HEALTHCARE REGULATORY CHECK-UP

IN THIS APRIL 2024 ISSUE

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APRIL REGULATORY UPDATE SUMMARY

This issue of McDermott's *Healthcare Regulatory Check-Up* highlights regulatory activity for April 2024. We discuss several US Department of Health and Human Services (HHS) agency actions, including the Calendar Year (CY) 2025 Medicare Advantage (MA) Capitation Rates and Part C and Part D Payment Policies released by the Centers for Medicare and Medicaid Services (CMS), new final rules related to nursing home staffing, access to Medicaid and the Children's Health Insurance Program (CHIP), and the Food and Drug Administration's (FDA) new final rule on laboratory-developed tests (LDTs). We also review the Federal Trade Commission (FTC) ruling to potentially ban the majority of noncompete agreements. Additionally, we discuss one favorable Office of Inspector General (OIG) advisory opinion 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).

NOTABLE ENFORCEMENT RESOLUTIONS AND ACTIVITY

OWNER OF TELEMEDICINE COMPANIES PLEADS GUILTY TO $110 MILLION MEDICARE FRAUD SCHEME

The owner of two telemedicine companies pled guilty for a $110 million telemedicine fraud scheme related to unnecessary durable medical equipment. The owner used his companies to enter into relationships with telemarketers who targeted Medicare beneficiaries to generate leads. The telemarketers paid the owner's companies on a per-order basis to create orders for these beneficiaries. The owner then partnered with medical staffing companies to find healthcare providers willing to review and approve prepopulated orders, often without any beneficiary contact. Once the orders were signed, the business owner submitted the claims to Medicare for reimbursement.

ONCOLOGY PRACTICE, PHYSICIANS AND REFERENCE LABORATORY TO PAY MORE THAN $4 MILLION TO SETTLE FCA ALLEGATIONS

A cancer practice, its physicians and its reference laboratory have agreed to pay more than $4 million in civil settlements with Texas and the United States to resolve FCA and AKS allegations concerning an arrangement with a diagnostic reference laboratory in which the practice paid $115 for every biopsy referred by the cancer practice and its physicians. The settlement also resolved allegations that

one of the cancer practice's physicians provided medically unnecessary tests to government payor beneficiaries and billed those government payors for reimbursement in violation of the FCA.

CALIFORNIA-BASED NURSING HOME CHAIN AND TWO EXECUTIVES TO PAY $7 MILLION TO SETTLE ALLEGED FALSE CLAIMS FOR NURSING HOME RESIDENTS WHO MERELY HAD BEEN NEAR OTHER PEOPLE WITH COVID-19

A nursing home chain and two executives reached a $7 million civil settlement with the United States and the state of California for allegedly submitting false claims to Medicare for nursing home residents. During the COVID-19 pandemic, CMS waived the requirement that a Medicare beneficiary must have had a hospital stay of at least three days before admission to a skilled nursing facility. The defendants allegedly knowingly took advantage of this waiver by submitting claims for nursing home residents who did not have COVID-19 and had merely been near people with COVID-19. Even when residents did not have any symptoms of COVID-19 or any other acute illnesses or injuries, the defendants would allegedly submit these claims for reimbursement in violation of the FCA.

DOCTOR CONVICTED FOR $5.4 MILLION MEDICARE FRAUD SCHEME

A New Jersey doctor was convicted for submitting more than $5.4 million in fraudulent claims to Medicare for orthotic braces ordered via a telemarketing scheme. The physician signed thousands of prescriptions for braces for more than 2,900 Medicare beneficiaries that he was connected to by telemarketers who convinced the beneficiaries to accept the unnecessary braces. Evidence showed that the physician could not have diagnosed the beneficiaries or determined that the braces were medically necessary during his calls with them. Nevertheless, he continued to prescribe the braces and would unnecessarily bill Medicare for reimbursement.

