNF PAYMENT RATE INCREASES

On July 29, 2022, CMS issued a final rule updating Medicare payment policies and rates for skilled nursing facilities (SNFs) under the SNF prospective payment system for FY 2023.

In April 2022, CMS had proposed cutting Medicare Part A payments to nursing homes by $320 million. The transition to a new nursing home payment model in 2019 inadvertently led to a 5% pay increase in FY 2020, requiring a decrease in payments the following year, according to the proposed rule. For additional analysis on the proposed rule, see our April 2022 *On the Subject*.

CMS changed course in the final rule and will phase in the payment correction over two years to ease the burden on providers still struggling with the COVID-19 pandemic. In FY 2023, nursing homes will receive a 2.7% increase in Medicare rates. This does not factor in value-based purchasing reductions for certain nursing homes, according to a CMS fact sheet.

The April 2022 proposed rule had also requested public comments on various quality issues, including minimum staffing requirements, SNF quality reporting measures and principles for measuring health equity. While CMS did not respond to all comments in the final rule, the agency indicated that will take the comments into consideration as it continues to work to increase transparency and quality in SNFs as part of its recent regulatory focus on nursing homes. For additional information on the Biden administration's focus on nursing homes, see our March 2022 *On the Subject*.

## CY 2023 PHYSICIAN FEE SCHEDULE PROPOSED RULE

On July 7, 2022, CMS released the CY 2023 Revisions to Payment Policies Under the Physician Fee Schedule and Other Revisions to Medicare Part B Proposed Rule, which was published in the *Federal Register* on July 29, 2022. The proposed rule includes proposals related to Medicare physician payment and the Quality Payment Program. Physicians face proposed cuts of more than 4% under the proposed fee schedule, along with significant proposed changes to accountable care organizations. The proposed rule also includes the following proposals:

- Launch the Merit-based Incentive Payment System (MIPS) Value Pathways as a voluntary option to the MIPS in 2023
- Permanently maintain certain services added to the telehealth list during the PHE; maintain certain services added as covered telehealth services but not given permanent or Category 3 status until 151 days post-PHE; and add several codes as Category 3 telehealth codes, which are slated to remain covered until the end of CY 2023
- Delay the in-person requirements for telehealth services furnished for purposes of diagnosis, evaluation or treatment of a mental health disorder until the 152nd day after the PHE ends
- Expand access to, and address shortages of, behavioral services and health providers by allowing licensed professional counselors and licensed marriage and family therapists to bill Medicare under general supervision, and create a new billing

code for general behavioral health integration services for clinical psychologists and clinical social workers when they are the focal point of integration

- Implement initiatives promoting health equity.

For additional analysis of the CY 2023 Medicare Physician Fee Schedule proposed rule, see McDermott+Consulting's article. Comments on the proposed rule are due by September 6, 2022.

### CLINICAL LABORATORY IMPROVEMENT AMENDMENTS OF 1988 FEES PROPOSED RULE

On July 26, 2022, CMS issued a proposed rule that would update the Clinical Laboratory Improvement Amendments of 1988 (CLIA) fee regulations. This proposed rule, if finalized, would provide sustainable funding for the CLIA program through a biennial two-part increase in CLIA fees. The proposed rule would ensure ongoing quality and safety of laboratory testing for the public by clarifying the methodology used to determine program compliance fees. The proposed rule also includes the following proposals:

- Incorporate limited/specific laboratory fees, including fees for follow-up surveys, substantiated complaint surveys and revised certificates
- Distribute the administrative overhead costs of test complexity determination for waived tests and test systems with a nominal increase in Certificate of Waiver (CoW) fees
- Amend histocompatibility and personnel regulations under CLIA to address obsolete regulations and update the regulations to incorporate technological changes
- Amend the provisions governing alternative sanctions (including civil money penalties, a directed plan of correction, a directed portion of a plan of correction and onsite state monitoring) to allow for the imposition of such sanctions on CoW laboratories.

### FY 2023 INPATIENT REHABILITATION FACILITY PROSPECTIVE PAYMENT RATES

On August 1, 2022, CMS issued a final rule that updates the prospective payment rates for inpatient rehabilitation facilities for federal FY 2023 for discharges occurring on or after October 1, 2022, and on or before September 2023.

### FY 2023 INPATIENT PSYCHIATRIC FACILITIES PROSPECTIVE PAYMENT SYSTEM FINAL RULE

On July 29, 2022, CMS issued a final rule that updates the prospective payment rates for inpatient psychiatric facilities, which include psychiatric hospitals and exclude psychiatric units of acute care hospitals and critical access hospitals. The final rule will be effective on October 1, 2022, and applies to discharges occurring on or after October 1, 2022, and on or before September 30, 2023.

