HEALTHCARE REGULATORY CHECK-UP

IN THIS MAY 2025 ISSUE

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MAY REGULATORY UPDATE SUMMARY

This issue of McDermott's *Healthcare Regulatory Check-Up* highlights regulatory activity for May 2025, including the rollout of a new Centers for Medicare & Medicaid Services (CMS) strategy to expand and enhance Medicare Advantage (MA) audits. We discuss several enforcement actions focusing on allegations under the Anti-Kickback Statute (AKS), the Stark Law, the False Claims Act (FCA), and other fraud and abuse laws, including allegations related to the submission of fraudulent claims to Medicare for reimbursement of over-the-counter COVID-19 test kits and billing federal healthcare programs for medically unnecessary services. This issue also discusses developments related to the One Big Beautiful Bill Act, the Make America Healthy Again Commission, and a jointly issued request for information on how to improve prescription drug price transparency.

NOTABLE ENFORCEMENT RESOLUTIONS AND ACTIVITIES

PHARMA COMPANY SETTLES ANTITRUST CLASS ACTION FOR $50 MILLION

A pharmaceutical company agreed to pay $50 million to settle a class action lawsuit accusing the company of scheming with another drug manufacturer to delay the release of a generic version of a narcolepsy drug, causing health plans to pay higher prices, in violation of US antitrust law. The proposed settlement, filed in the US District Court for the Northern District of California, resolved claims from plaintiffs, including Blue Cross Blue Shield Association; the city of Providence, Rhode Island; and the New York State Teamsters Council Health and Hospital Fund, that the company paid the other manufacturer to keep a generic version of a narcolepsy drug off the market longer than it otherwise would have been while raising the price of its brand-name narcolepsy drug by more than 800%. The manufacturer of the generic drug separately agreed in April 2025 to pay $145 million to resolve the claims against it. Both settlements ultimately require approval by Chief US District Judge Richard Seeborg.

$3.6 MILLION SETTLEMENT RESOLVES FENTANYL FALSE CLAIMS ALLEGATIONS

A pharmaceutical company agreed to pay $3.6 million to resolve claims that it violated the FCA by causing the submission of false claims for a transmucosal immediate-release fentanyl (TIRF) drug for individuals who did not have breakthrough cancer pain. The company's marketing efforts allegedly included focused marketing to pain specialists who were high prescribers of TIRF products and placing high-volume TIRF prescribers on the company's speakers bureau and advisory boards. The United States contended that these marketing efforts caused 13 high-volume prescribers to write prescriptions for Medicare and TRICARE beneficiaries who

did not have breakthrough cancer pain, resulting in the submission of false claims to Medicare and TRICARE. The settlement includes the resolution of *qui tam* claims brought by two individuals formerly employed by the pharmaceutical company as sales representatives.

TWO CHARGED IN $227 MILLION MEDICARE FRAUD SCHEME RELATED TO COVID-19 TEST KITS

An Illinois man and a foreign national were arrested on criminal charges related to their alleged submission of more than $227 million in fraudulent claims to Medicare. The two individuals owned and operated purported medical laboratories and allegedly installed foreign nationals to act as nominee owners at the laboratories and submit fraudulent claims to Medicare for the provision of over-the-counter COVID-19 test kits. Under the alleged arrangement, it was understood that the nominee owners would flee the US when they learned that their laboratories were under investigation.

The indictment alleged that the defendants rarely provided COVID-19 test kits to Medicare beneficiaries but submitted claims for reimbursement on behalf of beneficiaries who had not requested COVID-19 test kits, including individuals who were deceased. The defendants also allegedly paid a marketing company to provide hundreds of thousands of Medicare beneficiary names, which the defendants used to submit fraudulent claims. In total, between September 2022 and June 2023, the defendants' laboratories billed Medicare approximately $227 million in fraudulent claims, of which Medicare paid approximately $136 million.

HEALTH SYSTEM RESOLVES ALLEGATIONS OF STARK LAW VIOLATIONS FOR MORE THAN $3 MILLION

A health system agreed to pay $3.29 million to resolve allegations that it knowingly submitted or caused to be submitted false claims to Medicare that were the result of Stark Law violations. The US Department of Justice alleged that the health system and its affiliated hospitals had financial relationships with nonemployee physicians who referred certain designated health services, including laboratory testing and hospital services, to the health system and its affiliated hospital, which then billed Medicare for the referred services. The government argued that the compensation arrangements were not commercially reasonable or the compensation received by the physicians exceeded fair market value, and that therefore the arrangements failed to meet any exceptions to the Stark Law. This case is the latest example of the increasing trend of FCA actions based on Stark Law allegations.

THIRD CIRCUIT REJECTS CHALLENGE TO DRUG PRICE NEGOTIATION PROGRAM

On May 8, 2025, the US Court of Appeals for the Third Circuit ruled against a pharmaceutical company's challenge to the Drug Price Negotiation Program. The Inflation Reduction Act of 2022 directed CMS to negotiate prices for certain drugs that result in high expenditures in Medicare. In furtherance of this statutory directive, CMS issued guidance explaining how it would select "qualifying single source drugs" for 2026, the first year of the Drug Price Negotiation Program, and setting forth a test to determine whether a drug lacks a generic competitor that is "approved and marketed," which would render the drug subject to negotiation.