CLINIC OWNER SENT TO PRISON FOR ORCHESTRATING $15 MILLION MEDICARE FRAUD AND KICKBACK SCHEME

The owner of a Houston mental healthcare clinic was sentenced to federal prison for fraudulently billing Medicare for services provided to adults with intellectual disabilities who did not require mental health services. For nearly a decade, the owner would submit fraudulent claims to Medicare for partial hospitalization program (PHP) services that were not provided or medically necessary. PHP services are a form of intensive outpatient care for severe medical illness that the clinic's patients did not require. Additionally, the owner admitted to falsifying the patients' medical records to make it seem like they were sicker than they actually were.

OIG UPDATES

OIG ISSUES FAVORABLE ADVISORY OPINION NO. 24-02 REGARDING PATIENT ASSISTANCE PROGRAM

OIG issued Advisory Opinion No. 24-02, posted on April 11, 2024, in response to a request by a nonprofit organization that proposed providing financial assistance to patients with certain rare medical conditions and demonstrated financial need through disease-specific funds. Under the proposed arrangement, the funds for each disease-specific fund would be provided by a single pharmaceutical manufacturer, and each disease fund would be targeted to rare disorders (*i.e.*, those affecting fewer than 200,000 Americans). The nonprofit organization would advertise this financial support to relevant communities, as well as the general public. To be selected for financial support, individuals would be required to submit financial and medical information, and the nonprofit would decide on a first-come, first-served basis which patients would receive assistance. The nonprofit certified that an individual's eligibility would not be dependent on the selection of a particular physician or pharmacy, nor on whether the individual has public, private or no health insurance. The nonprofit would not provide its donors with any identifying information related to the disease funds' patient recipients, and donors would not be able to influence how the nonprofit provides any financial assistance.

Under the arrangement, the disease funds would provide different types of support to patients, including cost-sharing subsidies for prescription drugs and other items or services, financial support to cover medical expenses that are not covered by insurance, insurance premium assistance subsidies, and emergency relief, which provides short-term, limited financial assistance associated with necessary, but non-medical, expenses that unexpectedly arise.

While OIG has long recognized the pivotal role that independent charitable patient assistance programs (PAPs) play in providing safety-net assistance to patients, OIG simultaneously has expressed concern about "significant" fraud and abuse risks posed by PAPs that are heavily reliant on pharmaceutical manufacturers for funding. In recent years, there have been numerous examples of enforcement actions and withdrawn advisory opinions related to PAPs that were closely affiliated with pharmaceutical manufacturers.

OIG concluded that the proposed arrangement implicates the federal AKS, as pharmaceutical manufacturers, through the nonprofit organization, provide remuneration to patients who have been diagnosed with a condition that could be treated by a drug manufactured by the pharmaceutical manufacturer. This remuneration could induce the purchasing or ordering of a prescription drug reimbursable by a federal healthcare program. OIG concluded that the proposed arrangement did not implicate the beneficiary inducements law, as a patient's eligibility is not contingent on selection of a particular physician or pharmacy. Because the arrangement would not influence an enrollee's selection of a provider or supplier for any item or service for which payment is made by Medicare or a state health care program, the arrangement does not implicate the beneficiary inducements law.

OIG provided a favorable opinion and concluded that OIG would not impose administrative sanctions on the requesting nonprofit based on the arrangement as proposed. However, due to statutory changes that eliminate and reduce certain cost sharing and out-of-pocket costs for Medicare Part D beneficiaries, OIG chose to limit the effective date of the favorable opinion to the period from April 8, 2024, until January 1, 2027. This limits the advisory opinion's effectiveness to two years after the implementation of the statutory changes. OIG expressed concern that, because of these statutory changes, its assessment of the risks and benefits under the proposed arrangement could change in the intervening years. OIG noted that the requesting nonprofit could submit a new advisory opinion request or request modification of the existing opinion.

