HEALTHCARE REGULATORY CHECK-UP

IN THIS MAY 2022 ISSUE

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This issue of McDermott's Healthcare Regulatory Check-Up highlights notable enforcement activity between April 21 and May 20, 2022, including a telemedicine case involving $64 million in false and fraudulent claims. We also review recent Office of Inspector General (OIG) advisory opinions on provider donations to a patient assistance program and a laboratory's proposed arrangement with hospitals, plus OIG's four new Work Plan items.

Recent Centers for Medicare & Medicaid Services (CMS) activity of note includes a proposed rule on the fiscal year (FY) 2023 Inpatient Prospective Payment System and new databases detailing change-of-ownership information for Medicare-enrolled hospitals and skilled nursing facilities. CMS also recently released the FY 2023 Skilled Nursing Facility Prospective Payment System proposed rule, which includes provisions seeking to advance the Biden administration's efforts to improve competition, transparency and quality for hospitals and nursing homes.

NOTABLE ENFORCEMENT RESOLUTIONS AND ACTIVITY

TELEMEDICINE ENFORCEMENT

The following two actions provide more examples of the government's scrutiny of telemedicine providers and Medicare's payment for items and services that result from those telemedicine visits.

Telemedicine Company Owners Admit to $64M in Healthcare Fraud

The two owners a telemedicine company based in Arizona, admitted their roles in conspiracies to bribe doctors and commit healthcare fraud. According to the US Department of Justice (DOJ), from September 2017 to December 2019, the owners conspired together and with others to submit and cause to be submitted false and fraudulent claims for federal healthcare benefit programs. They did this through a circular scheme of kickbacks and bribes paid to doctors and solicited from marketing companies, pharmacies and DME providers. The DOJ alleged that the scheme involved the following elements:

- Pharmacies and DME providers agreed to pay bribes and kickbacks to marketing companies in exchange for drug prescriptions and doctor's orders for DME.

- The marketing companies obtained the personal information of Medicare and Tricare beneficiaries, which they sent to the company along with pre-filled prescriptions and DME orders. The company then gave the beneficiary information and pre-marked prescriptions and DME orders to doctors, to whom it paid bribes and kickbacks.

- The doctors often approved the prescriptions and DME orders without having any contact with the beneficiaries, and without making *bona fide* assessments that the medications or DME were medically necessary.

- The company submitted the signed prescriptions and orders to pharmacies and DME providers around the United States for fulfillment and billing. When the pharmacies filled the prescriptions and orders and were reimbursed by healthcare benefit programs, they sent a portion of the reimbursement amount to the marketing companies, which then shared those funds with the company and its owners to purchase additional prescriptions and DME orders.

As part of their guilty pleas, the owners admitted that they and their conspirators caused the submission of false and fraudulent claims to healthcare benefit programs totaling more than $64 million.

Case number unavailable (D.N.J.)

Physician Pleads Guilty to Causing $4M in False Medicare Claims

An individual pled guilty to defrauding Medicare and admitted that he caused more than $4 million in false and fraudulent claims to be submitted while working for telemedicine companies based in Florida and Georgia. As an independent contractor for those companies, the individual claimed that he had consultations with patients and signed off on claims for durable medical equipment (DME) (*e.g.*, ankle, back and knee braces). In most instances, however, he never spoke to the patients. In one case, the individual sent a claim to Medicare for an ankle brace worth about $550 for a patient who had both legs amputated more than 20 years prior.

USA v. Pelehac, Case No. 1:22-cr-00247 (N.D. III).

Health IT Company to Pay $3.15M to Settle False Claims Allegations

A healthcare information technology company based in Florida that operates Medicare-enrolled independent diagnostic testing facilities agreed to pay $3.15 million to resolve allegations that it submitted or caused to be submitted false claims to Medicare for reimbursement. Allegations against the company involved false identification of the place of service in order to obtain a higher rate of Medicare reimbursement. These allegations in particular related to the billing of overnight pulse oximetry claims. Along with the civil settlement, the company entered into a corporate integrity agreement with OIG that requires retaining an outside expert to perform annual claims reviews that address the place of service identified on the claim.

