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 May 21 and June 20, 2022. Key updates include a case in which a California-based rheumatologist agreed to pay approximately $1 million to settle allegations that he violated the False Claims Act (FCA) by charging Medicare for drugs not approved by the United States Food and Drug Administration (FDA) and associated services related to the treatment of osteoarthritis pain. The Supreme Court of the United States also overturned Medicare payment cuts applicable to 340B drugs in 2018 and 2019, finding that the US Department of Health and Human Services (HHS) failed to carry out a required survey of hospital drug acquisition costs before implementing the cuts.

In addition to examining recent Office of Inspector General (OIG) advisory opinions, we provide an update on the No Surprises Act and the first fines issued against hospitals for noncompliance with the price transparency rules that took effect in January 2021. Finally, we take a look at recent Centers for Medicare & Medicaid Services (CMS) activity, including its recommendations for Medicare Part B premium reexamination and a comment notice regarding the self-referral disclosure protocol.

NOTABLE ENFORCEMENT RESOLUTIONS AND ACTIVITY

RHEUMATOLOGIST SETTLES FCA VIOLATION ALLEGATIONS FOR $1M

A California-based rheumatologist agreed to pay approximately $1 million to settle allegations that he violated the FCA by charging Medicare for non-FDA-approved drugs and associated services related to the treatment of osteoarthritis pain. The drugs were packaged and labeled for use in foreign markets, and were for additional uses not approved in the United States, according to at least some of the labeling.

PHYSICIAN, FENTANYL SALES REP FOUND GUILTY OF CONSPIRACY, ILLEGAL KICKBACKS

A federal jury found a physician and sales representative guilty of conspiring to pay and receive kickbacks and bribes in the form of speaker fees in return for prescribing the fentanyl spray Subsys. The physician owned and operated a pain management medical practice where he prescribed a large volume of Subsys. The sales representative was employed in the physician's territory by the company that formerly formerly manufactured and sold Subsys. Through the sales representative, the company actively marketed Subsys to the physician by holding sham speaker events, for which the physician was paid $2,400 to $3,000 per event in return for

writing more prescriptions and prescriptions for higher dosages. The speaker events were often only attended by the physician's family and friends or repeat attendees, and included many falsified or forged attendee signatures. The company also bribed the physician by hiring his then-girlfriend to work as a company liaison to facilitate the approval of insurance forms for Subsys, including those submitted for Medicare patients. The physician was also employed as a consultant by a local pharmacy, where he referred his patients to fill prescriptions for Subsys and other medications.

The physician was paid more than $278,000 in illegal kickbacks and bribes over a period of less than three years, and the sales representative earned more than $737,000 in salary and sales commissions over a period of two and a half years. Both individuals are facing a maximum penalty of five years in federal prison on conspiracy counts and up to 10 years for each substantive kickback violation, as well as monetary judgments in the amount of the proceeds of the kickbacks.

FOURTH CIRCUIT AFFIRMS ADULT CARE HOMES' INTERPRETATION OF MEDICAID POLICY

The US Court of Appeals for the Fourth Circuit affirmed summary judgment in favor of 45 adult care homes in North Carolina and their manager in a whistleblower action alleging that the defendants improperly billed North Carolina's Medicaid program using patient census rather than tracking time their employees actually spent providing personal care services to individual residents. The Fourth Circuit found that North Carolina's Medicaid policy was ambiguous as to how adult care homes should bill for personal care services, and thus defendants' interpretation of the policy was reasonable or, at most, an error in judgment or a mistake. Citing to *United States ex rel. Sheldon v. Allergan Sales, LLC*, the Court discussed the two-step analysis to evaluating the reckless disregard standard of the FCA, noting that where statutes, relevant court and agency guidance allow for more than one reasonable interpretation, it would be difficult to find that one acted recklessly, even if the reading of such statutes, court and/or agency guidance was ultimately erroneous. Click here for a discussion of the *Allergan* decision and its implications.

