HEALTHCARE REGULATORY CHECK-UP

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This issue of McDermott's *Healthcare Regulatory Check-Up* highlights significant regulatory activity for June 2023. We discuss several civil enforcement actions involving false claims, the Anti-Kickback Statute (AKS) and patient health information allegations. We also discuss notable developments around Transitional Coverage for Emerging Technologies (TCET) and other healthcare regulatory updates.

NOTABLE CIVIL ENFORCEMENT RESOLUTIONS AND ACTIVITY

CALIFORNIA PROVIDERS SETTLE "ENHANCED SERVICES" FALSE CLAIMS ALLEGATIONS FOR $68 MILLION

Three California providers agreed to pay a combined $68 million to resolve allegations that they violated the federal False Claims Act (FCA) and the California False Claims Act by submitting or causing the submission of false claims related to the Patient Protection and Affordable Care Act's (ACA's) Medicaid Adult Expansion. The providers had entered into a contract with the California Department of Health Care Services, which contract included a provision stating that if the providers did not spend at least 85% of the funds they received for the Medicaid Adult Expansion population on "allowed medical expenses," they would be required to pay back to California the difference between 85% and the percentage of the received funds they actually spent—and in turn, California would need to requisition such amount to the federal government. The US Department of Justice (DOJ) alleged that the providers submitted false claims for "enhanced services" in order to exceed the 85% threshold and to avoid returning funds to California.

DIGITAL HEALTH COMPANY ORDERED TO PAY $100,000 FOR FAILURE TO PROTECT PATIENT HEALTH INFORMATION

A federal court entered into a stipulated order with the developer of an ovulation and period-tracking app to pay $100,000 in civil penalties in response to allegations that it had (1) shared persistent identifiers of consumers without their notice or consent and had shared sensitive personal health information with third-party companies in violation of the company's privacy promises, (2) failed to disclose to users how those third parties could use such personal information (including for third-party advertising), and (3) failed to take reasonable measures to assess and address the privacy and data-security risks created by incorporating third-party software into its mobile app. In addition to mandating the civil fine, the stipulated order required the corporation to (1) implement a comprehensive privacy and data-security program with safeguards to protect consumer data, and (2) hire an independent third party to regularly assess the corporation's compliance with said security program for the next 20 years. Furthermore, the corporation was enjoined from (1) sharing health information with third parties for advertising purposes, (2) sharing health information with third

parties for other purposes without obtaining users' affirmative express consent and (3) making misrepresentations about its privacy practices.

CALIFORNIA-BASED SKILLED NURSING FACILITY AND MANAGEMENT COMPANY SETTLE KICKBACK ALLEGATIONS FOR $3.825 MILLION

A California-based skilled nursing facility and its management company have entered into a $3.825 million settlement agreement with the United States and California. The allegations included the following: (1) paying kickbacks to physicians (in the form of expensive gifts, dinners, vacations, gift cards and more) to induce patient referrals, which resulted in false Medicare and Medicaid claims, and (2) providing various financial and other incentives to patients in order to induce them to stay in the skilled nursing facilities for 100 days (Medicare will pay for rehabilitation services for a patient for up to 100 days). In connection with the settlement, the entities entered into a five-year corporate integrity agreement with the US Department of Health and Human Services Office of Inspector General (HHS-OIG), which requires that the entities' physician relationships be reviewed by an independent review organization.

TWO TEXAS-BASED MEDICAL PRACTICES AGREE TO PAY $513,000 TO RESOLVE FRAUDULENT BILLING FOR P-STIM DEVICES

Two Texas-based medical practices have entered into settlement agreements, valued at approximately $513,000 in total, to resolve allegations that the medical practices violated the federal False Claims Act by billing Medicare for an electric acupuncture device worn behind the ear known as a "P-Stim," even though P-Stims are not reimbursable under Medicare. The medical practices had allegedly falsely claimed that they had implanted neuro-stimulators (a procedure which is reimbursable under Medicare).

KENTUCKY-BASED SUBSTANCE ABUSE RECOVERY CENTER SETTLES FALSE CLAIMS ALLEGATIONS FOR $300,000

A Kentucky-based substance abuse recovery center entered into a settlement agreement to pay $300,000 to resolve allegations that it had improperly billed Kentucky Medicaid for urine drug screens for patients who had not received personalized medical assessments and for residential patients, despite the center only being licensed for outpatient services. In connection with the second allegation, Kentucky Medicaid does not pay for residential services performed by outpatient providers.

MARYLAND-BASED DIAGNOSTIC LABORATORY BILLING COMPANY AGREES TO PAY $300,479 TO SETTLE FALSE CLAIMS ALLEGATIONS

A Maryland-based company that provides billing services for diagnostic laboratories has agreed to pay $300,479.58 to resolve allegations that it caused the submission of false claims to Medicare for medically unnecessary respiratory pathogen tests. The company had performed services for a Georgia diagnostic laboratory that had provided COVID-19 testing services for residents living in senior-living communities. For certain of the senior-living communities, the diagnostic laboratory allegedly ordered the Maryland-based billing company to bill Medicare for respiratory pathogen panels that were allegedly ordered by a particular physician; however, the respiratory pathogen panels were not actually ordered by said physician and said physician was also ineligible to provide treatment to Medicare beneficiaries.

