# HEALTHCARE REGULATORY CHECK-UP

**IN THIS JULY 2024 ISSUE**



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# JULY REGULATORY UPDATE SUMMARY

This issue of McDermott's *Healthcare Regulatory Check-Up* highlights regulatory activity for July 2024. We discuss several US Department of Health and Human Services (HHS) agency actions, including a final rule on provider information blocking disincentives, a telehealth policy proposal from the Centers for Medicare & Medicaid Services (CMS), new CMS guidance for the Medicare Drug Payment Program, and the US Food and Drug Administration's (FDA's) new draft guidance on combating medical product misinformation. We also discuss two similar Office of Inspector General (OIG) advisory opinions and several enforcement actions pertaining to healthcare fraud, including alleged violations under the False Claims Act (FCA) and federal Anti-Kickback Statute (AKS).

# NOTABLE ENFORCEMENT RESOLUTIONS AND ACTIVITY

## HOME HEALTH PROVIDERS TO PAY $4.5M TO SETTLE KICKBACK-BASED FCA ALLEGATIONS

Three home health agencies and their owner agreed to pay almost $4.5 million to settle claims that they paid kickbacks to assisted living facilities and physicians in exchange for Medicare referrals. The agencies allegedly gave benefits such as lease payments, wellness services, and sports tickets to facilities and physicians that referred patients to the agencies from 2013 to 2022, then billed Medicare for the home services they provided to the referred patients in violation of the FCA and AKS. The settlement takes into consideration the agencies' efforts to disclose the conduct, identify the individuals involved, assist in the determination of losses caused to Medicare, and generally cooperate with the US Department of Justice (DOJ).

## CLINICAL LABORATORIES TO PAY $2.45M TO SETTLE FCA ALLEGATIONS OF ALTERING DIAGNOSIS CODES

Three clinical laboratories agreed to pay $2.45 million to settle alleged FCA violations arising out of Medicare and Medicaid billing practices. The settlement resolves allegations that the labs used manipulated diagnosis codes generated by a macro, rather than those provided by beneficiaries' physicians, in claims submitted from 2017 to 2021. The *qui tam* suit was initially brought by a relator who was a former employee of one of the labs, and the government intervened. One of the labs filed for Chapter 11 bankruptcy,

necessitating US bankruptcy court approval of the settlement, which was granted on July 9, 2024. Concurrent with the settlement, the labs entered a five-year corporate integrity agreement with OIG.

### MEDICARE PART D PLAN SPONSOR SETTLES FCA ALLEGATIONS RELATED TO DRUG REBATE REPORTING FOR $101M

A Medicare Part D Plan Sponsor and its subsidiaries agreed to pay $101 million to resolve claims under the FCA that they failed to accurately report drug rebates to the Medicare program between 2014 and 2020. The government alleged that during this period, the company and its subsidiaries improperly reported to CMS portions of rebates received from manufacturers as bona fide service fees, even though manufacturers did not negotiate with the companies to pay such fees. The government further alleged that one of the subsidiaries knew the retained rebates did not meet the regulatory definition of bona fide services fees under Part D. The lawsuit was originally brought by a relator who was previously employed by one of the subsidiary companies, and the government intervened. The settlement is based on the companies' ability to pay and was approved by a bankruptcy court as part of the company's reorganization plan.

### DOJ FILES COMPLAINT AGAINST HEALTH SYSTEM ALLEGING STARK LAW VIOLATIONS

On July 26, 2024, the DOJ announced that it had filed a complaint against a health system in the US District Court for the Western District of North Carolina alleging that the health system violated the Stark Law through improper employment relationships with its physicians. The DOJ alleged that such relationships were not covered by the Stark Law's employment exception because the compensation paid to the physicians was well above fair market value. The case was originally filed as a *qui tam* lawsuit. OIG's special agent on the case noted that "this complaint serves as a warning to health care entities that attempt to increase profits through improper financial arrangements with referring physicians." The filing represents further focus on Stark Law enforcement, which we discuss in more detail here.