United States ex rel. Gugenheim v. Meridian Senior Living, LLC, No. 20-1583 (4h Cir., May 26, 2022)

BEHAVIORAL HEALTH PROVIDER TO PAY $2.1M TO RESOLVE FALSE CLAIMS ALLEGATIONS

A North-Carolina-based behavioral healthcare provider agreed to pay $2.1 million to resolve allegations that it violated the FCA by billing claims to Medicaid programs that were not reimbursable under the North Carolina Medical Clinical Coverage Policy. The allegations arose from a lawsuit filed by a whistleblower, who alleged that the case management services provider, who provides such services for Medicaid beneficiaries under the North Carolina Community Alternatives Program for Disabled Adults, submitted claims for reimbursementto North Carolina Medicaid, and received payment for such claims, for services that were not covered by Medicaid from January 1, 2016, through October 31, 2019.

SETTLEMENT OF IMPROPER LAB BILLING SCHEME EMPHASIZES OIG FOCUS ON "UNBUNDLED" SERVICES

A Texas-based laboratory agreed to pay almost $3 million to resolve allegations that it violated the FCA in an alleged nationwide scheme to improperly bill Medicare for laboratory tests. The laboratory allegedly sought to improperly submit claims and receive reimbursement from Medicare by circumventing Medicare's 14-Day Rule, which prohibits laboratories from separately billing Medicare for tests performed on specimens if a physician orders the test within 14 days of the patient's discharge from a hospital stay either in an inpatient or outpatient setting. This action reflects OIG's ongoing scrutiny of practices and courses of dealing that it believes result in the improper "unbundling" of services furnished to Medicare beneficiaries.

SUPREME COURT OVERTURNS 2018–2019 PAYMENT CUT FOR 340B DRUGS

The Supreme Court of the United States overturned a Medicare payment cut applicable to 340B drugs in 2018 and 2019, finding that HHS failed to conduct the required survey of hospital drug acquisition costs prior to implementing the cuts. In a unanimous decision, the Supreme Court found that HHS's payment cut was unlawful and remanded the case for further proceedings consistent with the Court's opinion.

DISTRICT COURT AFFIRMS DOJ CASE AGAINST EXECUTIVE RELATED TO $69M IN FRAUD

The US District Court of the Northern District of California denied a defendant's motion to dismiss a case brought by the US Department of Justice (DOJ) for conspiracy to commit healthcare fraud and wire fraud. The president of a California-based medical technology company was charged in an indictment in connection with his participation in schemes to mislead investors and commit healthcare fraud related to the submission of more than $69 million in false and fraudulent claims for allergy and COVID-19 testing. The complaint alleges that the defendant and others paid kickbacks and bribes to recruiters and doctors to run allergy screenings for 120 allergens on every patient, regardless of medical necessity, then made misrepresentations to investors about the company's allergy test sales, financial condition and future prospects.

The indictment also included an alleged violation of the Eliminating Kickbacks in Recovery Act (EKRA), 18 USC § 220. The parties disputed whether EKRA requires a marketer to work directly with individual patients. The defendant argued that it does and contended that because the indictment premised EKRA liability on his use of marketers to directly recruit patients, the indictment counts pertaining to ERKA should be dismissed. The district court noted that there is no requirement of "directness" in EKRA. Instead, the court looked to the plain meaning of the statute and found that to "induce a referral of an individual" includes situations where a marketer causes an individual to obtain a referral from a physician. As such, the court held that the executive's conduct fell within the scope of EKRA. Note that this court reached the opposite conclusion from the first federal court that considered whether EKRA applied to employed sales representative compensation where the sales representative only marketed to physicians and not patients. *See* S&G Labs Haw., LLC v. Graves, 2021 WL 4847430 (D. Haw. Oct. 18, 2021).

U.S. v. Schena, No. 5:20-cr-00425-EJD-1 (N.D. Cal. May. 28, 2022)

PENNSYLVANIA AG TARGETS FALSE CLAIMS FOR URINE DRUG TESTING

The US Attorney General's Office for the Middle District of Pennsylvania reached a settlement with an individual who agreed to pay $900,000 for violations of the FCA and agreed to be excluded from all federal healthcare programs for 22 years. The individual allegedly caused the submission of false claims for payment to Medicare through a group of pain clinics between 2017 and 2019. These claims were for presumptive and definitive urine drug tests that were not medically reasonable or necessary, and were not used in the diagnosis or treatment of patients.

