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NOVEMBER REGULATORY UPDATE SUMMARY

This issue of McDermott's *Healthcare Regulatory Check-Up* highlights regulatory activity for November 2023. We discuss several US Department of Health and Human Services (HHS) agency actions, including the new General Compliance Program Guidance (GCPG), revisions to the Designated Health Services Code List and to the Hospital Outpatient Prospective Payment and Ambulatory Surgical Center Payment Systems Final Rule, changes to ownership disclosure requirements for skilled nursing facilities (SNFs) and nursing homes, and a No Surprises Act (NSA) consumer toolkit. We also discuss several criminal and civil enforcement actions that involve alleged violations of the False Claims Act (FCA) and the Anti-Kickback Statute (AKS).

HHS REGULATORY DEVELOPMENTS

OIG PUBLISHED THE GENERAL COMPLIANCE PROGRAM GUIDANCE FOR HEALTHCARE INSTITUTIONS

On November 6, 2023, the HHS Office of Inspector General (OIG) published the GCPG, a reference guide for healthcare institutions when setting up and evaluating compliance programs. The GCPG differs from previous OIG compliance program guidance documents as it is intended to apply to a wider variety of healthcare institutions. The OIG will continue to update and publish industry-specific compliance program guidance (ICPG) documents, though future updates will be published online and not through the *Federal Register*.

The GCPG summarizes key federal laws related to healthcare compliance, discusses the seven elements of a compliance program, addresses factors impacting small and large entities, and highlights trends in enforcement. The GCPG also provides cross references to compliance tools previously published by the OIG. The GCPG indicates that the OIG is focused, in part, on "new entrants" in the healthcare sector, such as private equity groups and emerging technology companies, and highlights the importance of data privacy and security.

McDermott lawyers have prepared a summary of the GCPG with industry insights, available here. Michael Peregrine and Tony Maida further reviewed the GCPG and analyzed its impact on healthcare governance as part of the *Governing Health* series, available here.

CMS RELEASED THE OUTPATIENT PROSPECTIVE PAYMENT AND AMBULATORY SURGICAL CENTER PAYMENT SYSTEMS FINAL RULE FOR CALENDAR YEAR 2024

On November 2, 2023, the Centers for Medicare & Medicaid Services (CMS) released the calendar year 2024 Hospital Outpatient Prospective Payment and Ambulatory Surgical Center Payment Systems Final Rule. This rule finalizes changes to payment rates for Medicare services provided under the outpatient prospective payment system (OPPS) and ambulatory surgery center (ASC) system. The changes went into effect on January 1, 2024.

CMS increased payment rates for several services within the final rule, including the Outpatient Department fee schedule, which was increased by a factor of 3.1%. The rule also added a 3.3% increase to the final inpatient hospital market basket under the hospital inpatient prospective payment system and continues the 2% reduction in payments for hospitals that fail the hospital outpatient quality reporting requirements. The rule increased payment rates by 3.1% for ASCs that meet quality reporting requirements. CMS estimates that total payments to ASCs will increase by approximately $207 million compared to 2023. These rate adjustments are based on claims data available for the past two years.

A more detailed overview of the rule and its impact is available here.

HHS AND DOJ PUBLISHED THE FISCAL YEAR 2022 HEALTH CARE FRAUD AND ABUSE CONTROL PROGRAM REPORT

In November 2023, HHS and the US Department of Justice (DOJ) published their annual report summarizing fraud and abuse enforcement actions and other work completed by the Health Care Fraud and Abuse Control Program (HCFAC) in fiscal year 2022. This reporting is required by the Social Security Act of 1935.

The annual report outlines that throughout 2022, the DOJ and HHS collected more than $1.7 billion to the US Department of the Treasury and CMS, including more than $170 million paid to relators and more than $603 million collected from criminal and civil penalties and asset forfeitures. The report is broken down into categories based on the reason the funds were collected and whom they were eventually paid to, delineating between restitution payments and penalties. FCA settlements and judgments alone exceeded $1.6 billion in 2022, some of which may result in future transfers and, therefore, are not included in this report. Based on the money expended by the HCFAC compared to the money returned, the HCFAC reports a return on investment of almost triple between 2020 and 2022, with $2.90 returned for every dollar spent.

Additionally, the report largely focuses on the outcomes of the investment in investigation and enforcement, summarizing the impact of the various agencies involved in healthcare fraud investigations. Enforcement actions are listed by provider type, showing that the government's enforcement activities involve many sectors of the healthcare industry. The report also discusses programs and initiatives that were active in 2022, including the US Food and Drug Administration's (FDA) involvement in fraud-related investigations and the Strike Force teams, both discussed below.