MARYLAND-BASED HEALTHCARE IT CONTRACTOR SETTLES FALSE CLAIMS ALLEGATIONS FOR MORE THAN $1.7 MILLION

A Maryland-based company has agreed to pay more than $1.7 million to resolve allegations that it violated the federal False Claims Act. The Maryland-based company had received a five-year grant from the National Institutes of Health (NIH) to establish a group of organizations with the goal of studying the impact and potential disparities of healthcare delivery systems in a specific minority community and developing solutions to eliminate any identified disparities. The company was also awarded a cost-reimbursable contract to provide information technology (IT) services for the NIH Cancer Therapy Evaluation Program. Allegedly, the company knowingly billed NIH for unallowable expenses under both the grant and the contract—including expenses for the costs of luxury vehicles, mortgage payments, maintenance services and wedding services—and falsely represented to the government that such expenses were incurred in support of its work related to the NIH grant and contract.

TWO FLORIDA-BASED COMPANIES AND THEIR OWNER AGREE TO SETTLE FALSE CLAIMS ACT ALLEGATIONS FOR AT LEAST $7.4 MILLION

Two Florida-based companies and their owner have agreed to pay at least $7.4 million to resolve allegations that they violated the federal False Claims Act by (1) adding a medically unnecessary drug to topical pain creams in order to increase reimbursements and (2) regularly waiving patient copayment obligations. The drug at the center of this allegation is aripiprazole, which is used to treat psychological conditions such as schizophrenia. Aripiprazole is approved by the US Food and Drug Administration (FDA) for oral use. Allegedly, the Florida-based companies and their owner allegedly crushed aripiprazole pills and inserted them into topical creams used for pain treatment, even though there was no clinical basis for them to have done so, in order to increase reimbursement from Medicare Part D and Tricare. Because Medicare Part D and Tricare provide reimbursements for the individual ingredients included in compounded drugs, the Florida companies and their owner allegedly sought to increase their reimbursement by including aripiprazole in their prescribed pain creams. Also, the Florida companies and their owner, in attempting to induce the patients to accept the pain cream prescriptions, allegedly waived the patient's copayments. While copayments may be waived by healthcare providers in certain limited contexts (*e.g.*, on the basis of financial hardship), the Florida companies and the owner allegedly waived copayments for patients without consideration for specific patient need. As part of the settlement, the owner will enter into a three-year corporate integrity agreement with HHS-OIG. The integrity agreement requires that an annual claims review be conducted on the Florida-based companies by an independent review organization.

NORTH CAROLINA-BASED CARDIOLOGIST AND PRACTICE SETTLE FALSE MEDICARE AND MEDICAID CLAIMS FOR $5,015,554

A North Carolina-based cardiologist and his practice have agreed to pay more than $5 million to North Carolina and the federal government to resolve allegations of false claims submitted to Medicare and Medicaid for performing unnecessary atherectomy procedures in order to remove minor plaque blockage from patients' leg arteries. The government alleged that the medical records of the cardiologist and the practice did not provide support for the performance of such procedures and jeopardized patient safety.

CMS REGULATORY UPDATE

CMS ISSUES NOTICE FOR TRANSITIONAL COVERAGE FOR EMERGING TECHNOLOGIES (TCET), A PATHWAY THAT MAY ACCELERATE MEDICARE COVERAGE OF NEW MEDICAL TECHNOLOGIES

On June 22, 2023, the Centers for Medicare and Medicaid Services (CMS) released a proposed procedural notice for a new pathway known as the Transitional Coverage for Emerging Technologies (TCET) that would provide expedited Medicare coverage of "breakthrough devices." The TCET pathway builds upon current national coverage determination (NCD) and coverage with evidence development (CED) processes and is only available to certain FDA-designated breakthrough devices. There are three stages to the proposed TCET pathway: (1) premarket, (2) coverage under the TCET pathway and (3) transition to post-TCET coverage. The premarket stage involves a manufacturer submitting TCET pathway nominations to CMS. The manufacturer's application must include the "state of development of the technology" and a list of peer-reviewed publications that support the nominated breakthrough device. CMS will notify the manufacturer if the nomination is complete or request additional information. Within 20 business days of receiving a complete nomination, CMS will offer the manufacturer an initial 30-minute meeting, to provide additional information. Within 30 business days, CMS will make a preliminary decision on whether it will accept or decline the nomination.

If the TCET pathway criteria is met, CMS may initiate a benefit-category review and, if it believes that the device will be coverable through a benefit category, the device may be accepted into TCET. CMS will initiate an evidence preview to be conducted by a contractor, which should require approximately 12 weeks to complete. The manufacturer may meet with CMS to discuss the evidence preview; other relevant agencies may also participate in the meeting. CMS will share the information from the evidence preview with the manufacturer and the Agency for Healthcare Research and Quality (AHRQ) and FDA for their feedback.