- This settlement is an example of how more technical billing requirements, such as place of service rules, can be examined by the government under the FCA.

Case No. 19-cv-61084 (S.D. Fla.)

Government Sues Medical Device Company for Alleged FCA Violations

The federal government filed suit in the Western District of Michigan against a manufacturer of pelvic muscle therapeutic systems and related rectal probes, and its president and sole owner. The government alleged that the defendants violated the False Claims Act (FCA) by causing healthcare providers to bill Medicare for services in which the providers improperly reused single-use rectal sensors and single-use catheters on multiple patients, thereby exposing vulnerable Medicare beneficiaries to the risk of serious bacterial, fungal and viral infections. The complaint further alleged that although defendants knew that the US Food and Drug Administration (FDA) had cleared their devices for single-use, for years they encouraged and instructed healthcare providers to reuse the devices on multiple patients by using a glove or condom to cover the probe, as a way to reduce the defendants' overhead costs. The government's complaint alleges that this reuse was not reasonable or necessary, and therefore was ineligible for Medicare coverage.

- This action is notable as an example of how manufacturers can receive enforcement scrutiny for allegations involving providing their customers with information that could be considered off-label or contrary to FDA cleared uses.

United States v. The Prometheus Group., et al., Case No. 1:22-CV-446 (W.D. Mich.)

Home Health Company Settles Improper Billing Allegations for 2.1M

A home health agency paid $2.1 million to the US government to settle FCA claims that they improperly billed Medicare for home health services provided to Florida beneficiaries.

In its compliant, the government alleged that between 2013 and 2017, the home health entities knowingly submitted false or fraudulent claims seeking payment from the Medicare program for home health services to Medicare beneficiaries who were not homebound, did not require certain skilled care, did not have a valid or otherwise appropriate plan of care in place, or did not have the necessary face-to-face encounters to be certified to receive home health services.

This matter arose from a message to the OIG complaint hotline and from a FCA *qui tam* complaint.

- This settlement is notable because home health is an area where we see increasing audit and enforcement activities.

United States ex rel. Barbara Mellott-Yezman and Patricia Rench v. SHC Home Health Services-Ocala, LLC et al., Case No. 15-cv-24713 (S.D. Fla.)

OIG REGULATORY DEVELOPMENTS

NEW OIG ADVISORY OPINIONS

Advisory Opinion 22-10, posted on May 2, 2022, modifying AO 15-14

The requestor, a 501(c)(3) charitable organization, asked OIG to modify the scope of Advisory Opinion (AO) 15-14 to include prior financial assistance for certain magnetic resonance imaging (MRI) tests and a second arrangement for the distribution of certain cooling and mobility items. OIG issued a favorable opinion.

Under AO 15-14, the requestor received approval of a program to help financially needy patients (including Medicare and Medicaid beneficiaries) obtain MRIs for diagnosis and evaluation of a specific disease by fully subsidizing the costs of the MRIs. The program requires patients to have an existing physician order for an MRI for diagnosis or continuing evaluation of the applicable disease state, and uses objective criteria to determine financial need. Patients are eligible for one requestor-subsidized MRI within a 24-month period and must re-apply for assistance each time. To fund the program, requestor solicits donations in the form of cash or cash equivalents. Donors may provide unrestricted donations or earmark contributions for the program. Donors may receive aggregated data, such as the number of MRIs provided through the program and patients' use of disease state treatments, but are not given individual patient information. In AO 15-14, OIG concluded that although the arrangement could generate prohibited federal Anti-Kickback Statute (AKS) remuneration, OIG would not impose administrative sanctions for the following reasons:

- Donors' contributions are not construed as payments to arrange for referrals, and there is sufficient insulation preventing requestor's assistance to patients being attributed to or influenced by donors.

- Requestor's provision of financial assistance is unlikely to influence any beneficiary's selection of a particular provider, practitioner or supplier for items or services payable by federal healthcare programs.

Subsequently, requestor asked OIG to expand AO 15-14 to include MRIs with a date of service up to six months prior to the individual's application if the individual met the program's eligibility requirements on the date of service.

