HEALTHCARE REGULATORY CHECK-UP

IN THIS JUNE 2024 ISSUE

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JUNE REGULATORY UPDATE SUMMARY

This issue of McDermott's *Healthcare Regulatory Check-Up* highlights regulatory activity for June 2024. We discuss several US Department of Health and Human Services (HHS) agency actions, including guidance regarding hospital price transparency, e-prescribing standards, Medicare Part B enrollment for pharmacies, Ryan White HIV/AIDS program funds, open payments, and the Merit-based Incentive Payment System (MIPS) final score review period. Additionally, we discuss two favorable Office of Inspector General (OIG) advisory opinions and several criminal and civil enforcement actions pertaining to healthcare fraud, including alleged violations under the False Claims Act (FCA), federal Anti-Kickback Statute (AKS) and Physician Self-Referral Law (Stark Law). Finally, we highlight a few material regulatory developments that impact the healthcare industry and discuss key decisions rendered by federal courts.

NOTABLE ENFORCEMENT RESOLUTIONS AND ACTIVITY

DOJ's FIRST PROSECUTION TARGETING DIGITAL HEALTH COMPANY THAT DISTRIBUTED CONTROLLED SUBSTANCES VIA TELEMEDICINE

The founder/chief executive officer and clinical president of a digital health company were arrested on charges of conspiracy to distribute controlled substances and distribution of controlled substances in connection with a $100 million alleged fraud scheme related to the distribution of Adderall and other stimulants. The indictment includes allegations that the digital health company facilitated the distribution of prescription stimulants without a legitimate medical purpose, including through social media ads. Per the Department of Justice (DOJ), these charges are the "first criminal drug distribution prosecutions related to telemedicine prescribing though a digital health company."

TEXAS MEDICAL CENTER, HEART SURGEONS TO PAY MORE THAN $15 MILLION TO SETTLE CONCURRENT SURGERY ALLEGATIONS

A hospital joint venture, medical school and affiliated practice entity have jointly agreed to pay $15 million to resolve FCA whistleblower allegations that, from 2013 to 2020, three program-leading heart surgeons engaged in a regular practice of running two consecutive operating rooms without designating a backup surgeon or appropriately notifying patients, contrary to Medicare teaching hospital regulations concerning medical resident supervision and teaching physician physical presence.

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NURSING HOME TELEMEDICINE PROVIDER TO PAY MORE THAN $4.5 MILLION TO SETTLE FCA ALLEGATIONS

A telemedicine practice holding company and its related practice affiliates have agreed to pay more than $4.5 million to resolve FCA allegations of submitting false claims to Medicare and Connecticut Medicaid concerning telehealth services provided to nursing home residents. Specifically, the DOJ alleged that the telemedicine company submitted claims for "telehealth originating site facility fees," which, under Medicare and Medicaid rules, may only be billed from the originating site, not the telemedicine company, when the originating site provides administrative services and clinical support to the patient. The government also alleged that the telemedicine company and its affiliates submitted false or fraudulent claims for psychological services provided to nursing home residents when those individuals had in fact been transferred to hospitals and admitted as inpatients.

DOJ ANNOUNCES 2024 NATIONAL HEALTH CARE FRAUD ENFORCEMENT ACTION

During a two-week period in June, the DOJ conducted its 2024 National Health Care Fraud Enforcement Action, working with 32 federal districts across the United States to identify $2.75 billion in potential false claims and $1.6 billion in actual losses. The combined efforts led to criminal charges being levied against 193 defendants and the seizure of $231 million in cash and other valuables. The DOJ highlighted six categories of cases that may serve as areas of heightened scrutiny in the future: (i) amniotic wound grafts that are medically unnecessary, exceed the size of the wound or fail to account for underlying infections; (ii) distribution of Adderall and other stimulants via electronic auto-refill policies without continued audio or visual interaction with a medical professional; (iii) unlawful diversion of HIV medication by buying back dispensed prescriptions from patients and reselling as new to pharmacies; (iv) recruiting vulnerable patients for substance abuse and addiction treatment services that were not provided or were of insufficient quality to serve any treatment purpose; (v) kickbacks between laboratories and telemedicine companies for referrals of unnecessary genetic testing; and (vi) illegal prescription and distribution of opioids.