After the evidence preview, the manufacturer can decide whether to continue with the TCET pathway. If a manufacturer chooses to continue with the TCET pathway, it will submit a formal national coverage determination (NCD) letter to CMS expressing the

desire to open an analysis. Additionally, the manufacturer should submit an evidence development plan (EDP) to address any gaps found in the evidence review; the EDP should be submitted as soon as possible after the manufacturer receives FDA market authorization. Thirty business days after receiving the manufacturer's EDP, CMS will provide the manufacturer with feedback and schedule a meeting to resolve any questions and to provide recommendations. CMS will have another 60 business days from after the meeting to adjust the EDP. CMS intends to have a finalized EDP approximately 90 business days following market authorization. If CMS does approve the EDP and the device receives FDA market authorization, the NCD process will be initiated and a tracking sheet will be posted by CMS, initiating a 30-day comment period. CMS plans on engaging a third-party contractor to conduct an updated evidence review within six calendar months of the review date specified in the EDP. After the updated evidence review, "CMS, when appropriate, will open an NCD reconsideration by posting a proposed decision." CMS intends to have a finalized TCET NCD within six months after market authorization.

CMS reported that it does not expect to accept more than five candidates per year and that it expects the TCET coverage period to last between three and five years.

OTHER NOTABLE DEVELOPMENTS

US SUPREME COURT REMAND HOLDS THAT SUBJECTIVE KNOWLEDGE DETERMINES "KNOWING" ELEMENT OF FCA VIOLATION

On June 1, 2023, the US Supreme Court released its opinion in *United States ex rel. Schutte v. SuperValu Inc., No. 21-1326,* and *United States ex rel. Proctor v. Safeway, Inc*., No. 22-111. The question the Court faced was this: where a complex regulation is ambiguous, does it violate the FCA to submit a claim for reimbursement that is consistent with one reasonable interpretation of the regulation if the party making the claim did not actually believe that interpretation was correct at the time? The Court ruled that this is indeed a violation of the FCA. The required scienter is present when an entity submits a claim that it does not believe is permitted, even if its lawyers can point to another interpretation of the regulation that would allow the claim.

The underlying cases allege that SuperValu's and Safeway's retail pharmacies violated the FCA by reporting the full retail price of prescription drugs as their public "usual and customary" price, a data point that Medicare and Medicaid regulations require, when in fact those drugs were provided at a significantly discounted price to many cash-paying patients. The relators (whistleblowers) alleged that not only were the pharmacies required to report the discounted price as their "usual and customary" price, but that the pharmacies in fact knew that they should have reported the discounted prices.

The US Court of Appeals for the Seventh Circuit previously ruled, in granting summary judgment in favor of the pharmacies, that they could not have acted "knowingly" if the pharmacies' actions were consistent with *any* objectively reasonable interpretation of the phrase "usual and customary"—even if they did not believe that interpretation at the time.

Writing for a unanimous Supreme Court, Justice Clarence Thomas disagreed with the Seventh Circuit's interpretation of the FCA's knowledge requirement, positing that this view would require a claim "to be objectively unreasonable, as a legal matter, before a defendant could be held liable for 'knowingly' submitting a false claim, no matter what the defendant thought."
Instead, *SuperValu* holds that a defendant's *subjective* knowledge and beliefs are what must be reviewed to determine if they acted "knowingly" under the FCA (a standard that includes reckless disregard). Thus, if a defendant both (1) "correctly interpreted" the relevant phrase *and* (2) "believed their claims were false" when submitting the claim, then they could have acted knowingly.

For further analysis of these cases, see our "On the Subject:" *Supervalu: It's Not Super Bad! A Practical Look at the Supreme Court's Recent FCA Scienter Ruling*.

US SUPREME COURT AGREES TO HEAR CASE INVOLVING THE CONSTITUTIONALITY OF ADMINISTRATIVE APPEAL PROCEEDINGS

On June 30, 2023, the US Supreme Court granted the US Securities and Exchange Commission's (SEC's) petition for a writ of certiorari in *Securities and Exchange Commission, Petitioner v. George R. Jarkesy, Jr., et al*., which considered the constitutionality of the SEC's administrative appeal process. Although this case is specific to the SEC's administrative appeal process, it may have

implications for the constitutionality of other government agency appeal processes, including those of HHS relating to enrollment and overpayment determinations for the Medicare and Medicaid programs.

The Supreme Court will consider the circuit court's ruling, which concluded that the SEC's administrative appeal process was unconstitutional for three reasons:

1. The SEC's administrative appeal process violated Jarkesy's Seventh Amendment right to a jury trial.

2. The SEC's administrative appeal process constitutes unconstitutionally delegated legislative power and is therefore prohibited.

3. The SEC's administrative appeal process violates the Constitution's "take care clause," where SEC administrative law judges may only be removed for good cause as determined by the Merit Systems Protection Board.

Although the HHS appeals process relies on different statutory authority, there may be elements of the Supreme Court's holding in Jarkesy that may be applicable to HHS appeals.

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