One of the pharmaceutical companies whose drug was selected for the first round of negotiation challenged CMS's guidance, alleging that CMS's method for identifying "qualifying single source drugs" and its determination of whether a drug is subject to generic competition violates the Administrative Procedure Act (APA). The pharmaceutical company also claimed that the Drug Price Negotiation Program itself violated the company's due process rights because it deprived the company of property interests in its drugs. The district court declined to reach the merits of the APA claim, which it dismissed for lack of standing. Affirming the district court, the Third Circuit observed that the only evidence the pharmaceutical company put forth showing standing was an affidavit from its vice president of US market access that failed to identify any actual decision about drug development or marketing and did not show how the CMS guidance shaped the company's behavior before or during its negotiations with CMS. The Third Circuit also rejected the pharmaceutical company's due process claim, holding that the company had no protected property interest in selling goods to Medicare beneficiaries at a price higher than what the government is willing to pay when it reimburses those costs.

This ruling is the first appellate decision upholding the legal viability of the Drug Price Negotiation Program, which has faced a handful of legal challenges from pharmaceutical companies. More appellate decisions on the program's viability are expected.

JUDGE DISMISSES SUIT ON GROUNDS THAT FCA *QUI TAM* PROVISIONS ARE UNCONSTITUTIONAL

On May 29, 2025, Judge Kathryn Kimball Mizelle of the District Court for the Middle District of Florida dismissed an un-intervened FCA *qui tam* lawsuit against a construction company and an insurance company, holding that the FCA's *qui tam* provisions are unconstitutional because they violate the Appointments Clause under Article II of the US Constitution. Judge Mizelle previously dismissed another FCA *qui tam* lawsuit against a medical provider in *U.S. ex rel. Zafirov v. Florida Medical Associates, LLC, et al.*, 8:19-cv-01236 (M.D. Fla.) on the same grounds, as discussed in our September 2024 *Healthcare Regulatory Check-Up* and *On the Subject*.

Judge Mizelle reiterated her holding from *Zafirov* that an FCA relator is an "officer" of the US that requires constitutional appointment and, because no one appointed the FCA relators in this case to this "office," their *qui tam* lawsuit against the FCA defendants violated the Appointments Clause. This decision is expected to be appealed to the Court of Appeals for the Eleventh Circuit, where an appeal to the *Zafirov* case is currently pending. This decision and the *Zafirov* decision could potentially reach the Supreme Court of the United States. If upheld, the decisions would have significant implications for FCA enforcement, which relies heavily on *qui tam* relator claims, and for anyone involved in *qui tam* litigation today or in the future.

MAGISTRATE JUDGE HOLDS THAT FCA *QUI TAM* PROVISIONS ARE CONSTITUTIONAL

A magistrate judge in the District Court for the Western District of New York rejected an FCA defendant's challenge to the FCA's whistleblower provisions as unconstitutional. The FCA defendant relied on comments made in Supreme Court Justices Amy Coney Barrett and Brett Kavanaugh's concurrence and Justice Clarence Thomas's dissent in *U.S. ex rel. Polansky v. Executive Health Resources, Inc.*, 599 U.S. 419, 423 (2023), as well as the *Zafirov* holding discussed above, to argue that the case should be dismissed as unconstitutional because the FCA's *qui tam* provisions violate the Appointments Clause under Article II of the Constitution.

The magistrate judge rejected the defendant's constitutionality argument, observing that "every federal court of appeals that has addressed this issue has rejected that argument," and that "[d]istrict courts have also overwhelmingly rejected Appointments-Clause challenges to the *qui tam* provisions of the FCA." The magistrate judge noted that the three justices in *Polasky* merely expressed interest in a legal question that was not before the court. The judge rejected application of the *Zafirov* case as "neither binding nor persuasive." The FCA defendant filed an objection, and the district court's decision whether to adopt the magistrate's decision is pending.

COURT ALLOWS FCA *QUI TAM* SUIT AGAINST EMERGENCY MEDICAL SERVICES CONTRACTOR TO PROCEED

The District Court for the Northern District of California denied an FCA defendant's motion to dismiss for failure to state a claim and rejected its argument that the FCA's *qui tam* provisions are unconstitutional.

The relator filed an FCA claim against the defendant, an emergency medical services contractor, alleging that it engaged in fraud by improperly pressuring providers to chart for critical care services when the threshold for such services had not been met, and by deliberately and inappropriately upcoding noncritical care to a higher, more profitable level of noncritical care. Moving to dismiss the lawsuit, the defendant argued that the complaint failed to plead fraud with materiality or the time period of the alleged fraud with particularity. The court disagreed, finding that the relator's allegations should survive a motion to dismiss because the relator alleged "that the billing codes determine what the government and private insurers reimburse, and that the government only pays for medically necessary and reasonable services."