OIG UPDATES

OIG ISSUES FAVORABLE ADVISORY OPINION NO. 24-03 REGARDING GENETIC TREATMENTS

The OIG issued Advisory Opinion No. 24-03, posted on June 17, 2024, in response to a request by a pharmaceutical manufacturer (the requestor) that offers Food & Drug Administration (FDA)-approved gene therapies for severe genetic diseases in patients over 12 years of age (the product). Treatments using the product occur after an initial consultation at an approved hospital treatment center (treatment center) followed by several transfusions, rounds of chemotherapy-based myeloablative conditioning regimens, and administrations of the product followed by four to six weeks of monitoring at the treatment center. Recognizing the time and financial burden of treatment, the requestor sought to provide certain travel and monetary assistance to patients who qualify. Specifically, the requestor would cover airfare or ground transportation, lodging and per-diem meal allowances for patients and their caregivers who meet certain income and location requirements. The requestor certified that it would provide these benefits to allow caregivers to remain near the treatment centers during the patients' treatments, which may positively impact the patients and their recovery. Additionally, the requestor certified that it will not provide the arrangement when insurance (*e.g.*, Medicaid or Medicaid managed care) or treatment center support is otherwise available. Further, the requestor certified that it will not advertise the arrangement beyond providing treatment centers, potential referring physicians and patients with a general overview of the patient support resources that are available for qualifying patients, nor will it use the arrangement as a marketing tool to drive product selection, utilization or referrals. Lastly, the requestor certified that it will not require physicians or treatment centers to prescribe or use the product exclusively.

Similar to several other opinions on the same type of arrangement, the OIG concluded that the arrangement implicates the federal anti-kickback statute (AKS) and issued a favorable opinion. The OIG explained that the arrangement removes a barrier to accessing medically necessary care that is furnished by treatment centers and facilitates access to the product for federal healthcare program enrollees by subsidizing travel expenses the patients otherwise would not be able to afford, thereby allowing the patients to receive potentially curative treatment. Second, the arrangement facilitates compliance with the product's drug label instructions, which recommend that a patient remains at a treatment center for an extended period of time (*i.e.*, four to six weeks). Third, the product is a one-time, potentially curative treatment, meaning if the patient requires future reimbursable follow-up services, the requestor would not be in a position to benefit financially from those services. The OIG also concluded that the arrangement does not generate

prohibited remuneration under the beneficiary inducements civil monetary penalty law, as it satisfies the law's promotes access to care exception. This is because the remuneration offered under the arrangement reduces financial barriers to patients receiving the product, thereby improving a beneficiary's ability to obtain items and services payable by Medicare or Medicaid and posed low risk of harm to Medicare and Medicaid programs and beneficiaries.

OIG ISSUES FAVORABLE ADVISORY OPINION NO. 24-04 REGARDING REFUND AND DISCOUNT PROGRAMS

The OIG issued Advisory Opinion No. 24-04, posted on June 20, 2024, in response to a request by a US corporate affiliate of a pharmaceutical manufacturer (the requestor) that produces a regenerative tissue-based therapy used to treat an ultra-rare pediatric primary immunodeficiency disorder (the condition). Patients with the condition require strict isolation measures, prolonged inpatient hospitalizations, frequent outpatient visits, home health care, significant diagnostic and monitoring testing, treatment and prophylactic medications, and diagnostic and surgical procedures. The drug produced by the requestor is a one-time, potentially curative treatment for the condition, and is the only available option to rebuild patients' immune systems. The drug is manufactured at a facility located on the campus of a single health care facility (the treatment center) and is delivered to the patient and implanted within three hours of manufacture. The requestor certified that no Medicaid program has declined to cover the drug in any qualifying cases to date.

The requestor sought an advisory opinion from the OIG for a two-part arrangement under which it seeks to make administering the drug more financially feasible for both the treatment center and patients (the arrangement).