Medical necessity of urine drug testing for Medicare beneficiaries has been the topic of several government enforcement actions. Organizations should consider evaluating their testing protocols to ensure that presumptive and definitive testing is medically necessary, and that such necessity is documented in the record.

HOME SLEEP TESTING COMPANY SETTLES WITH DOJ FOR $3.5M

A suburban Chicago home sleep testing company agreed to pay the DOJ $3.5 million to settle FCA claims that the company submitted false claims to Medicare and four other federal healthcare programs through kickbacks and unnecessary home sleep testing. The lawsuit alleged that the founder directed the company to "submit claims for patients' second and third nights of home sleep testing when, in fact, the company knew that only a single night of testing was needed to effectively diagnose obstructive sleep apnea and that it routinely tested and claimed only one night for patients with private health insurance." The suit alleged that as a result of this practice, the company multiplied the copays received from Medicare beneficiaries. The government also alleged that the company relied several unlawful kickback schemes that encouraged physicians and their staff to refer home sleep testing to the company.

BUSINESS OWNER PLEADS GUILTY TO SCHEME RELATED TO COVID-19 TESTING, CANCER SCREENING

A Georgia individual pled guilty for his role in a conspiracy to commit healthcare fraud and receipt of kickbacks in connection with COVID-19 testing claims and cancer genetic screening. The individual owned and operated a company that conducted business with medical testing companies. Between September 2019 and March 2020, the individual agreed to help in a scheme that provided medical testing companies with qualified patient leads for medically unnecessary cancer genetic screening tests for Medicare

beneficiaries. In exchange, the individual received kickbacks of approximately $1,000 to $1,500 for each test that resulted in a reimbursement from Medicare. In March 2020, the scheme expanded to include COVID-19-related testing. The individual also admitted to entering into a sham contract and used sham invoices to make the payments appear legitimate.

TELEMEDICINE COMPANY OWNER SENTENCED TO 14 YEARS FOR $20M IN FRAUD

The owner and operator of several telemedicine and telemarketing companies was sentenced to 14 years in prison for healthcare and wire fraud that cost Medicare more than $20 million. The individual allegedly used his companies to market medically unnecessary genetic tests to Medicare beneficiaries and to sell prescriptions (*i.e.*, doctors' orders) for medically unnecessary genetic tests to laboratories in exchange for kickbacks and bribes.

PROVIDER, HOSPITAL SELF-DISCLOSE FRAUDULENT CLAIMS FOR HYPERBARIC OXYGEN TREATMENT

A wound care provider and a hospital self-disclosed to OIG and agreed to pay just over $426,000 for allegedly violating the CMP law. OIG alleged that certain of the wound care provider's employees caused the hospital to submit claims to, and receive reimbursement from, federal healthcare programs for units of hyperbaric oxygen treatment that were in excess of the units actually provided to the patient.

HOSPITAL SYSTEM SELF-DISCLOSES EMPLOYMENT OF INDIVIDUAL EXCLUDED FROM FEDERAL HEALTHCARE PROGRAMS

An Illinois hospital system self-disclosed to OIG and agreed to pay almost $263,000 for allegedly violating the CMP law. OIG alleged that the hospital system employed an individual that it knew or should have known was excluded from participation in federal healthcare programs.

FORMER MEDICAL TESTING LAB CEO SENTENCED TO PRISON, $7.6M IN RESTITUTION

The US District Court for the Western District of Washington sentenced the former chief executive officer of a medical testing laboratory company to two years in prison and $7.6 million in restitution for a conspiracy to solicit kickbacks. Between 2013 and 2015, the CEO conspired with others to receive kickbacks from medical testing labs in exchange for government testing business referred to the labs. The company's activities have been the subject of extensive civil and criminal litigation. The company, now dissolved, pleaded guilty in February 2021 and was sentenced to pay more than $8 million in restitution, joint and several with the other criminal defendants. To date, the labs and individuals involved in this investigation have agreed to pay more than $14 million to settle related civil allegations. Two other defendants await sentencing.