- The FDA Pharmaceutical Fraud Program (PFP) received $11.9 million in funding from the HCFAC in fiscal year 2022. This program focuses on the detection of fraud through pharmaceutical, biologic and medical device use. The report states that the PFP focuses on fraud within the application process for device and pharmaceutical approval alongside post-market activities like marketing schemes and manufacturer-related violations. Through the PFP, 16 criminal investigations were opened in fiscal year 2022.
- The report also summarizes actions taken across the nation by the Health Care Fraud Strike Force teams. There are 27 districts, including the National Rapid Response Strike Force, that focus on using technology and data analytics to combat and investigate

potential healthcare fraud. In 2022, the Strike Force teams filed 266 indictments involving approximately $2.2 billion in charges to federal and private healthcare insurers and brought cases that led to 323 defendants being sentenced to prison.

Fiscal year 2022 saw more than 1,000 criminal actions and 1,500 civil investigations or actions brought by either the DOJ or OIG.

CMS UPDATED THE LIST OF CPT AND HCPCS CODES IDENTIFYING DESIGNATED HEALTH SERVICES

CMS published the annual update to the Designated Health Services (DHS) Code List on November 29, 2023. Under the Physician Self-Referral Law (aka the Stark Law), a physician may not refer a patient to a healthcare entity for the furnishing of DHS paid for by Medicare if the physician (or an immediate family member) has a financial relationship with the DHS entity—unless an applicable exception applies. The DHS Code List identifies items and services included within certain DHS categories, as well as codes that may qualify for certain exceptions under the Stark Law. The most significant updates are the addition of definitive drug testing codes and COVID-19 vaccine service codes. These code revisions went into effect on January 1, 2024. Stakeholders should note that the DHS Code List only includes codes for six out of 12 DHS categories. Entities should remember to check their services against CMS's fee schedules more broadly or consult their lawyers to confirm the full scope of DHS services they provide.

For more information, please see McDermott's deep dive into the November 2023 update to the DHS Code list.

MEDICARE AND MEDICAID PROGRAMS FINALIZED RULE RELATED TO OWNERSHIP AND ADDITIONAL DISCLOSURE IN SKILLED NURSING FACILITIES

On November 15, 2023, CMS published a final rule implementing certain portions of the Affordable Care Act (ACA) that require disclosures on ownership and oversight of Medicare SNFs and Medicaid nursing facilities. The final rule requires Medicare SNFs and Medicaid nursing facilities to disclose all information detailed in Section 1124(c) of the ACA on an updated CMS-855a form. For Medicare SNFs, this data needs to be reported when there is a change of ownership and if there is any changes to the data. This update also requires informational disclosures for "additional disclosable parties," which now include persons or entities that

- Exercise financial control over the SNF
- Lease or sublease real property to the SNF
- Own a whole or part interest equal to or exceeding 5% of the total value of such real property
- Provide to the SNF administrative services, clinical consulting services, accounting or financial services, policies or procedures for any of the SNF's operations, or cash management services.

These disclosures must be made publicly available, consistent with the ACA. CMS has provided background information on the impetus for these rules, including data about the involvement of private equity in nursing home management, and accordingly has provided new definitions in the proposed rule for private equity companies and real estate investment trusts. Although reporting ownership is not a new requirement by CMS, this update expands the content and scope of the reporting. McDermott's in-depth analysis on the final rule is available here.

CMS PUBLISHED A NO SURPRISES ACT TOOLKIT FOR CONSUMER ADVOCATES

To aid consumer advocates who are trying to help individuals navigate medical billing issues, CMS published a toolkit that walks through the NSA and advises on how to identify and address surprise bills. The toolkit reviews the NSA's background and intent

and provides tools for reviewing surprise bills and advocating for changes. CMS states that it intends for this toolkit to help in identifying keywords to assist in recognizing a surprise bill and how to analyze whether the biller followed the process required under the NSA. The toolkit also includes a decision tree to help consumer advocates work These through bills with affected individuals.

While this resource is targeted at consumer advocates aiding individuals who have received potentially uncompliant bills, the toolkit provides healthcare institutions with information on CMS's views on what is required for billing patients under the NSA. The document also goes into considerations for certain types of services, like air-lift emergency services, and compiles tools for compliance with the Good Faith Estimate and the Notice and Consent Exception.