The first part of the arrangement is a refund program. Under this program, the requestor has proposed to: (i) waive or refund the treatment center 100% of the wholesale acquisition cost (WAC) of the drug if an insurer refuses to reimburse the treatment center despite initially approving the drug for a particular patient; or (ii) allow the treatment center to delay payment for the drug in the event of reimbursement delays for a particular patient. The refund program would be limited in duration: the requestor began the program approximately seven months after the drug received FDA approval and proposes to continue it for a three-year period, with the possibility of a waiver or refund extending for an additional 18 months beyond that period. In the event the requestor provides a refund or waiver for the WAC of the drug to the treatment center under the refund program, the treatment center would return to the patient any collected cost-sharing amounts that apply to the drug. In other words, the requestor would assume the financial risk that otherwise would be held by the patient if the insurer denies coverage of the drug. Ultimately, this would result in the patient receiving the drug for free. However, in the requestor's experience, no insurer has denied coverage of the drug after providing written approval indicating the drug is covered.

The second part of the arrangement is a discount program. Currently, there are many months between the date that the treatment center first enters into an agreement with the patient's insurer specifying how the insurer will reimburse the treatment center for the drug and the date that the drug is manufactured and implanted in the patient. The latter date is the date that payment for the drug is due to the requestor. The requestor reported that it is possible that the WAC of the drug could change during the months that pass between these dates. Accordingly, under the discount program, the requestor would reduce the price it charges the treatment center if the WAC for the drug increases during the aforementioned time period. This discount is equal to the amount of the price increase, which is the amount that would not be reimbursed by the insurer.

The OIG concluded that the refund program implicates the AKS in two ways. First, in exchange for the treatment center's agreement to purchase the drug, the requestor offers or pays remuneration to the treatment center in the form of a reimbursement guarantee, *i.e.*, waiving or refunding the WAC of the drug if the patient's insurer denies reimbursement, or delaying the payment date if the insurer delays reimbursement. Second, the requestor indirectly offers or pays remuneration to patients who receive treatment with the drug, some of whom are federal healthcare program beneficiaries, in the form of assuming the financial risk that otherwise would be held by the patient if the insurer denies coverage of the drug. The OIG stated that no safe harbors apply to the refund program, but nevertheless, it believes the risk of fraud and abuse under the AKS is low.

To begin with, the refund program is limited in scope and time; the potential universe of patients who may be eligible is extremely small (*i.e.*, less than 25 patients are born with the condition each year); and the conditions of the refund program require the treatment center to receive written approval from the patient's insurer indicating that it will cover the drug. Second, the nature of the condition and the drug reduces the risk that the refund program would result in interference with clinical decision-making, overutilization or inappropriate utilization. The drug is a one-time, potentially curative treatment, is not mass produced, and is the only treatment option available to rebuild the immune system of a patient diagnosed with the condition; there are no competing treatment options. Further,

the patient's referring physician would likely receive no financial benefit from the referral or procedure to implant the drug, because it can only be administered by qualified surgeons at a single treatment center. Third, the risk of inappropriate utilization of the drug by the treatment center is lowered, because it is in the treatment center's financial interest to administer the drug only in circumstances that satisfy the requirements for coverage. Finally, the refund program is unlikely to inappropriately increase costs to federal healthcare programs.

The OIG also concluded that the refund program does not generate prohibited remuneration under the beneficiary inducements civil monetary penalty law. The OIG reached this conclusion because the offered remuneration is not likely to influence patients to select the treatment center as their care provider, as the drug can *only* be administered at the treatment center.

Similar to the refund program, the OIG concluded that the discount program implicates the AKS. Specifically, in exchange for the treatment center's agreement to purchase the drug (which may be paid for by a federal healthcare program), the requestor offers remuneration to the treatment center in the form of a discount on the price of the drug. However, the OIG concluded that this arrangement is protected by the statutory exception and regulatory safe harbor for discounts, because it meets the applicable statutory definition of a "discount," and the requestor meets the applicable obligations of an "offeror." Accordingly, the OIG resolved that it would not impose administrative sanctions on the requestor in connection with the discount program.

FEDERAL REGULATORY UPDATES

CMS ISSUES UPDATED HOSPITAL PRICE TRANSPARENCY FAQS

CMS posted 30 updated FAQs regarding compliance with the agency's hospital price transparency regulations that require hospitals to publicize the standard charges of provided items and services, many of which became effective July 1, 2024. The updated FAQs focus on the standardized way in which a hospital's standard charges should be presented, including the format of machine-readable files and the specific information required to be reported along with the standard charges (*e.g.*, hospital information, item and service descriptions, billing/accounting codes, standard charge methods and payer/plan names).