Requestor also asked OIG to modify AO 15-14 to include a program ancillary to the current arrangement, through which requestor distributes certain cooling and mobility items to low-income individuals diagnosed with a particular disease state. These items are intended to alleviate symptoms; improve safety, mobility, activities of daily living and wellness; or both.

Under this ancillary program, individuals seeking assistance must submit an application including proof of disease state and income, and identifying the desired cooling and/or mobility item. Requestor contracts with manufacturers and suppliers of the cooling and

mobility items and does not bill qualifying individuals for any items. Requestor compensates suppliers in full for the cost consistent with fair market value.

Requestor funds the distribution program through soliciting donations. Individuals and entities who make donations that are suppliers or affiliates of suppliers would not be able to earmark contributions to the distribution program (*i.e.*, would only make unrestricted donations to requestor). Any other donors can earmark their contributions for the current arrangement or distribution program, but not for specific individuals, treatments, items or services. Requestor does not refer or arrange for the use of any item or service furnished by donors.

OIG Analysis

OIG concluded in AO 22-10 that the proposed modification to AO 15-14 would not materially change the current arrangement's risk level under the AKS or the beneficiary inducement civil monetary penalty (CMP). OIG found the distribution program is (i) unlikely to result in increased costs to federal healthcare programs because the cooling and mobility items are not billed to federal healthcare programs; (ii) unlikely to steer or influence individuals toward suppliers in the future, because nothing from a clinical perspective would require individuals to order such items or services, and individuals are unlikely to need to reorder the items; and (iii) independent of donors' financial interests, and individual eligibility determinations are based on objective, uniform criteria related to disease state and financial need.

- This opinion is noteworthy because it involves a charity's use of donations made by providers and suppliers to fund patient assistance programs. Patient assistance programs involving charitable donations and foundations have been the subject of terminated AOs and enforcement scrutiny, but OIG found that this donation arrangement presented low risk.

Advisory Opinion 22-09, posted on April 28, 2022

The requestor, a clinical laboratory, sought an AO regarding a proposed arrangement in which requestor would compensate hospitals for certain specimen collection services for laboratory tests furnished by requestor. OIG issued an unfavorable opinion.

Under the proposed arrangement, requestor would enter into contracts with hospitals throughout the United States, pursuant to which requestor would pay the hospitals on a per-patient-encounter basis to collect, process and handle specimens that would then be sent to requestor's clinical laboratories for testing (the "Services"). Requestor would bill any applicable third-party payor, including federal healthcare programs, for the testing. The Services would be performed by a hospital-employed or hospital-contracted phlebotomist at the contract hospital.

Under the arrangement, requestor would compensate hospitals only for the Services performed in connection with individuals who presented with orders for testing and who were not currently inpatients or registered outpatients of the hospital. Requestor would not compensate hospitals if the Services were performed in connection with individuals who were inpatients or registered outpatients of the hospital at the time of the service. If individuals presented to a hospital with laboratory testing orders that did not specify which laboratory would conduct the testing, the hospital would have the opportunity to choose the laboratory to which it would send the specimens. Requestor certified that the per-patient-encounter compensation rate would be consistent with fair market value for the Services in an arm's-length transaction. Contracts between contract hospitals and requestor would prohibit contract hospitals from separately billing any payors or patients for the Services performed under the proposed arrangement.

OIG Analysis

OIG concluded that the proposed arrangement would implicate the AKS because it would involve remuneration from a laboratory to a party that was in a position to make referrals to the laboratory for, or otherwise arrange for the laboratory to furnish, items and services that may be paid for in whole or in part by a federal healthcare program.

- The arrangement would not be protected by the safe harbor for personal services and management contracts and outcomes-based payment arrangements because the per-patient-encounter compensation methodology would take into account the volume or value of referrals or other business generated for which payment may be made in whole or in part under a federal healthcare program.