NOTABLE CRIMINAL ENFORCEMENT RESOLUTIONS AND ACTIVITIES

PHARMACY HOLDING COMPANY CHIEF COMPLIANCE OFFICER SENTENCED TO PRISON TERM AND A $21.7 MILLION FINE

The chief compliance officer (CCO) of a pharmacy holding company was sentenced to four years and six months in prison and was ordered to pay a $21.7 million restitution penalty for his role in a Medicare fraud scheme. The holding company was found to be fraudulently billing Medicare for dispensing lidocaine and diabetic testing supplies that beneficiaries did not need or want. The investigation also found that the CCO and his co-conspirators took steps to hide their scheme, including enrolling their mail-order pharmacies as brick-and-mortar retail pharmacies, concealing company owners and transferring patients between pharmacies without patient consent. The CCO was convicted of conspiracy to commit healthcare fraud and wire fraud.

FLORIDA-BASED PHARMACY OWNERS AND EMPLOYEES SENTENCED FOR TRICARE FRAUD

Three men were sentenced to prison time for their involvement in a $54 million fraud scheme related to TRICARE. The scheme alleged that the three men—one part-owner and CEO, one part-owner and senior sales manager, and one lead sales representative of a Florida pharmacy—paid bribes and kickbacks to induce prescription referrals from physicians who treated TRICARE beneficiaries. The pharmacy was also found to have modified prescription components and compounded drugs to maximize reimbursement from TRICARE. The three men kept a percentage of the amount that TRICARE reimbursed for the prescriptions, and the kickbacks were facilitated through a series of companies that one of the part-owners had set up to receive and funnel the payments.

HOSPICE CENTER CONVICTED OF DEFRAUDING MEDICARE OF APPROXIMATELY $62 MILLION

A federal jury convicted a hospice center owner in Louisiana on 23 counts of healthcare fraud for Medicare billings submitted between January 2013 and December 2019. The owner was convicted of various fraudulent practices, including improperly admitting ineligible patients to hospice, billing for physician services when they were not performed by a physician, billing medically unnecessary services

and engaging the owner's family in hand-copying certain forms used to bill instead of being completed and performed by employed physicians. These counts carry a maximum sentence of up to 10 years in prison.

DME OPERATOR PLEADED GUILTY TO $11 MILLION KICKBACK SCHEME

The DOJ reported that the owner of two durable medical equipment (DME) companies providing orthotic braces and various other medical equipment pleaded guilty for his role in a kickback scheme that resulted in more than $11 million in reimbursements from Medicare. The owner was accused of paying weekly kickbacks to an individual in exchange for signed doctors' orders for braces. The owner disguised the kickbacks as marketing expenses, sham contracts or fraudulent invoices.

PHARMACY OWNERS AND A RELATED DOCTOR CONVICTED FOR $145 MILLION FRAUD SCHEME

A Texas-based pharmacy system was part of a recent DOJ case, wherein a jury convicted three men for their roles in a $145 million fraud scheme. Two owners of the pharmacy and a doctor were convicted of defrauding the US Department of Labor (DOL) through orders of medically unnecessary prescription compound creams for federal workers. The pharmacies, referred by the convicted doctor, billed the DOL more than $145 million in less than three years.

NURSE PRACTITIONER PLEADED GUILTY TO TELEMEDICINE DME FRAUD SCHEME

The DOJ announced that a nurse practitioner pleaded guilty to conspiracy to commit healthcare fraud for her connection to a $7.8 million DME fraud scheme. The nurse practitioner worked with a telemedicine company and signed orders for medically unnecessary DME for orthotics. The nurse practitioner will face the greater of either a maximum fine of $250,000 or up to twice gross pecuniary gain, along with up to 10 years in prison.

NOTABLE CIVIL ENFORCEMENT RESOLUTIONS AND ACTIVITIES

CALIFORNIA SKILLED NURSING MANAGEMENT COMPANY SETTLED FCA CLAIMS FOR NEARLY $46 MILLION

A set of six California SNFs, the SNF management company and the management company's owner agreed to enter into a consent judgment for $45.6 million in connection with a whistleblower complaint that was filed by the management company's former vice president of operations and chief operating officer. This consent agreement settles allegations that the SNFs were regularly entering into medical director agreements that veiled kickbacks paid in proportion for referrals to the SNFs. The judgment will be paid in installments over the next five years, based on the defendant's current inability to pay.

LABORATORY SETTLES FCA ALLEGATIONS FOR $1.1 MILLION

A Florida-based clinical laboratory has agreed to pay $1.1 million to settle allegations for hiring multiple marketing companies that were tasked with recommending that local healthcare providers order the laboratory's tests. The marketing companies allegedly shared their commissions with healthcare providers through purported investment returns on management services organization (MSO) ownership. The outcome resolves allegations that the laboratory submitted the laboratory testing claims to Medicare despite knowing of the kickback scheme for referrals. This settlement continues a trend of enforcement actions involving laboratories and marketing companies using MSO ownership interests as alleged vehicles to pay kickbacks to ordering physicians.

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