## OIG UPDATES

### OIG ISSUES AO NO. 24-05 ON ASSISTANCE PROGRAMS FOR GENE THERAPY PATIENTS

On July 22, 2024, OIG issued Advisory Opinion (AO) No. 24-05 in response to a request by a publicly traded biotechnology company that offers FDA-approved gene therapies for patients with severe genetic diseases. The AO discusses the requestor's proposed assistance program for patients receiving one of two gene therapy treatments. Drug A is a gene therapy that aims to achieve transfusion independence in patients who require regular blood transfusions. Drug B is a gene therapy that works to stabilize the patient's disease, with the goal of achieving major functional disability-free survival. Both drugs are one-time treatments administered by infusion. Under the proposed arrangement, the assistance program includes two forms of support: travel support and fertility support.

The travel support program is designed to cover travel, lodging, meals, and other related expenses for patients undergoing gene therapy treatments whose household income is at or below 600% of the federal poverty level (FPL) and meets certain other requirements. The travel support, potentially including round-trip airfare (limited to coach/economy), would be available for patients or caregivers living more than 300 miles away from the nearest treatment center that accepts the patient's insurance. Ground transportation would be available for patients and caregivers living between 100 and 300 miles away from the nearest treatment center that accepts the patient's insurance. During different phases of treatment, requestor would also cover lodging costs at a "modest" hotel for patients and caregivers living more than 100 miles or two hours driving distance from the nearest treatment center. The travel support also would include a $50 per person per day allowance to cover actually incurred costs for meals, parking, and local transportation during the patient's gene therapy treatment, for patients living more than 100 miles or two hours driving distance from the nearest treatment center that accepts the patient's insurance. Requestor would not advertise the availability of such travel support beyond providing treatment centers, potential referring physicians, and patients with a general overview of the patient support resources that would be available. The travel support would be implemented and administered by requestor and a travel agency.

OIG evaluated whether this support would constitute prohibited remuneration under the AKS and the beneficiary inducements CMP. OIG concluded that although the travel support could be seen as remuneration if an intent to induce referrals was present, OIG would

not impose administrative sanctions on the requestor for such travel support. In analyzing implications of the AKS, OIG stated that the risk of fraud and abuse presented by the travel support was sufficiently low for several reasons:

- The travel support would remove a barrier to accessing medically necessary care that is furnished by treatment centers.
- The travel support would facilitate compliance with the drug label's instructions for the patient to remain at a treatment center for weeks or months following infusion.
- The drugs are one-time treatments such that the travel support likely would not lead to additional referrals.
- The travel support includes additional safeguards that mitigate the risk of fraud and abuse, including the requirement that the requestor not authorize travel support for any expenses for which insurance or third-party assistance is available.

Regarding the beneficiary inducements CMP, OIG determined that the travel support would satisfy the promotes access to care exception. OIG emphasized that its decision was based on the specific facts and assurances provided by the requestor.

The fertility support program would offer up to $22,500 per patient to cover fertility preservation procedures and storage. The fertility support is intended to assist patients who may otherwise forego treatment with one of requestor's drugs because of the risk of infertility associated with the required conditioning treatment prior to infusion, as well as patients' inability to afford fertility preservation services. Like the travel support, this fertility support is aimed at patients with household incomes at or below 600% of the FPL and meeting certain other requirements, including exhausting other insurance or fertility support options. Requestor would not advertise the availability of this fertility support or use it as a marketing tool, but would provide treatment centers, potential referring physicians, and patients with a general overview of the support.