CMS UPDATES E-PRESCRIBING STANDARDS FOR MEDICARE PART D ENROLLEES

CMS and the Office of the National Coordinator for Health Information Technology (ONC) issued a final rule on June 17, 2024, revising the Medicare Prescription Drug Benefit (Part D) and ONC regulations to implement changes related to electronic prescribing and health information technology standards. The rule is effective July 17, 2024, and provides that Part D entities, including Part D sponsors, prescribers and dispensers of covered Part D drugs, must comply with ONC-adopted standards when electronically transmitting prescriptions and prescription-related information.

In short, this means that Part D sponsors, prescribers and dispensers of covered Part D drugs for Part D eligible individuals must comply with the NCPDP SCRIPT standard version 2023011 by January 1, 2028, and the NCPDP Formulary and Benefit (F&B) standard version 60 by January 1, 2027. Part D sponsors also must comply with the NCPDP Real-Time Prescription Benefit (RTPB) standard version 13 by January 1, 2027.

CMS ISSUES UPDATED GUIDANCE TO PHARMACIES REGARDING MEDICARE PART B COVERAGE OF PrEP MEDICINES

On June 25, 2024, CMS released FAQs to aid pharmacies in Medicare Part B enrollment and billing processes in anticipation of a national coverage determination (NCD) for pre-exposure prophylaxis (PrEP) using antiretroviral drugs to prevent HIV, which is anticipated in late September 2024. These FAQs instruct pharmacies that no new enrollment is needed if the pharmacy is already enrolled in Medicare as a Part B pharmacy or a durable medical equipment, prosthetic, orthotics and supplies (DMEPOS) supplier. However, if the pharmacy is not currently enrolled in Medicare, they should consider enrolling as a Part B pharmacy rather than a DMEPOS supplier so that they are not subject to the supplier standards, accreditation and surety bond requirements.

Pharmacies are also instructed on the appropriate ICD-10 CM diagnosis codes and J-codes to include with claims and instructed to enter the date of service as the date the drug is picked up or mailed. Additionally, pharmacies that are filling injectable PrEP orders

to be administered by qualified practitioners are instructed that claims for a supply fee may be included with claims for the drug when appropriate.

HRSA AUTHORIZES RYAN WHITE PROGRAM TO PAY FOR HOUSING SECURITY DEPOSITS

The Ryan White HIV/AIDS Program (RWHAP) helps low-income individuals living with HIV access medical care, medications and essential support services by providing grants to cities, states, counties and community-based groups. On June 26, 2024, the Health Resources & Services Administration (HRSA) published a letter to stakeholders clarifying that the support services that RWHAP funds may be used for include housing security deposits. Because RWHAP operates as a grant, recipients and subrecipients must adhere to federal uniform grants administration requirements, cost principles and audit obligations, and use funds solely for authorized purposes. HRSA emphasizes that a key component of RWHAP is a prohibition of cash payments going directly to individuals living with HIV who are participating in RWHAP. Accordingly, HRSA recommends implementing policies and procedures to ensure that any returned security deposit goes to the recipient or subrecipient of RWHAP funds, not the person living with HIV. The policy should also address how obligations regarding a partial return of a security deposit will be addressed.

2023 OPEN PAYMENTS DATA PUBLISHED

On June 28, 2024, CMS made available on the Open Payments portal data from program year 2023, as well as newly submitted and updated payment records from 2017 through 2022. The 2023 data reflects $12.75 billion in payments and ownership and investment interests made by applicable manufacturers and group purchasing organizations predominantly to physicians, but also to physician assistants, advanced practice nurses and teaching hospitals, with approximately two-thirds of such funds consisting of research-related payments. Covered recipients have until December 31, 2024, to review the published data and either affirm or dispute any payments tied to their name.

2023 MIPS INCENTIVE PAYMENT SYSTEM FINAL SCORE PREVIEW PERIOD BEGINS

On June 28, 2024, CMS opened the final score preview period for MIPS, allowing practices, virtual groups and alternative payment model entities to preview the MIPS final score for the 2023 performance period via the Quality Payment Program website before payment adjustments are finalized in August 2024. This preview period includes data pertaining to performance category-level scores and weights, bonus points, measure-level performance data and scores, and activity-level scores. CMS reminds clinicians that the 2023 MIPS final score will be used to determine their 2025 MIPS payment adjustment.