In reviewing the facts and circumstances, OIG stated that the proposed arrangement warranted careful scrutiny because laboratory services may be particularly susceptible to the risk of steering, and the arrangement would involve a "per-click" fee structure (in the

form of a per-patient-encounter compensation methodology), which generally is inherently reflective of the volume or value of referrals or business otherwise generated between the parties. OIG cited to its Special Fraud Alert: Laboratory Payments to Referring Physicians (hhs.gov) (June 25, 2014) as part of its discussion of these risks. OIG found that the per-patient-encounter fee that would be offered under the proposed arrangement could induce contract hospitals to refer specimens to requestor for testing, including testing that may be reimbursable, in whole or in part, by a federal healthcare program. While requestor certified that the compensation it would pay contract hospitals for the services would be consistent with fair market value, and that contracts for the proposed arrangement would prohibit the contract hospitals from separately billing any payors or patients for the services performed or requiring or directing physicians to use the requestor for lab tests, OIG found that these safeguards did not overcome the risk of inappropriate steering to requestor, given the financial incentive inherent to a per-patient-encounter compensation methodology.

- This opinion demonstrates the scrutiny to which OIG subjects arrangements between laboratories and their customers. It is important to note that the OIG's standard for issuing a favorable opinion is rather strict: the arrangement must to present a minimal risk of fraud and abuse. OIG's conclusion that "because of the possibility that the per-patient-encounter fee would be used to induce or reward referrals" OIG was not able to find the arrangement posed a minimal risk does not necessarily preclude a properly structured and functioning arrangement from being compliant with the AKS.

Advisory Opinion 22-08, posted on April 27, 2022

The requestor is a federal qualified health center that serves predominantly low-income individuals, including federal healthcare program beneficiaries. Requestor sought an AO regarding an arrangement whereby it loans limited-use smartphones to certain existing patients to facilitate their access to telehealth services. OIG issued a favorable opinion.

Requestor offers telehealth services to its patients through an application that can be downloaded to a smartphone. Requestor loaned approximately 3,000 limited-use phones and chargers on a first-come, first-served basis to existing patients who did not have a device capable of running the application. The patients currently in possession of a loaned phone are the only patients who will participate in the arrangement. The phones restrict use to making and receiving telephone calls, sending and receiving text messages, using the telehealth application and viewing the patient's medical record.

The purpose of the arrangement is to enable patients to access health services via telehealth and to combat social isolation by allowing patients to talk and text with others, including during the COVID-19 public health emergency (PHE). A patient may keep the smartphone as long as requestor furnished at least one service (in-person or via telehealth) to the patient in the prior 24-month period. Patients must return the phones if they no longer receive services from requestor. The phones may be used for telemedicine visits with other providers, but the only telemedicine application that can be used is the application designated by requestor.

Requestor received funding from the Federal Communications Commission (FCC) and a local charitable organization to purchase the smartphones, and certified that it was in compliance with all requirements imposed by both funding sources. The grant funding requestor received from the FCC and the local charity covered the voice and data services required to operate the smartphones for the first 12 months that each smartphone was in use. The voice and data plans for all loaned smartphones have since expired. Requestor used its own funds to provide voice and data service for two months after the initial funding expired, but it does not independently have the financial ability to cover voice and data services for the loaned smartphones in the longer term and will not use its own funds to purchase voice and data services in the future. Therefore, patients participating in the arrangement must secure their own voice and data services. Patients who fail to do so will not be able to utilize the smartphones. Requestor has instructed patients on how to apply for voice and data services funding under the FCC's Affordable Connectivity Program and encourages individuals who do not qualify for such program to identify similar programs that may fund the voice and data services for the loaned smartphones.

OIG Analysis

OIG concluded that the arrangement would generate prohibited remuneration under AKS if the requisite intent were present, and could also generate prohibited remuneration under the beneficiary inducements CMP. However, OIG will not impose administrative sanctions.

OIG determined that the provision of limited-use smartphones and chargers satisfies the promotes access to care exception during the PHE by improving beneficiaries' ability to obtain items and services payable by Medicare or Medicaid[1]. OIG noted that 94% of

[1] OIG specifically stated that it could not opine on whether the exception would apply after the PHE because it does not know whether the telehealth services will be covered by Medicare and Medicaid.

requestor's patients report incomes at or below 200% of the federal poverty guideline, and therefore found that the arrangement may remove socioeconomic barriers to accessing telehealth services.