OIG expressed concerns about the fertility support, indicating that it could lead to improper remuneration under the AKS and the beneficiary inducements CMP. OIG concluded that it lacked sufficient data showing that the fertility support would improve patient access to the gene therapies, especially because cell and gene therapies are novel and payors still are adapting to their proliferation in the marketplace. Consequently, OIG could not conclude that the fertility support would enhance patients' ability to obtain federally reimbursable items or services. However, OIG expects additional data to become available regarding the ability of federal healthcare program enrollees to access these important treatments. For example, OIG noted that data related to fertility services provided by a pharmaceutical manufacturer at no cost to Medicaid enrollees who receive gene therapy treatments from the Cell and Gene Therapy Access Model developed by CMS could be helpful to this assessment. As more data become available, OIG may consider it in future risk assessments regarding arrangements similar to the fertility support.

## OIG ISSUES UNFAVORABLE AO NO. 24-06 ON PROPOSED FERTILITY ASSISTANCE FOR GENE THERAPY PATIENTS

OIG issued Advisory Opinion No. 24-06 on July 23, 2024, regarding a pharmaceutical manufacturer's proposed arrangement to offer an FDA-approved gene editing therapy for severe genetic diseases (a different product than the drugs at issue in AO No. 24-05 discussed above). The drug at issue has been approved for two different conditions. The first condition renders the patient dependent on blood transfusions to avoid severe anemia, and the second is a debilitating blood disorder causing recurrent vaso-occlusive crises. The AO discusses the requestor's proposed financial support arrangement for eligible patients receiving the drug. The program would include provision of fertility services to patients receiving the drug who may otherwise forego treatment because of the risk of infertility associated with the drug and patients' inability to afford fertility services.

Under the proposed arrangement, the pharmaceutical manufacturer would provide up to $70,000 for fertility services (including patient counseling, fertility drugs, collection and storage of oocytes or sperm, genetic testing, intrauterine insemination, and in-vitro fertilization procedures, as applicable to the individual patient) to eligible male and female patients, including federal healthcare program enrollees, who are prescribed the drug, have an annual income at or below 670% of the FPL, and whose insurance does not cover fertility services. Requestor would use a vendor to identify fertility providers and coordinate these services. Neither requestor nor the vendor would select the fertility providers or treatments. The vendor would pay providers for the fertility services, and neither the requestor nor the vendor would make any payments to patients or caregivers for fertility services. Requestor's employees would provide non-promotional information, such as patient eligibility criteria, to treatment centers and would not use the proposed arrangement as a marketing tool.

OIG analyzed whether this proposed arrangement would subject requestor to sanctions under the AKS and the beneficiary inducements CMP. Mirroring the rationale for the fertility support program outlined in AO No. 24-05, OIG concluded that it lacked the requisite data to determine that this proposed arrangement would be sufficiently low risk to issue a favorable AO. Treatments such as the drug

at issue are novel, and OIG stated that "much is yet unknown about them and optimal arrangements for ensuring appropriate access to them." OIG noted that while the drug is a one-time, potentially curative treatment for severe genetic conditions, the proposed fertility support could constitute remuneration to treatment centers and physicians. This remuneration might improperly influence physicians' decision to recommend the drug over other treatments, raising concerns about improper steering and increased healthcare costs. Accordingly, OIG declined to grant a favorable advisory opinion.

### OIG PUBLISHES NEW FAQS ON HOSPITAL FINANCIAL ASSISTANCE POLICIES

On July 8, 2024, OIG added four new Q&As to its General Questions Regarding Certain Fraud and Abuse Authorities webpage, addressing questions from providers about patient financial assistance policies. The guidance clarifies that hospitals may provide relief to Medicare beneficiaries who cannot afford their Medicare cost-sharing amounts by waiving their patients' co-pay amounts without violating the AKS or the beneficiary inducements CMP. Such cost-sharing waivers, and hospitals' financial assistance policies overall, should be structured so that they would be protected by an AKS safe harbor or an exception to the beneficiary inducements CMP, or otherwise would present sufficiently low risk to avoid sanctions under those statutes (*e.g.*, be made pursuant to a good-faith individualized assessment of the beneficiary's need, not a routine waiver).