PHYSICIAN SETTLES ALLEGATIONS OF FRAUDULENT BILLING

The US Attorney's Office for the Western District of New York announced that a physician agreed to pay almost $603,000 to resolve allegations of FCA violations. From at least January 1, 2014, to December 31, 2019, the physician allegedly billed Medicare and Medicaid for procedures that were not performed at all or were not documented in patient medical records.

OIG ADVISORY OPINIONS

ADVISORY OPINION 22-11, POSTED ON MAY 25, 2022

The requestor is a medical practice group specializing in pain management, where 70% of its patients are treated for injuries covered by a workers' compensation (WC) program. Requestor also separately treats federal healthcare program beneficiaries.

In 2019, requestor hired a chiropractor to perform administrative tasks related, in part, to federal healthcare program beneficiaries. This individual had previously been excluded from the state's WC system, the state's Medicaid program and federal healthcare programs. Requestor placed the excluded individual on unpaid administrative leave in May 2021 and submitted a self-disclosure to the OIG in connection with requestor's employment of excluded individual.

Requester sought to reestablish excluded individual's employment as a WC payor relations representative, whose responsibilities would include marketing requestor's medical services to WC payors and lawyers who work with individuals covered by WC payors. Requestor certified that the excluded individual's responsibilities would primarily consist of meeting with representatives from WC payors and WC attorneys to explain requestor's services and the benefits of working with requestor and market requestor's ability to provide medical services to their clients. The excluded individual would also develop marketing materials, research potential contacts within the state's WC industry, participate in WC industry groups, provide information on WC to requestor's management, and work on a team that fields billing and payment inquiries from WC payors. The excluded individual would not provide any marketing, billing or other services to federal healthcare program beneficiaries or to any providers or supplies that refer federal healthcare program beneficiaries to requestor. He would also work from one of requestor's administrative offices where no patient visits occur, and thus would not have any interaction with federal healthcare program beneficiaries and would not otherwise provide any items or services for which payment would be made by a federal healthcare program. Requestor certified that it would create a separate payroll dedicated to WC, from which revenues derived from the reimbursement requestor receives from non-federal-healthcare-program payors would be pooled, and from which the excluded individual's salary and benefits would exclusively be paid.

OIG Analysis

Pursuant to a 2013 Updated Special Advisory Bulletin, titled "the Effect of Exclusion from Participation in Federal Healthcare Programs," the OIG noted that "if Federal healthcare programs do not pay, directly or indirectly, for the items or services being provided by the excluded individual, then a provider that participates in Federal healthcare programs may employ or contract with an excluded person to provide such items or services." Under the proposed arrangement, the excluded individual would not provide items or services directly or indirectly to federal healthcare program beneficiaries and would be paid from segregated payroll funds derived only from non-federal-healthcare-program reimbursement (thus, federal healthcare programs would not pay, directly or indirectly, for the excluded individual's salary). As such, the excluded individual's employment would not involve the provision of items or services for which payment may be made under a federal healthcare program. Based on the facts provided by requestor, the OIG concluded that the proposed arrangement would not constitute grounds for the imposition of sanctions.

The OIG noted several caveats:

- This conclusion does not affect the excluded individual's exclusion from federal healthcare programs.
- This conclusion does not reflect the OIG's opinion as to whether the proposed arrangement would implicate or violate the terms of the excluded individual's suspension from participation in the state's WC system.
- Requestor's proposal to employ the excluded individual in a marketing role designed to encourage WC payors and WC attorneys to refer their clients to requestor for medical services raises meaningful compliance risks for requestor based on the excluded individual's history of participating in kickback schemes involving referrals of WC patients.

ADVISORY OPINION 22-12, POSTED ON MAY 26, 2022

A Medigap plan and a preferred hospital organization (PHO) requested an opinion from the OIG regarding an arrangement to incentivize the Medigap plan policyholders to seek inpatient care from hospitals within the PHO's network.