OIG also concluded that the provision of smartphones and chargers poses low risk of harm. Nothing in the facts suggests that permitting patients to use the smartphones and chargers would skew the clinical decision-making of requestor-affiliated medical professionals who provide services to patients via telehealth visits. The risk of increased costs to federal healthcare programs arising from the arrangement through overutilization or inappropriate utilization is also low, particularly since the arrangement is limited to existing patients who already have the smartphones and who only must receive one service from requestor within the preceding 24-month period to remain eligible.

OIG also noted that nothing in the arrangement suggests that requestor would provide telehealth services when doing so could pose patient safety or quality-of-care concerns.

OIG stated that although the arrangement does not fit within an AKS safe harbor, it poses no more than a minimal risk of fraud and abuse based on the aforementioned safeguards. OIG cited certain additional features of the arrangement that reduce the risk of fraud and abuse, including the fact that the requestor received funding from the FCC and a local charity—neither of which have a financial interest in patients receiving services from requestor—to purchase the smartphones. Requestor certified that it has used the funding in compliance with all requirements imposed by the FCC and the local charity in connection with receiving the funding.

Even though requestor will permit patients to continue to use the smartphones under the arrangement after the PHE ends, nothing in the facts suggests that requestor will use the smartphones to inappropriately increase utilization of federally reimbursable services after the PHE.

- This opinion is the latest in a large number of opinions that favorably view various programs that provide beneficiaries with different forms of assistance. As many organizations are examining ways to assist patients in reducing or eliminating barriers to accessing care, this opinion provides further insight into how OIG views these programs.

Advisory Opinion 22-07, posted on April 25, 2022

Requestors sought an AO for a proposed arrangement whereby certain physicians have an ownership interest in a medical device company that manufactures products that may be ordered by the physician owners and a physician spouse of one of the physician owners. OIG issued a favorable opinion.

The arrangement involves three physicians (Physician A, Physician B and Physician C). All three physicians are orthopedic surgeons and members of the same medical group. Physician A is a surgeon and inventor of surgical technologies, Physician B is Physician A's daughter, and Physician C is Physician B's husband.

Physician A is involved in inventing the medical device company's surgical technologies but does not participate in the day-to-day operations of the company. The company employs dozens of individuals and is responsible for the full range of its operations (*i.e.*, product design, product development, quality control, marketing, inventory managements).

Currently, majority ownership in the medical device company is held by Physician A and two irrevocable trusts: one trust that benefits Physician A's spouse and children (including Physician B), and one that benefits Physician A and the children (including Physician B). The remaining ownership interests are held by company managers and employees. None of these managers and employees are healthcare practitioners or family members of any of the physicians, and none have immediate family members who order products from the company.

The physicians order company products, but according to requestors, those orders, as well as orders by other members of the medical group, generate a relatively small percentage of the company's revenues.

To date, the company has not made any profit distributions to the owners except annual distributions to cover each owner's income tax obligation deriving from the ownership interest. The company certified that any future profit distributions to owners will be to all owners and in direct proportion to each owner's investment interest in the company, except that any distributions to the trusts will be reduced by the amount of revenue generated by orders from any physician or other medical group member (or if applicable, any other non-medical-group physician performing surgeries at an ambulatory surgical center (ASC)) that would otherwise be owed to the trusts. The company certified that it does not loan funds or guarantee loans to the physicians or any other company owner. The

company also certified that the trusts' ownership interest is not contingent on any of the physicians or their medical group partners generating business for the company.

The physicians certified that they may order company products for surgeries they personally perform at hospitals and ASCs that permit the use of company products, and may recommend company products to others, but the physicians will not otherwise attempt to influence hospitals or ASCs to purchase the company's products. Additionally, the physicians certified that they do not, and will not, condition referrals to hospitals or ASCs on the purchase of company products by, for example:

- Stating or implying that they will perform surgeries or refer patients elsewhere if a hospital or an ASC does not purchase medical devices from the company
- Promising or implying that they will move surgeries to a hospital or an ASC if it purchases medical devices from the company
- Requiring a hospital or an ASC to enter into an exclusive-purchase or minimum-purchase arrangement with the company.