OTHER NOTABLE DEVELOPMENTS

US SUPREME COURT ISSUES THREE DECISIONS AGAINST ADMINISTRATIVE AGENCIES

In a widely anticipated but nevertheless impactful decision, the US Supreme Court, on June 28, 2024, issued a ruling in *Loper Bright Enterprises v. Raimondo*, decided together with *Relentless, Inc. v. Department of Commerce*, stating that a reviewing court is no longer obligated to give binding deference to agency interpretations when faced with ambiguous statutes. Instead, the Court stated that a reviewing court must "use every tool at [its] disposal to determine the best reading of the statute and resolve the ambiguity." In such circumstances where a statute delegates discretionary authority to an agency, the court will evaluate whether the agency is operating within the bounds of the delegated authority and whether the decision-making process was reasonable.

On the heels of *Loper Bright*, the Court decided *Corner Post, Inc. v. Board of Governors of the Federal Reserve System*, holding that an Administrative Procedure Act (APA) claim accrues when a plaintiff is injured by final agency action pursuant to the statute of limitations under 28 U.S.C. § 2401(a), notwithstanding the government action being challenged occurring much earlier. The Court held that the plaintiff's suit was timely because it was filed within six years of the injury caused to the plaintiff by the regulation. The Court's analysis centered on three statutory provisions: 5 U.S.C. §702 and §704, which are the relevant APA provisions, and 28 U.S.C. § 2401(a), the applicable statute of limitations. The Court held that a plaintiff cannot bring an APA claim unless and until they suffer an injury resulting from a final agency action.

Finally, in *Securities and Exchange Commission v. Jarkesy*, the Court considered an appeal by an investment adviser and his firm of the SEC's imposition of civil monetary penalties (CMPs) after finding violations of various antifraud provisions of the Securities

Act, the Securities Exchange Act and the Investment Advisers Act. The statutes at issue permit the SEC to choose between bringing the action in the SEC's administrative process, which includes a hearing before an administrative law judge (ALJ) and appeal to the SEC, or in federal court. The SEC chose the administrative process. The Court held that the administrative process violated the defendant's right to a jury trial under the Seventh Amendment for lawsuits "at common law." In examining this issue, the Court articulated a two-step analysis process: (i) whether the CMP action "replicated" a common law action and, if so, (ii) whether the "public rights" exception applies.

The Court's decisions in *Loper Bright, Corner Post* and *Jarkesy* will likely have significant impact on the enforceability of agency regulations and CMP authorities, leading to legal challenges to agency regulations, and will also provide regulated organizations with additional tools to challenge government enforcement actions. Accordingly, in defending such an enforcement action, healthcare and life sciences organizations should carefully evaluate the facts, the government or whistleblower's allegations, and the statutory and regulatory bases for such claims in formulating a defense strategy.

For more information, we encourage those interested to review our client alert and our July 9 and July 24 webinar slides. The July 24 webinar discussed emerging litigation trends and policy developments in a post-*Loper Bright* world.

US SUPREME COURT ALLOWS EMERGENCY ABORTIONS IN IDAHO TO CONTINUE

On June 27, 2024, the US Supreme Court issued a *per curiam* ruling in *Moyle v. United States* that dismissed the case as improvidently granted without ruling on the merits. The case involved a 2020 Idaho "trigger" law criminalizing most abortions that was to go into effect if and when *Roe v. Wade* was overturned. When the US Supreme Court issued its decision in *Dobbs v. Jackson Women's Health Organization* in June 2022, the Biden administration sued the state in the US District Court for the District of Idaho before Idaho's law could take effect, claiming that Idaho's law conflicts with the Emergency Medical Treatment and Labor Act (EMTALA), which requires Medicare-funded hospitals to provide essential stabilizing care, including abortions, to patients experiencing medical emergencies. The district court agreed with the Biden administration and enjoined the Idaho law from becoming effective, which injunction the US Court of Appeals for the Ninth Circuit ultimately upheld. By dismissing the petitioner's appeal, the injunction granted by the Idaho district court remains in place, meaning Medicare-funded hospitals in Idaho should continue providing emergency abortions to patients when necessary to stabilize a patient who arrives at the hospital with an emergency condition, subject to hospitals' and providers' rights of conscience.