The proposed arrangement comprises three elements:

- Medicare Part A Discount: The Medigap plan's policies cover the Medicare Part A inpatient deductible, among other benefits. Through its arrangement with the PHO, each network hospital provides a discount (which is set in advance in a written agreement between the PHO and its network hospitals and the PHO and the Medigap plan) on the Medicare Part A deductible that the Medigap plan would otherwise cover for its policyholders. The discount is offered uniformly to all policyholders for a term of at least one year, and neither the PHO nor any network hospital provides anything else of value to the Medigap plan.

- Policyholder Premium Credit: The Medigap plan offers a $100 premium credit to each policyholder who selects a network hospital for a Medicare-Part-A-covered inpatient stay. This credit is applied to the next premium payment due to the plan after the policyholder's applicable inpatient stay. Policyholders are eligible to receive only one $100 premium credit per Medicare Part A benefit period. The arrangement does not otherwise affect the liability of any policyholder for payment obligations stemming from Medicare Part A-covered inpatient services, regardless of whether the hospital is a network hospital (and, in the converse, a policyholder is not penalized for not selecting a network hospital). The plan does not advertise this arrangement to potential enrollees, but it provides information about network hospitals and the premium credit to policyholders upon enrollment and through periodic mailings thereafter.

- PHO Administrative Fee: The PHO and the Medigap plan entered into a written agreement pursuant to which the plan pays the PHO a monthly fee for establishing the hospital network and arranging for the network to discount the Medicare Part A inpatient deductible. The fee is a percentage of the aggregate savings that the Medigap plan realizes from the network hospitals' discounts on policyholders' inpatient deductibles in a given month. As such, the fee varies based on the number of policyholder claims for which network hospitals provided a discount on inpatient deductibles and the amount of the discount. The parties certified that this fee reflects fair market value.

OIG Analysis

The OIG concluded that the proposed arrangement poses a low risk of fraud and abuse, and thus would not constitute grounds for administrative sanctions, for the following reasons:

- Federal Anti-Kickback Statute (AKS) – Medicare Part A Discount and Policyholder Premium Credit: OIG explained that the network hospitals' discounts on Medicare Part A inpatient deductibles and the Medigap plan's offer of premium credits constituted remuneration, which could influence referrals of federal healthcare program business. The discount could induce the Medigap plan to arrange for or recommend federally reimbursable items or services by the network hospitals on behalf of the plan's policyholders. The premium credit could influence potential enrollees to select and/or re-enroll in the Medigap plan and to select a network hospital as their inpatient hospital provider. Although no safe harbor exists for this arrangement, the OIG found that these two streams of remuneration presented low risk under the AKS. The OIG found that it was unlikely that these streams of remuneration would result in overutilization of healthcare items or services, or pose a risk of increased costs to federal healthcare programs, as it is in the Medigap plan's financial interest to ensure appropriate utilization and costs. The OIG also found it unlikely that the premium would serve as an improper inducement for policyholders to utilize inpatient care, particularly as patients generally do not control whether they are admitted as an inpatient and the premium credit comes in the form of a reduction in the amount owed to the plan versus an affirmative payment (such as a check). The OIG also noted that the arrangement would not impact patient choice, as policyholders could select any hospital to receive care without an increase in cost-sharing obligations or premiums, and that the two streams of remuneration would be unlikely to significantly impact competition.

- Beneficiary Inducements Civil Monetary Penalty (CMP) – Premium Credit: The offer of a premium credit to policyholders implicates the beneficiary inducements CMP, but for the reasons explained above, the OIG determined that it would not impose administrative sanctions with respect to this component of the arrangement.

- Federal AKS – PHO Administrative Fee: Although no safe harbor exists for this component of the arrangement, the OIG found that the payment of this fee to the PHO is low risk under the AKS. The fee is consistent with fair market value and, although it is tied to the volume or value of referrals between the Medigap plan and the network hospitals, the fee ultimately reflects a percentage of the savings realized by the plan versus revenue generated by the network hospitals. The OIG also found it favorable that the Medigap plan certified that it does not advertise this component of the program and does not otherwise pass on or shift the cost of the administrative fee to any federal healthcare program.