The physicians and other medical group members provide certain disclosures related to the arrangement to patients. When the physicians and their medical group partners are able to consult with their patients prior to performing surgery using a company product (*i.e.*, when patients are first seen at the medical group's practice prior to undergoing surgery), they provide written notice of each physician's ownership interest in the company or relationship with an immediate family member with an ownership interest in the company, as applicable.

OIG Analysis

The arrangement implicates the AKS because the physicians are either beneficiaries of, or the spouse of a beneficiary of, the trusts, which hold an ownership interest in the company; the physicians order products from the company that may be reimbursable by federal healthcare programs; and the physicians may recommend the company's products to others. The arrangement fails to satisfy the small entity investment safe harbor because the trusts collectively hold more than 40% of the investment interests in the company, and the physicians (each of whom is either a beneficiary of the trusts or a spouse of a beneficiary) are in a position to make or influence referrals to, furnish items or services to, or otherwise generate business for the company.

OIG repeated its longstanding concerns[2] regarding physician-owned entities that derive revenue from selling, or arranging for the sale of, implantable medical devices ordered by their physician owners, and even described such arrangements as "inherently suspect." However, OIG concluded that this arrangement poses a sufficiently low risk of fraud and abuse under the AKS for the following reasons:

- The arrangement does not exhibit the suspect characteristics sometimes associated with physician-owned entities related to the entity's legitimacy as a business in context of the AKS. OIG found that the entity had characteristics of a real entity (rather than a "shell"), such as developing medical products that it sells domestically and internationally; employing dozens of individuals; and being responsible for the full range of operations of a medical device company, including product design, development and testing of products, quality control, the submission of regulatory filings with the FDA and international regulatory bodies, marketing and inventory management. Additionally, Physician A's initial ownership interest in the company, which led to the trusts' ownership interest, stemmed from Physician A's own inventions.
- The manner in which the company would make future profit distributions reduces the risk of the harms that the AKS statute is designed to prevent (*e.g.*, overutilization or inappropriate utilization, corruption of medical decision-making, increased costs to federal healthcare programs and unfair competition). The arrangement meaningfully dilutes the financial incentives that the physicians may have to order the company's products by reducing any distributions to the trusts by a "carve-out amount."
- The physicians and other medical group members generate a very limited amount of business for the company (less than 1% of all gross revenue generated from company sales in the United States in each of the last three years).

[2] See, *e.g.*, OIG, Special Fraud Alert: Physician-Owned Entities, 78 Fed. Reg. 19,271 (Mar. 29, 2013).

- The arrangement does not exhibit characteristics of other physician-owned entity arrangements that select or retain physician investors in suspect ways, such as by retaining the right to repurchase physicians' ownership interests or requiring physician owners to divest their interests if they cease practicing medicine or refer less business to the physician-owned entity.

- The physicians certified that although they may recommend company products and order company products for surgeries they personally perform at hospitals and ASCs that permit the use of company products, the physicians will not otherwise attempt to influence hospitals or ASCs to purchase the company's products. The physicians also certified that they do not, and will not, condition referrals to hospitals or ASCs on the purchase of company products.

- The physicians and their medical group partners are transparent about the trusts' ownership interest in the company.

OIG Work Plan Updates

In May 2022, OIG released four new work plan items:

- Audit of the Administration for Children and Families award of an Unaccompanied Children Program sole source contract to Family Endeavors, Inc., a nonprofit social service agency, to operate as an emergency intake site and provide services for the unaccompanied children. The expected issue date of the report is 2023.

- Study of the accuracy of falls reporting in the Outcome and Assessment Information Set (OASIS) for home health. OIG plans to use Medicare claims to identify hospitalizations due to falls with major injuries among Medicare beneficiaries in home healthcare. OIG will then assess the extent to which those falls were reported in OASIS assessments. OIG will describe the characteristics of beneficiaries who did not have their falls reported. Finally, OIG will describe the characteristics of home health agencies that have particularly low reporting rates. The expected issue date of the report is 2023.