RIGHTS OF CONSCIENCE OPPOSITIONS EMBOLDENED BY MIFEPRISTONE DECISION

On June 13, 2024, the US Supreme Court issued a unanimous ruling in *FDA v. Alliance for Hippocratic Medicine*, finding that the plaintiff physicians and medical groups lacked standing and returning the case to the US Court of Appeals for the Fifth Circuit. The underlying case involved a challenge to the FDA's 2016 and 2021 decisions to expand the approved use of mifepristone, an abortifacient, through the 10th week of pregnancy and to allow non-physician healthcare providers to prescribe the drug, including without an in-person visit. The Court concluded that the plaintiffs' general opposition to abortion was insufficient to demonstrate an injury; however, *in dicta*, the Court observed that "doctors would have standing to challenge a government action that likely would cause them to provide medical treatment against their "consciences." As we reported, the Court's statement provides a significantly more absolute view of the rights of conscience protections granted to healthcare providers under federal law. As a result, healthcare provider employers should anticipate an increase in objections to certain healthcare services by staff on moral or religious grounds and should consider whether to establish safeguards that ensure that they are able to balance their obligations towards honoring rights of conscience with their obligations to provide nondiscriminatory care to patients.

STATE LAWS BANNING GENDER-AFFIRMING CARE FOR MINORS GOING TO US SUPREME COURT

In 2023, Tennessee passed a state law that categorically bans gender-affirming care for transgender minors. Plaintiffs sued Tennessee in the US District Court for the Middle District of Tennessee in the matter of *L.W. v. Skrmetti*, and the court preliminarily enjoined Tennessee from enforcing its ban. On appeal, the US Court of Appeals for the Sixth Circuit combined *Skrmetti* with *Doe v. Thornbury,* which involved a similar Kentucky state law that was enjoined by the US District Court for the Western District of Kentucky, to determine whether the due process clause and the equal protection clause of the 14th Amendment of the US Constitution entitle the plaintiff minors to gender-affirming care. Finding that the United States does not have a "deeply rooted" tradition of preventing governments from regulating the medical profession in general or certain treatment in particular, the court observed that state and federal governments have a long history and interest in regulating health and welfare – which interest is

heightened in circumstances involving minors. Accordingly, the Sixth Circuit did not find Tennessee or Kentucky in violation of the due process clause.

Similarly, the Sixth Circuit found on September 28, 2023, that Tennessee and Kentucky did not violate the equal protection clause when viewed through an age-based lens, because the court observed that the laws allow adults to undergo gender-affirming procedures, and age-related distinctions are commonplace in rules involving medical treatment (*e.g.*, drug dosages). Even when evaluating the laws' unequal treatment based on medical condition or sex, the court was unswayed by the plaintiffs, finding that the states were rational in adopting a "wait until age 18" approach in treating gender dysphoria, and finding that the laws were blind to sex as they prohibit sex-transition treatments for all minors, regardless of sex. On November 23, 2023, the plaintiffs, along with the Department of Justice acting as intervenor, filed a petition for a writ of *certiorari* with the US Supreme Court, which was granted on June 24, 2024.

Shortly after *certiorari* was granted in *Skrmetti,* and citing *Loper Bright* in their decisions, district courts in Mississippi, Florida and Texas enjoined HHS from implementing rules promulgated under Section 1557 to the extent such rules interpret prohibitions on discrimination on the basis of sex to include gender identity. Specifically, in *Tennessee v. Becerra*, the US District Court for the Southern District of Mississippi issued a nationwide stay on the effective date of Section 1557's gender identity-related rules, concluding that HHS likely exceeded its authority by applying the Supreme Court's Title VII analysis in *Bostock v. Clayton County* to Section 1557's Title IX protections on the basis of sex. This means that the majority of Section 1557's final rules became effective on July 5, 2024, but allegations of gender identity discrimination will not be considered a form of sex discrimination. We believe it is highly likely that Section 1557's interpretation of "sex" will be addressed directly or *in dicta* by any decision granted by the Supreme Court in *Skrmetti*.