OIG reached a favorable conclusion for the following reasons:

- The disease funds vary substantially in the proportion of funds spent to support the purchase of donors' drugs. Additionally, the arrangement defines the disease funds based on established disease states, awards assistance without regard to the treatment prescribed for a particular patient, limits the information that is shared with donors and requires an application for financial eligibility.
- The disease funds provide aid to financially needy patients with rare disorders, assistance that could be highly impactful for those patients. More than two-thirds of the funds spent under the arrangement were not direct payments for prescription drugs, but rather were funds that were intended to reduce cost-sharing obligations for items and services that are not drugs and to provide for medical assistance, premium support and emergency relief.

CMS REGULATORY UPDATES

CMS FINALIZES PAYMENT UPDATES FOR 2025 MEDICARE ADVANTAGE AND MEDICARE PART D PROGRAMS

On April 1, 2024, CMS released the Announcement of CY 2025 MA Capitation Rates and Part C and Part D Payment Policies, otherwise known as the rate announcement. The rate announcement is released annually and includes updates to the methodologies used to calculate MA plan payments, as well as other payment policies that impact Part D. The CY 2025 rate announcement largely finalizes the policies CMS previously proposed in its Advance Notice released on January 31, 2024.

CMS estimates that the policy changes in the final notice will result in a 3.7% increase in MA payments in 2025. This is the same estimate that was included in the advance notice, and CMS notes that this would result in an increase of more than $16 billion in MA plan payments from 2024 to 2025. CMS is proceeding with the phase-in of the Part C Risk Adjustment Model by blending 67% of the risk score calculated using the updated 2024 MA risk adjustment model with 33% of the risk score calculated using the 2020 MA risk adjustment model. This blended MA risk score trend for CY 2025 is 3.86%. Overall, the impact of the risk model revisions and normalization policies are estimated to have a net -2.45% impact on plans compared to CY 2024.

CMS also finalized updates to the Part D risk adjustment model as required by the Inflation Reduction Act. CMS finalized measure specification updates and the list of measures included in the Part C and D Improvement Measures and Categorical Adjustment Index for the 2025 Star Ratings. CMS established a list of disasters that are eligible for the Extreme and Uncontrollable Circumstances Policy.

In both the advance notice and the rate announcement, CMS discusses the remedy for the 340B drug payment policy that is in effect for payments under the Medicare Outpatient Prospective Payment System (OPPS) for CYs 2018 – 2022 (340B remedy rule) and contemplates how the 340B remedy rule might impact MA rates for future years, although it does not impact MA payments for 2025. Notably, 340B hospitals that received lump-sum payments under the 340B remedy rule that are contemplating legal action against MA plans or CMS to compel similar payments from MA plans should take note: While CMS made retroactive adjustments to certain rate-setting metrics for 2018 – 2022 to account for the lump-sum payments, and it has indicated that it will incorporate the downward budget neutrality adjustment beginning in 2026 to offset the lump-sum payments, it has not yet determined how it will address the 340B payment cut remedy as to MA plans. Further, CMS has indicated that it expects to address this issue in future policymaking communications. For more information, please see our insights on the rate announcement here and 340B considerations here.

CMS FINALIZES COMPLIANCE OBLIGATIONS FOR PACE ORGANIZATIONS

On April 4, 2024, CMS issued a final rule and press release revising the regulations governing the MA Program, Medicare Prescription Drug Benefit Program and Programs of All-Inclusive Care for the Elderly (PACE). The final rule addresses policy and technical changes for CY 2025 and finalizes several key provisions that were first proposed – but never finalized – in a proposed rule originally published on December 14, 2022. The final rule includes significant changes for MA plans, including revisions to permissible payment structures for agents and brokers, supplemental benefits and utilization management.. The rule also includes meaningful new compliance obligations for PACE organizations, as discussed here.