Hospitals may make patients aware of a financial assistance policy that permits lawful waivers of beneficiary co-pay amounts, but pursuant to the beneficiary inducements CMP exception at 42 C.F.R. § 1003.110, the hospital may not offer the waiver "as part of any advertisement or solicitation." OIG acknowledged that whether a communication constitutes an "advertisement or solicitation" under the statute depends on the facts and circumstances. For example, if a hospital makes all patients aware of a financial assistance policy on its website and suggests patients contact the hospital's billing office for more information, the hospital is likely not advertising or soliciting. On the other hand, if a hospital announces on its website that it offers "insurance only" billing to all patients as an inducement to attract patients to the hospital, that would be an "advertisement or solicitation" and would present risk under the beneficiary inducements CMP and the AKS. Separately, OIG reiterated that neither the AKS nor the beneficiary inducements CMP prohibits hospitals from furnishing free or discounted items or services to uninsured or commercially insured patients who are unable to pay their hospital bills.

## CMS REGULATORY UPDATES

### CMS RELEASES TELEHEALTH PROPOSAL TO ADDRESS COVID-19-ERA FLEXIBILITIES

On July 10, 2024, CMS published its proposed 2025 Medicare Physician Fee Schedule, which aims to continue certain pandemic-era telehealth policies. For example, the rule proposes maintaining suspension of visit frequency limits for certain in-person nursing facility and critical care visits and allowing audio-only telehealth services in certain circumstances.. However, CMS maintains it has limited statutory authority to extend most Medicare telehealth policies and without congressional intervention, the major Medicare telehealth waivers will expire on December 31, 2024, and return to pre-COVID-19-public-health-emergency (PHE) policies.

The telehealth industry saw significant growth during the pandemic largely due to relaxed policies and is advocating for permanent policy changes to sustain patient access. While the proposed rule represents progress, stakeholders emphasize that congressional action is essential to secure telehealth access long-term, and the expansion of COVID-19-era flexibility is gaining traction in Congress. For example, Representative Buddy Carter (R-GA) introduced the Telehealth Modernization Act (H.R. 7623), which would broaden the types of practitioners eligible to bill Medicare for telehealth services and would allow Medicare to retain the expanded list of telehealth services added during the pandemic. The bill also would provide federally qualified health centers and rural health clinics the ability to bill Medicare for telehealth services. Read more about these proposals here.

### CMS PROPOSES PHYSICIAN MEDICARE REIMBURSEMENT CUTS FOR 2025

In another part of the proposed 2025 Medicare Physician Fee Schedule, CMS proposed to reduce Medicare payments to physicians and clinicians by an average of 2.93%. The reduction would result from a decrease in the "conversion factor" used to determine provider reimbursement in traditional Medicare. CMS said the proposed conversion factor change incorporates the 0% overall update required by statute, the expiration of the 2.93% increase in payment for 2024 required by statute, and a small adjustment. Many specialty providers, including vascular surgeons, interventional radiologists, and diagnostic testing facilities, would see reimbursements decline by 2%. Plastic surgeons, orthopedic surgeons, and urologists would face a 1% reduction under the proposal.

Other providers would experience increases in reimbursement: clinical social workers would see a 4% increase, clinical psychologists a 3% increase, and anesthesiologists a 2% increase. However, provider associations such as the American Medical Association are urging Congress to address the problem of Medicare payment reductions, especially because CMS predicts medical practice costs will increase 3.6% next year.

### CMS ISSUES PROPOSED CHANGES TO OVERPAYMENT RULE

In response to comments on CMS's 2022 proposed changes to the overpayments regulation, CMS proposed additional changes to the overpayment rule to clarify that the obligation to report and return requires quantification of the overpayment as part of identification. However, CMS proposed a strict time period for conducting reviews of overpayment issues. Under the proposed rule, the statutory 60-day clock would start to run either on the date of completion of the investigation or 180 days from the date on which the initial overpayment was identified, whichever is earlier. This proposal raises several questions and appears contrary to the overpayment statute. For further analysis, see our *On the Subject*.