- Audit of Medicare Part B add-on payments for COVID-19 tests through review of providers' supporting documentation to determine whether the documentation complied with Medicare requirements.

- Follow-up review of inpatient claims under the Post-Acute-Care Transfer (PACT) policy. A prior OIG review identified Medicare overpayments to hospitals that did not comply with PACT policy (42 CFR § 412.4(c)). OIG's review found that the CMS Common Working File edits that detected inpatient claims under the PACT policy were working appropriately. However, some Medicare contractors did not receive automatic notifications of improperly billed claims or did not act to adjust those claims. As a result, OIG recommended that CMS recover the identified overpayments in line with its policies and procedures, and ensure that the Medicare contractors received the notifications and acted to recover the overpayments. CMS concurred with all OIG recommendations and detailed how it addressed them. This follow-up audit will determine whether CMS's Common Working File edits are working properly in detecting inpatient claims under the PACT policy and are automatically recovering overpayments, and whether Medicare contractors are receiving the automatic notifications and acting to recover overpayments.

In May 2022, OIG also launched specific resources on compliance and quality of care for providers serving American Indian and Alaska Native communities. The series includes web-based trainings, job aids and videos for grantees and healthcare providers who serve American Indian and Alaska Native communities.

OIG Report on Medicare Advantage Payment Denials.

In April 2022, OIG released Report OEI-09-18-00260, in which it described its findings based on a case file review of prior authorization request denials by Medicare Advantage Organizations (MAOs). OIG determined that MAOs sometimes delayed or denied Medicare Advantage beneficiaries' access to services that met Medicare coverage rules. OIG further determined that MAOs denied payments to providers for some services that met both Medicare coverage rules and MAO billing rules. Although some of the denials that OIG reviewed were ultimately reversed by the MAOs, OIG stated that avoidable delays and extra steps may create an administrative burden for beneficiaries, providers and MAOs.

Based on its findings, OIG recommend that CMS take the following actions:

- Issue new guidance on the appropriate use of MAO clinical criteria in medical necessity reviews

- Update its audit protocols to address the issues identified in this report, such as MAO use of clinical criteria and/or examining particular service types

- Direct MAOs to take steps to identify and address vulnerabilities that can lead to manual review errors and system errors.

CMS concurred with all three recommendations.

CMS REGULATORY UPDATES

FY 2023 SNF PROSPECTIVE PAYMENT SYSTEM PROPOSED RULE

On April 11, 2022, CMS issued the FY 2023 proposed rule for Medicare payment policies and rates for nursing homes under the Skilled Nursing Facility Prospective Payment System (SNF PPS) that includes several potential metrics for the SNF Quality Reporting Program and the SNF Value-Based Program for FY 2023. In addition to proposed rate adjustments, the proposed rule discusses several elements showcasing CMS's continued efforts to prioritize the value, rather than volume, of certain services patients receive in nursing homes. These value-based proposals include the following:

- Updated payment rates and recalibrated parity adjustments under the SNF PPS, which CMS estimates would result in a net decrease of approximately $320 million in Medicare Part A payments to SNFs in FY 2023 compared to FY 2022

- Minimum staffing requirements (*e.g.*, nurses, aids and other professionals) for long-term care facilities to ensure resident needs are met and to improve resident function and quality of life

- Adoption of the Influenza Vaccination among Healthcare Personnel measure, which would report the percentage of healthcare personnel who receive an annual influenza vaccine from the time the vaccine first becomes available through March 31 of the following year

- Adoption of four measures as part of the SNF Value-Based Purchasing Program to incentivize SNFs paid under the SNF PPS based on the quality of care they provide to Medicare beneficiaries.

For more information on the SNF PPS proposed rule, see McDermott's *On the Subject*, "Biden Administration Takes Action to Improve Competition, Transparency and Quality for Hospitals and Nursing Homes."

New Hospital and SNF Ownership Databases

On April 20, 2022, CMS released for the first time data on mergers, acquisitions, consolidations and changes of ownership from 2016 to 2022 for hospitals and SNFs that are enrolled in Medicare.