CMS RELEASES NURSING HOME STAFFING FINAL RULE

On April 22, 2024, CMS released a final rule that will require long-term care facilities (LTCFs) to satisfy minimum nurse staffing standards with the goal of addressing patient quality of care and safety concerns. Over the next five years, Medicare- and Medicaid-certified LTCFs, with limited exceptions, must meet the following requirements:

- Ensure that a registered nurse (RN) is on site 24 hours per day, seven days per week to provide skilled nursing care to all residents in accordance with resident care plans (with a temporary exemption possible);
- Provide, at a minimum, 3.48 hours per resident day of total nurse staffing hours;
- Ensure that RNs provide a minimum of 0.55 hours per resident day of direct patient services, and that nurse aides (NAs) provide a minimum of 2.45 HPRD, regardless of the individual LTCF's patient case-mix; and
- Continue to perform an annual facility-wide assessment of resources that are necessary to provide both routine and emergency care to residents and to adjust nurse staffing to meet acuity requirements of the resident population.

All LTCFs must comply with the assessment requirements within 90 days of the final rule's publication. LTCFs located in urban areas must fully comply with the staffing requirements within three years of the final rule based on a staggered implementation schedule. Rural LTCFs will be allowed five years to fully comply. For more information, please see our full summary, available here.

CMS RELEASES MEDICAID ACCESS FINAL RULE

On April 22, 2024, CMS published the Medicaid Program; Ensuring Access to Medicaid Services final rule. The final rule focuses on home- and community-based services (HCBS), including direct care worker compensation requirements, HCBS waitlists, grievance process development, critical incident reporting definitions and HCBS quality reporting. The final rule also seeks to increase transparency more broadly in payment rates. In the rule, CMS maintains the proposed policy to require that at least 80% of Medicaid payments for personal care, homemaker and home health aide services be spent on compensation for direct care workers (as opposed to administrative overhead). However, the final rule makes modifications to exclude some costs from the 80% calculation and create an exemption process that states can utilize for small providers and those experiencing hardships, among other modifications. The final rule requires states to (1) publish all fee-for-service Medicaid payment rates on a publicly available and accessible website; (2) compare their fee-for-service payment rates for primary care, obstetrical and gynecological care, and outpatient mental health and substance use disorder services to Medicare rates; and (3) publish that information every two years. The final rule also requires states to publish the average hourly rate paid for personal care, home health aide, homemaker and habilitation services every two years. States will be required to establish and operate the newly named Medicaid Advisory Committee and a Beneficiary Advisory Council one year after the rule's effective date. The comprehensive McDermottPlus summary is available here.

CMS RELEASES MEDICAID AND CHIP MANAGED CARE FINAL RULE

On April 22, 2024, CMS published the Medicaid and CHIP Managed Care Access, Finance, and Quality final rule. Largely finalized as proposed, the rule includes several substantial updates to the Managed Care Rule with implications for state directed payments (SDPs), payment transparency, medical loss ratios, wait time standards and in lieu of services. The final rule includes process- and transparency-related changes to SDPs, including a requirement that SDP amounts for inpatient hospital services, outpatient hospital services, nursing facility services and qualified practitioner services at an academic medical center do not exceed the average commercial rate. Among other things, the final rule establishes a framework for states to implement a Medicaid and CHIP quality rating system (MAC QRS) as a one-stop shop for enrollees to compare Medicaid or CHIP managed care plans based on quality of care, access to providers, covered benefits and drugs, cost and other plan performance indicators. CMS finalized five modifications to its initial proposal to further reduce MAC QRS implementation burdens with minimal impact on beneficiaries' access to information. The rule becomes effective on July 9, 2024. The comprehensive McDermottPlus summary is available here.

OTHER NOTABLE DEVELOPMENTS

FDA ESTABLISHES CENTER FOR TRIAL INNOVATION

On April 15, 2024, the FDA announced the establishment of the Center for Drug Evaluation and Research (CDER) Center for Clinical Trial Innovation (C3TI). C3TI will serve as the central support hub for innovative approaches to clinical trials designed to improve the quality and efficiency of drug development and regulatory decision-making. Following a public solicitation of comments, the FDA determined that the establishment of C3TI would enhance CDER's ability to address those barriers and foster innovation. For more information, see our OTS here.