### CMS PROPOSES TO BOOST PAYMENT FOR HOSPITAL OUTPATIENT SERVICES, AMBULATORY SURGICAL CENTERS

On July 10, 2024, CMS issued a proposed rule that would generate a 2.6% increase in Medicare payments for hospital outpatient services and ambulatory surgical centers in 2025, totaling $88.2 billion and $7.4 billion, respectively. This represents a $5.2 billion increase for hospital outpatient services and a $202 million increase for ambulatory surgical centers compared to 2024. The proposal introduces new policies aimed at reducing maternal mortality and improving health equity, including requirements for Medicaid and Children's Health Insurance Program eligibility, additional payments for Indian Health Services facilities, and equity measures in quality programs. The rule also aims to facilitate Medicare enrollment for former inmates and covers approximately 3,600 facilities across various healthcare sectors. The proposal is open for public comment until September 9, 2024.

### CMS ISSUES PART TWO OF GUIDANCE FOR MEDICARE PRESCRIPTION PAYMENT PLAN

On July 16, 2024, CMS issued final guidance further exploring the requirements of the Medicare Prescription Payment Plan, which allows Medicare prescription drug plan enrollees to pay their out-of-pocket costs in monthly installments. The guidance deals with plan outreach and education about the program. It follows part one of the guidance, which targets drug plans that participate in the program. Medicare beneficiaries must opt in to the plan to use the new benefit, which will launch in 2025 when Medicare prescription drug enrollees will have their annual out-of-pocket prescription drug costs capped at $2,000. The new guidance complements a forthcoming national outreach effort by CMS to educate Part D plans, pharmacies, providers, drug manufacturers, and beneficiary advocates about the program's implementation.

## OTHER NOTABLE DEVELOPMENTS

### HHS ISSUES PROVIDER INFORMATION BLOCKING DISINCENTIVES FINAL RULE

On July 1, 2024, CMS and the Assistant Secretary for Technology Policy/Office of the National Coordinator for Health Information Technology published a final rule in the *Federal Register* to implement a 21st Century Cures Act provision establishing penalties (called "appropriate disincentives") for certain healthcare providers determined by OIG to have committed information blocking. Healthcare providers have been subject to the information blocking regulations since April 5, 2021, but prior to this final rule, there was no enforcement mechanism under the Cures Act. The disincentives for certain Medicare-participating hospitals and clinicians became effective July 31, 2024, and disincentives associated with the Medicare Shared Savings Program (MSSP) will become effective January 1, 2025. Key takeaways from the final rule include the following:

- While the final rule moves the industry towards full enforcement of the information blocking regulations, it applies penalties only to healthcare providers that participate in certain Medicare programs and not to all healthcare providers that are covered actors under the information blocking regulations.

- HHS has not proposed any disincentives for healthcare providers that do not participate in the Medicare Promoting Interoperability Program or MSSP, or that serve a limited number of Medicare beneficiaries.

- In a press release accompanying the final rule, HHS emphasized that the final rule complements OIG's July 2023 final rule establishing penalties for information blocking actors other than healthcare providers. OIG's information blocking civil monetary penalty (CMP) authority does not extend to healthcare providers except to the extent that they meet the definition of a health IT developer of certified health IT or a health information network and health information exchange.

For more information, read our *On the Subject*.

## FDA OUTLINES INDUSTRY MECHANISM TO COMBAT MEDICAL PRODUCT MISINFORMATION

On July 8, 2024, the FDA issued draft guidance on how to effectively address the growing problem of online misinformation about medical products. The new draft guidance, titled Addressing Misinformation About Medical Devices and Prescription Drugs: Questions and Answers, replaces earlier draft guidance from 10 years ago and proposes to grant leeway to companies when addressing third-party misinformation about or related to their cleared or approved medical products. The revised draft guidance is open for public comment until September 9, 2024.