The OIG issued advisory opinions evaluating almost identical arrangements in 2021 (Advisory Opinions 21-03, 21-04 and 21-05). Those arrangements had the same three streams of remuneration, and the OIG similarly concluded that although they implicated the AKS and the beneficiary inducements CMP, they ultimately posed sufficiently low risk of fraud and abuse.

ADVISORY OPINION 20-02, ORIGINALLY POSTED ON JANUARY 15, 2020, AND MODIFIED ON JUNE 1, 2022

The OIG previously issued Advisory Opinion 20-02 opining on requestor's provision of financial assistance for travel, lodging and other expenses to certain patients in connection with administration of the requestor's personalized drug at an approved treatment center. Requestor subsequently sought to modify the proposed arrangement.

Under the modified proposed arrangement, eligible patients may receive financial assistance for one round trip from the patient's and each caregiver's place of residence to an approved treatment center for leukapheresis in addition to the round trip to the treatment center for drug infusion and post-treatment monitoring. Requestor offers travel assistance only to the treatment center closest to the patient's residence that is accepting patients and that accepts the patient's insurance (except in certain circumstances, e.g., when a patient has been receiving treatment from a physician associated with a treatment center located farther from the patient's home and, for continuity of treatment, the patient desires to continue treatment with the same physician or healthcare team). For each of these two round trips, requestor arranges for a modest, single shared hotel room located near the treatment center for the patient and caregiver(s) and reimburses certain meal and other travel expenses up to $50 per day per person (e.g., meals and parking or taxi fare between the hotel and the treatment center). Because leukapheresis generally takes three days to complete, under the modified proposed arrangement, eligible patients may receive up to two nights of lodging to obtain leukapheresis at a treatment center.

OIG Analysis

The OIG concluded that the modified proposed arrangement does not affect the conclusion it initially issued in Advisory Opinion 20-02. Accordingly, the OIG concluded that although the modified proposed arrangement would generate prohibited remuneration under the federal AKS if the requisite intent were present, the OIG would not impose administrative sanctions on requestor. The OIG also concluded that the modified proposed arrangement does not constitute grounds for the imposition of sanctions under the beneficiary inducements CMP.

OIG concluded that the modified proposed arrangement implicates the federal AKS in two ways. First, the free travel, lodging and meal assistance constitute remuneration to eligible patients who are federal healthcare program beneficiaries, which may induce them to purchase requestor's drug. Second, because the travel, lodging and meal assistance allow federal healthcare program beneficiaries to travel to, and stay near, a treatment center that they might not otherwise have selected for drug treatment or leukapheresis, the assistance constitutes remuneration to the treatment centers and the physicians performing services related to drug treatment in the form of an opportunity to earn fees related to drug treatment. Such opportunity may induce the treatment centers and physicians to order the drug. This remuneration is inherently tied to the volume of referrals of requestor's drug, and it potentially benefits the treatment centers and physicians by steering business that is reimbursable by a federal healthcare program to them.

While the provision of remuneration by a manufacturer to a beneficiary to facilitate the manufacturing of a drug for that beneficiary could raise significant concerns, OIG concluded that the modified arrangement presents a minimal risk of fraud and abuse under the federal AKS for several reasons. First, the financial assistance requestor furnishes to eligible patients for leukapheresis is narrowly tailored to remove barriers to undergoing the leukapheresis process, which reduces the risk that the assistance results in inappropriate steering to the drug. The remuneration under the modified arrangement is subject to numerous limitations:

- The remuneration is available only to patients who meet financial eligibility criteria, live a significant distance from a treatment enter and do not have insurance for non-emergency medical travel.

- Requestor does not authorize lodging when it has knowledge, or should have knowledge based on widely available public information, that the patient is eligible to receive free lodging without charge from the treatment center and such lodging is available for that patient's use.

- Requestor offers travel assistance only to the treatment center closest to the patient's residence that is accepting patients and that accepts the patient's insurance, except in certain limited circumstances.

Second, all safeguards and other standards applicable to the arrangement apply to the modification. For example:

- Requestor does not advertise the financial assistance available under the Modification.

- Patients do not learn about, or become eligible for, assistance under the modification until they have been diagnosed with an FDA-approved indication and prescribed the requestor's drug.