# OTHER NOTABLE DEVELOPMENTS

### INFLATION REDUCTION ACT PERMITS MEDICARE DRUG PRICE NEGOTIATION

On August 16, 2022, President Biden signed into law the Inflation Reduction Act of 2022 (IRA), which is intended to fight inflation, invest in domestic energy production and manufacturing, and reduce carbon emissions by roughly 40% by 2030. The law also contains unprecedented healthcare provisions, such as allowing Medicare to negotiate with manufacturers on prescription drug prices.

The IRA's healthcare provisions include the following:

- Establishing a Medicare Drug Price Negotiation Program

- Requiring drug manufacturers to pay a rebate for certain drugs if the average increase in total allowed charges for a drug outpaces inflation increases
- Establishing a price cap on insulin
- Establishing a $2,000 out-of-pocket cap for beneficiary payments under Medicare Part D plans
- Extending the premium tax credits established under the ACA for three years, until January 1, 2026.

For more information on the IRA's healthcare provisions, see McDermott+Consulting's article, "The Inflation Reduction Act of 2022: Healthcare Provisions Updated: 08/16/2022."

## HOUSE PASSES BILL TO EXTEND TELEHEALTH FLEXIBILITIES THROUGH 2024

The US House of Representatives passed a bill to extend telehealth reimbursement flexibilities established during the COVID-19 pandemic for two years. The bill, HR 4040, easily passed by a vote of 416–12 and is currently in committee in the Senate. The bill provides that certain flexibilities would continue to apply until December 31, 2024, if PHE ends before that date. The bill would allow the following:

- Medicare beneficiaries to continue to receive telehealth services at any site, regardless of type or location (*e.g.*, the beneficiary's home)
- Occupational therapists, physical therapists, speech-language pathologists and audiologists to continue to receive reimbursement for telehealth services furnished to Medicare beneficiaries
- Federally qualified health centers and rural health clinics to continue to serve as the distant site (*i.e.*, the location of the healthcare practitioner) during a telehealth encounter
- Providers to render evaluation and management and behavioral health services via audio-only technology
- Hospice physicians and nurse practitioners to continue to complete certain requirements relating to patient recertifications via telehealth.

The bill would also delay implementation of certain in-person evaluation requirements for mental health telehealth services until January 1, 2025, or the first day after the end of the PHE, whichever is later. The bill has been referred to the Senate Finance Committee.

## HHS REPEALS RULES ON GUIDANCE, ENFORCEMENT, AND ADJUDICATION PROCEDURES

HHS repealed two procedural rules in the July 25, 2022, *Federal Register* that were both promulgated during the previous administration's last days to implement executive orders issued on October 9, 2019. The first executive order required all federal agencies, not just HHS, to treat guidance documents as legally non-binding and to publish all their guidance on a website. The second executive order created new requirements about the standards (including those spelled out in guidance) on which HHS agencies rely to bring administrative enforcement actions, make decisions and enforce punishments. The Biden administration revoked both executive orders in January 2021 and instructed HHS to rescind the corresponding final rules.

HHS articulated several policy bases for the repeal of the procedural rules. HHS stated that the rules ran counter to the administration's goals of advancing public health and welfare, imposed burdensome standards and procedures, harmed historically underserved

constituencies, impeded department flexibility and diverted limited department resources. HHS formally announced in an October 2021 notice of proposed rulemaking that it would repeal the rules.

HHS also formally withdrew a related final rule that would have terminated almost every HHS regulation on its 10th anniversary. The department posted notice that it was withdrawing the rule in late May 2022.

## JOINT COMMISSION TO ADD HEALTH EQUITY STANDARDS TO ACCREDITATIONS

The Joint Commission announced that effective January 1, 2023, it will implement new and revised requirements to reduce healthcare disparities. These requirements will apply to organizations in the Joint Commission's ambulatory healthcare, behavioral healthcare and human services, critical access hospital and hospital accreditation programs. The updated standards include designating an officer to lead a strategy for reducing health disparities and screening patients for social determinants of health.

The Joint Commission will also require accredited organizations to add demographic breakdowns to quality and safety data, which will assist organizations in identifying disparities in health outcomes. The Joint Commission will require organizations to develop an action plan to eliminate these disparities, track their progress, and regularly update internal leaders and staff.

## DEPARTMENTS ISSUE NO SURPRISES ACT RULES, FACT SHEET

On August 19, 2022, HHS and the US Departments of Labor and the Treasury released the Requirements Related to Surprise Billing: Final Rules, along with a fact sheet. The rules finalize certain requirements under the July 2021 interim final rules relating to information regarding the qualifying payment amount that group health plans and health insurance issuers offering group or individual health insurance coverage must share. The final rules also finalize select provisions of the October 2021 interim final rules related to information that a certified independent dispute resolution entity must consider when making a payment determination under the federal independent dispute resolution process. For additional analysis, see our *On the Subject*.

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