HHS ISSUES 340B ADMINISTRATIVE DISPUTE RESOLUTION FINAL RULE

On April 18, 2024, the HHS Health Resources and Services Administration (HRSA) issued the long-awaited 340B Administrative Dispute Resolution (ADR) Final Rule. The final rule represents the latest development in establishing the 340B ADR process, which has been delayed for more than a decade. The process was mandated under the Affordable Care Act in 2012 but did not come into existence until 2021, and no ADR claim reviews have been completed under the process. The final rule generally retains the provisions of the November 2022 proposed rule, but it incorporates several material changes based on comments received regarding the proposed rule and in response to ongoing litigation challenging the current ADR rule. Our prior analysis of the proposed rule is available here, and our analysis of the rule implementing the current ADR process is available here.

Of particular note to 340B stakeholders, the final rule explicitly allows 340B covered entities to bring claims against manufacturers for restrictions on sales of drugs at the 340B ceiling price. It also removes the provision that would have suspended review of claims similar to those pending in federal court and allows manufacturers to bring claims against 340B covered entities alleging Medicaid duplicate discount violations for drugs purchased for Medicaid managed care enrollees. The final rule will be effective on June 18, 2024. HRSA has indicated that it will provide additional information on implementation of the new ADR process prior to the effective date, including a webinar on filing a claim. For more information, see our OTS here.

OCR RELEASES HIPAA REPRODUCTIVE HEALTHCARE PRIVACY FINAL RULE

On April 22, 2024, the HHS Office for Civil Rights (OCR) announced a final rule that strengthens reproductive healthcare privacy under the Health Insurance Portability and Accountability Act of 1996 (HIPAA) Privacy Rule. Specifically, the final rule prohibits the disclosure of certain protected health information (PHI) when individuals travel to different states to seek reproductive services.

FTC VOTES TO BAN NONCOMPETE CLAUSES

On April 23, 2024, the FTC voted 3 – 2 along party lines to ban all new noncompete agreements nationwide and render existing noncompete agreements binding most workers unenforceable. The final rule, slated for publication in the *Federal Register*, provides that employers' use of noncompete agreements amounts to an "unfair method of competition" that runs afoul of Section 5 of the FTC Act. The final rule is set to become effective 120 days after its publication in the *Federal Register* but is already facing court challenges.

Nonprofits, including many health systems and hospitals, may be exempted from the final rule, but the FTC has warned that merely claiming tax-exempt status is not enough. The FTC noted that it will consider the entity's facts and circumstances to determine whether it is within the FTC's jurisdiction. For more information on the final rule, read our summary here.

FDA ISSUES LONG-AWAITED FINAL RULE REGULATING MANY LABORATORY-DEVELOPED TESTS AS MEDICAL DEVICES

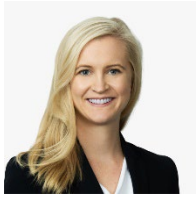
On April 29, 2024, the FDA issued the final rule around the regulation of LDTs, which are *in vitro* diagnostic products (IVDs) that the FDA has described as intended for clinical use and designed, manufactured and used within a single clinical laboratory that meets certain regulatory requirements. The final rule amends the FDA's regulations to make explicit that IVDs are devices under the Federal Food, Drug, and Cosmetic Act, including when the manufacturer of the IVD is a laboratory. Along with this amendment, the FDA finalized its policy to phase out, over the course of four years, its general enforcement discretion approach for many LDTs. The agency also issued targeted enforcement discretion policies for certain categories of IVDs manufactured by laboratories. For more information, see our OTS here.

AUTHORS & CONTACT

TONY MAIDA
PARTNER
tmaida@mwe.com
Tel +1 212 547 5492

EMILY COOK
PARTNER
ecook@mwe.com
Tel +1 310 284 6113

MONICA WALLACE
PARTNER
mwallace@mwe.com
Tel +1 312 984 7757



CAROLINE REIGNLEY
PARTNER
creignley@mwe.com
Tel +1 202 756 8548

MARISSA HILL DALEY
ASSOCIATE
mhilldaley@mwe.com
Tel +1 202 756 8548

JACOB WEISSMAN
ASSOCIATE
jweissman@mwe.com
Tel +1 202 951 6661

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