- Patients and caregivers must agree not to request reimbursement from any federal healthcare program for costs covered under the modification.

- Requestor does not bill or otherwise shift the costs of the modification to any federal healthcare program.

OIG concluded that the modified proposed arrangement implicates the beneficiary inducements CMP because it is likely to influence a federal healthcare program beneficiary to select a particular physician or treatment center that they may not otherwise have selected to receive items and services reimbursable by federal or state healthcare programs. However, OIG concluded that, for the same reasons that the original proposed arrangement satisfied the Promotes Access to Care Exception, as explained in Advisory Opinion 20-02, the modified proposed arrangement also satisfies this exception.

OTHER NOTABLE DEVELOPMENTS

NO SURPRISES ACT UPDATE

AHIP and the Blue Cross Blue Shield Association (BCBS) surveyed more than 80 commercial health insurance companies and received responses from 31 companies, which collectively represent 115 million commercial health plan members. These companies reported receiving 600,000 claims covered by the No Surprises Act in January and February 2022. However, based on claims experiences from prior years and factoring in processing delays this year, AHIP and BCBS estimate the true number of NSA-eligible claims in the first two months of 2022 was actually more than 2 million. AHIP and BCBS project that the No Surprises Act could prevent more than 12 million in surprise bills in 2022 alone.

HOSPITAL PRICE TRANSPARENCY RULES: FIRST FINES ISSUED

CMS issued its first fines for failure to comply with federal price transparency rules that took effect in January 2021. CMS previously issued warning notices to two Georgia based hospitals, and each submitted a corrective action plan. Despite these corrective action plans, CMS found that both hospitals were still noncompliant with the rules. Neither hospital posted a comprehensive list of standard charges: one hospital failed to make available a consumer-friendly list of 300 shoppable services, and the second hospital told CMS that patients should call or email for price estimates. CMS fined the hospitals almost $1.1 million.

MEDICARE PART B PREMIUM REEXAMINATION

CMS released a report recommending that cost savings from lower-than-expected Medicare Part B spending be passed along to individuals with Medicare Part B beneficiaries in the calculation of the 2023 Part B premium. CMS's recommendations are based upon the development of the Part B premium and the potential effects of factors that have changed since a premium was announced on Aduhelm (a drug used for the treatment of Alzheimer's disease). CMS builds in a reserve to ensure the Medicare Supplementary Medical Insurance (SMI) Trust Fund remains adequately financed for the year. In 2021, CMS built in a reserve to ensure the SMI Trust Fund could cover the potential costs of Aduhelm and similar drugs.

COMMENT NOTICE REGARDING SELF-REFERRAL DISCLOSURE PROTOCOL

CMS issued a comment notice regarding the current voluntary self-referral disclosure protocol (SRDP), pursuant to which providers and suppliers may disclose actual or potential violations of the Physician Self-Referral Law (known as the Stark Law) to CMS. The comment notice seeks input from the public on the "collection of information" required to be submitted when a physician practice discloses group practice noncompliance issues, proposing an alternate methodology. Under the proposal, the disclosing physician practice would submit the following documentation:

- The SRDP disclosure form
- A single group practice information form covering all physicians in the practice who made prohibited referrals to the practice
- A financial analysis worksheet.

All other entities would continue using the SRDP disclosure form, separate physician information forms for each physician covered in the self-disclosure, and a financial analysis worksheet. Comments are due to CMS by August 8, 2022.

OIG SPRING 2022 SEMIANNUAL REPORT TO CONGRESS

On June 6, 2022, OIG released its Spring 2022 Semiannual Report to Congress. The report highlights almost $3 billion in expected recoveries as a result of OIG audits and investigations, and provides an overview of OIG's activities from October 1, 2021, through March 31, 2022. For this period, OIG reported 320 criminal enforcement actions against individuals or entities that engaged in crimes affecting HHS programs, and 320 civil actions, which include false claims and unjust-enrichment lawsuits filed in federal district court, CMP settlements and administrative recoveries related to provider self-disclosure matters. CMS also excluded 1,043 individuals and entities from participation in federal healthcare program.

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