This guidance stems from FDA's concern that misinformation shared by independent third parties presents a significant public health concern because it can lead patients and healthcare providers to forgo treatments that are safe and effective or choose treatments that are not. Such misinformation is especially harmful when it is shared by an internet user with a large following or someone who holds a position of trust, and when the misinformation relates to medical products that treat or prevent serious or life-threatening diseases. However, industry players have been limited in what they can legally say about their medical products, curtailing their ability to address potentially harmful false statements. The revised draft guidance eases restrictions for certain types of communications, allowing companies to play a more active role in the fight against misinformation.

Under the new draft guidance, companies may choose to address such misinformation with a "tailored responsive communication," which, if published in line with the FDA's guidance, will not be subject to traditional promotional marketing requirements. For example, if an independent third party posts on its blog that a new prescription drug (Drug X) has been approved to treat non-small-cell lung cancer, but according to Drug X's prescribing information it is a second-line treatment approved for certain patients with non-small-cell lung cancer who have unsuccessfully tried a chemotherapy regimen containing platinum, then the blogger's post is false, inaccurate, and/or misleading because it omits material facts regarding the full indication for Drug X. Therefore, Drug X's manufacturer may post a response to address the misinformation about Drug X's indication if the company's post comports with the guidance's requirements. For more information on the draft guidance, read our summary here.

## FDA PUSHES TO DIVERSIFY CLINICAL STUDIES, RELEASES DRAFT INDUSTRY GUIDANCE

On June 26, 2024, the FDA released its much-anticipated draft guidance on Diversity Action Plans to Improve Enrollment of Participants from Underrepresented Populations in Clinical Studies. The draft guidance describes which clinical studies would require diversity action plans, what clinical study sponsors should include in their plans, and when FDA may determine that a sponsor can waive the diversity action plan requirement. The draft guidance was issued pursuant to FDA's obligation under the 2022 Food and Drug Omnibus Reform Act to update its guidance on diversity action plans. Once finalized, this guidance will replace FDA's April 2022 draft guidance on diversity plans in clinical studies.

The draft guidance provides insight into the actions that FDA expects clinical study sponsors to take to address the historical underrepresentation of certain populations based on age, ethnicity, biological sex, and race in clinical studies. It also provides sponsors and other interested parties the opportunity to potentially shape FDA's expectations by submitting comments on the draft guidance. The obligation to prepare and implement diversity action plans falls primarily on sponsors. However, other stakeholders that support the design and implementation of clinical studies, such as contract research organizations, site management organizations, subject recruitment solution providers, and research sites, should consider how the recommendations in the draft guidance may impact their obligations and business strategies. Comments on the draft guidance must be submitted by September 26, 2024. For more information on the draft guidance, read our summary here.

## FDA HOLDS PUBLIC WORKSHOP ON USE OF AI IN DRUG DEVELOPMENT

On August 6, 2024, the FDA held a public workshop titled "Artificial Intelligence in Drug and Biological Product Development," per a *Federal Register* notice. The workshop was supported by the Clinical Trials Transformation Initiative and gathered AI experts and drug developers to discuss guiding principles for the responsible use of AI in the development of safe and effective drugs and biological products. The workshop included presentations and panel discussions in a hybrid format, available both virtually and in-person.

## TEXAS COURT POSTPONES FTC NONCOMPETE BAN

On July 3, 2024, the US District Court for the Northern District of Texas stayed the September 4, 2024, implementation date of the Federal Trade Commission's (FTC's) final rule that bans all new noncompete agreements nationwide and renders existing noncompete agreements binding most workers unenforceable. The court preliminarily enjoined the FTC from enforcing the final rule against the parties to a lawsuit filed by a private tax services firm. The court will make its final injunction decision on August 30, 2024. For more information on the preliminary injunction, read our summary here. Of note, later in July, a ruling by a federal court in Pennsylvania upheld the ban, highlighting potential inconsistencies in judicial interpretations concerning this rule and its enforceability.

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