The hospital dataset provides information on individual and organizational ownership interest and managerial control associated with the buyer and seller organizations, as well as the role of the owner, association date, address of the organizational owner and other ownership details.

The SNF dataset includes information on the buyer and seller organizations' legal business names, provider type, change of ownership type and effective date of ownership change.

CMS expects to release updated change of ownership data for both databases on a quarterly basis. This information will permit the public to identify when a Medicare-enrolled hospital or SNF has been purchased or leased by another organization, when a Medicare-enrolled hospital or SNF purchases or has been purchased by another enrolled provider, and when two or more enrolled Medicare hospitals or SNFs consolidate to form a new business entity.

In addition to providing change of ownership information, the datasets include detailed information about the direct and indirect owners of Medicare-enrolled hospitals and SNFs. The data is intended to enable researchers, enforcement officials and the public to analyze trends and examine the relationship between healthcare facility ownership and variables such as costs and patient outcomes.

The release of the database aligns with the Biden-Harris administration's policy intentions as stated in the 2021 Executive Order on Promoting Competition, in which the administration expressed concerns that hospital consolidation has resulted in increased healthcare prices and inadequate options in some areas of the country.

For more information on the hospital and SNF databases, see McDermott's *On the Subject*, "Biden Administration Takes Action to Improve Competition, Transparency and Quality for Hospitals and Nursing Homes."

FY 2023 Inpatient Prospective Payment System Proposed Rule

On May 10, 2022, CMS posted the FY 2023 Inpatient Prospective Payment System (IPPS) proposed rule, along with proposed policy and regulation changes (87 FR 28108). Comments are due by June 17, 2022.

The proposed rule would update Medicare payment policies and quality reporting programs relevant for inpatient hospitals, and would seek to address health disparities and improve the safety and quality of maternity care. The proposed rule includes payment updates and policy changes to graduate medical education (GME) that would increase IPPS payments, but the projected increase would be offset by projected reduction in the uncompensated care payment pool, outlier payments, new technology add-on payments, and the expiration of Medicare dependent hospitals and low-volume hospital payment adjustments. Highlights of the proposed rule include the following:

- The proposed FY 2023 standardized amount for hospitals that successfully participate in the Hospital Inpatient Quality Reporting Program and that are meaningful electronic health record users would be $6,315.77, an increase of 3.2% compared to 2022.
- The proposed rule includes waiver of penalties for certain quality programs and modifications to measures and measure calculations in response to the COVID-19 pandemic's ongoing effect on hospitals.
- CMS proposes to limit the Section 1115 patient days that may be included in the calculation of the Medicare disproportionate share hospital adjustment and to use the two most recent years of audited Worksheet S-10 data to distribute uncompensated care payments.
- CMS proposes to make changes to the calculation of GME full-time-equivalent caps for certain hospitals, and to allow certain urban and rural hospitals participating in rural training tracks to enter into Medicare GME affiliation agreements in order to share full-time-equivalent caps.
- CMS estimates that the proposed rule would decrease IPPS payments to hospitals in FY 2023 by approximately $300 million.

For more information, see McDermott+Consulting's article, "CMS Releases FY 2023 IPPS Proposed Update."

State Medicaid Payments to Third Parties

On May 16, 2022, CMS issued a final rule allowing state Medicaid programs to make payments to third parties on behalf of individual practitioners, if the individual practitioner consents to such payments.

OTHER NOTABLE DEVELOPMENTS

Increased FCA Penalties

Effective May 9, 2022, the DOJ increased the FCA penalties to reflect inflation. The new maximum penalty under the Program Fraud Civil Remedies Act is $12,537. The new minimum penalty under the FCA is $12,537, and the new maximum penalty is $25,076.

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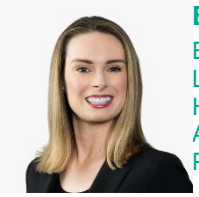

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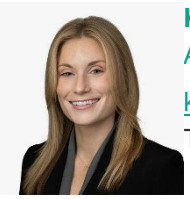

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