DISPROPORTIONATE SHARE HOSPITAL PAYMENTS UNDER SUPREME COURT REVIEW

On June 10, 2024, the US Supreme Court granted *certiorari* to Advocate Christ Medical Center and 208 other hospitals that appealed a decision from the US Court of Appeals for the District of Columbia regarding the methodology used by HHS for calculating disproportionate share hospital (DSH) payments. Although hospitals receive fixed payments from Medicare for costs provided to beneficiaries, for those hospitals serving a disproportionate share of low-income patients, the fixed payment formula is adjusted based on the percentage of Medicare patients who are entitled to supplemental security income (SSI) benefits and the percentage of patients who are eligible for Medicaid.

The dispute at hand involves the Medicare component of the DSH adjustment, which is calculated as number of patient days attributable to Medicare patients who are entitled to SSI benefits compared to patient days attributable to all Medicare patients. HHS provides SSI benefits to financially needy individuals who are aged, blind or disabled, who meet certain income and resources criteria, and who apply for the benefit. Once qualified, an individual receives a monthly SSI payment until the individual fails to qualify for 12 consecutive months. HHS argues that "entitled to SSI benefits" means only those patients who are entitled to the monthly cash payment – meaning that if an individual is enrolled in the SSI program but does not receive a payment during a particular month due to exceeding the applicable income and resources threshold, that individual should not be included in the DSH fraction. The plaintiffs argue that "entitled to SSI benefits" should mean all patients enrolled in the SSI program at the time of hospitalization, irrespective of whether they qualified for the monthly cash payment. The DC circuit court agreed with HHS' interpretation of the statute and, on September 1, 2023, affirmed the lower court's granting of summary judgment on behalf of HHS.

CHANGE HEALTHCARE UPDATES

On June 17, 2024, CMS announced that the Accelerated and Advanced Payment (AAP) program will conclude on July 12, 2024. Launched in March 2024 in light of the cyberattack on Change Healthcare, the AAP program was designed to mitigate cash flow issues by offering expedited payments to facilities and providers. As reported by CMS, since its inception, the AAP program has successfully issued more than $2.55 billion to more than 4,200 Medicare Part A providers and $717.18 million to more than 4,722 Medicare Part B providers. In addition, Change Healthcare has uploaded a substitute breach notice to its website describing the February 2024 cyberattack. While additional affected individuals may be identified, Change Healthcare states that its review of personal information potentially involved in the incident is "in its late stages." We will continue to monitor the Change Healthcare security incident for further updates.

UTAH AND MISSOURI CITED FOR NONCOMPLIANCE WITH AMERICANS WITH DISABILITIES ACT INTEGRATED SETTING REQUIREMENTS

In order to comply with requirements under Section 504 of the Rehabilitation Act and the Americans with Disabilities Act (ADA) not to discriminate on the basis of disability, entities that receive federal assistance to provide services for individuals with disabilities must ensure that such services are provided in *the most integrated* setting appropriate to the needs of the disabled individuals. Both Utah and Missouri have recently been cited as providing services to disabled individuals in non-integrated settings.

Utah's use of sheltered facilities, such as industrial workshops where disabled individuals have limited interaction with non-disabled individuals, was deemed by the DOJ to violate the ADA's ban on the unnecessary segregation of disabled individuals. Similarly, Missouri was found to have violated the ADA by unnecessarily institutionalizing individuals with mental health disabilities by improperly relying on appointed guardians, who would frequently place such individuals in nursing facilities rather than using community-based services. Utah and Missouri must now focus on providing more community-based integrated services to avoid isolating disabled individuals from the rest of society. The DOJ will attempt to collaborate with both states to remedy the ADA violations, and lawsuits will likely follow if those efforts are unsuccessful.

These enforcement actions are instructive to all entities subject to Section 504 of the Rehabilitation Act, particularly given HHS's recently finalized rules applicable to recipients of HHS funds. Recipients were reminded that integration means a setting that allows individuals with disabilities to fully interact with non-disabled persons and to live, work and receive services in the greater community.

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Allie Kelley, a summer associate in the Chicago office, also contributed to this newsletter.

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