> **This case displays another attempt by FCA defendants to rely on the *Zafirov* holding to dismiss *qui tam* cases on constitutionality grounds.**

Citing the *Zafirov* case discussed above, the defendant also argued that the relator's claim should be dismissed because the FCA's *qui tam* provisions violate the Appointments Clause under Article II of the Constitution. The court rejected this argument, noting that the Court of Appeals for the Ninth Circuit found the *Zafirov* holding to be unpersuasive in *U.S. ex rel. Kelly v. Boeing Co.*, 9 F.3d 743, 759 (9th Cir. 1993). The district court emphasized that "*Kelly* remains good law in this circuit."

This case displays another attempt by FCA defendants to rely on the *Zafirov* holding to dismiss *qui tam* cases on constitutionality grounds. This case is expected to be appealed. If there is ultimately a split between the Eleventh Circuit's decision in *Zafirov* and another appellate court's decision on this constitutionality issue, likely the Supreme Court will review and ultimately decide on this issue.

CMS REGULATORY UPDATES

CMS ROLLS OUT AGGRESSIVE STRATEGY TO ENHANCE, ACCELERATE MA AUDITS

On May 21, 2025, CMS announced that it will expand its auditing of MA plans by auditing all eligible MA contracts for each payment year and by investing additional resources to expedite the completion of audits for payment years 2018 through 2024.

Generally, MA plans receive risk-adjusted payments through a complex formula that is based in part on the diagnosis codes MA plans submit to CMS for their enrollees, resulting in higher payments for patients with more serious or chronic conditions. CMS conducts risk adjustment data validation (RADV) audits of the data submitted by MA plans to confirm that the data is supported by medical records. CMS is several years behind in completing these audits, with the last significant recovery of MA payments occurring after the audit of payment year 2007. The audits are controversial and regularly contested by MA plans on various grounds.

In apparent response to this backlog, CMS introduced a plan to complete all remaining RADV audits for payment years 2018 through 2024 by early 2026. CMS said that it will deploy advanced systems to efficiently review medical records and flag unsupported diagnoses; increase its team of medical coders from 40 to approximately 2,000; and use technology to increase its auditing volume (*i.e.*, the total number of MA plans audited and number of records per health plan reviewed). CMS also will collaborate with OIG to recover uncollected overpayments identified in past audits.

MA plans and providers should anticipate increased RADV audit activity and prepare to respond to audit requests and challenge any flawed audit findings. Given the scale and speed at which CMS plans to expand its audit capabilities, the accuracy of these audits may be suspect, and CMS has not addressed stakeholders' other concerns with the RADV audit program.

CMS RELEASES DRAFT GUIDANCE FOR THIRD CYCLE OF MEDICARE DRUG PRICE NEGOTIATION

On May 12, 2025, CMS released draft guidance for public comment regarding the third cycle of negotiations under the Medicare Drug Price Negotiation Program. The draft guidance includes policies to incorporate drugs payable under Medicare Part B into the program for the first time and solicits comments on how to facilitate access to any negotiated maximum fair prices (MFP) for drugs payable under Part B. It also outlines how CMS would choose certain drugs for renegotiation that were negotiated for initial price applicability years 2026 or 2027, clarifies how participating manufacturers would make any negotiated MFPs available in 2026 and 2027, and would extend these policies for drugs covered under Part D to 2028.

By February 1, 2026, CMS will announce up to 15 drugs covered under Part D or payable under Part B for potential renegotiation. These 15 drugs are in addition to the first set of 10 drugs covered under Part D for which negotiations concluded in August 2024 and the second set of 15 drugs for which negotiations are currently underway.

To be considered by CMS, comments must be received by 11:59 pm PDT on June 26, 2025. Across the draft guidance, CMS seeks input on a range of topics to promote greater transparency in processes, reduce administrative burden for participating manufacturers, and evolve the negotiation program to achieve greater value for beneficiaries and taxpayers.

OTHER NOTABLE DEVELOPMENTS

HHS SUED OVER REMOVAL OF HEALTH DATA

Nine organizations representing physicians, nurses, medical researchers, hospitals, and public health practitioners sued HHS, alleging that it violated the APA by illegally purging websites containing critical public health information related to transgender individuals, HIV care, vaccines, and prevention of communicable disease outbreaks. The organizations argued that deletion of such information stemmed from two executive orders (EOs) issued in January 2025: EO 14168, aimed at gender ideology, and EO 14151, targeting diversity, equity, and inclusion. As a result, the removal of information was allegedly a violation of the separation of powers and was arbitrary and capricious since it was done without the required notice to the public.

BILLING DISPUTE CONSULTING COMPANY SUED OVER ALLEGED NO SURPRISES ACT VIOLATIONS

An insurance company sued a billing dispute consulting company and two hospital-based providers, alleging that they conspired to exploit the No Surprises Act (NSA) when they won higher reimbursements through the act's independent dispute resolution system. The insurance company estimated that it has spent nearly $6 million on excess reimbursements and dispute resolution fees and requested that the court vacate all dispute resolutions between it and the consulting company.

HHS, LABOR, AND TREASURY AIM TO BOOST HEALTHCARE PRICE TRANSPARENCY

On May 22, 2025, HHS and the US Departments of Labor and the Treasury (collectively, the departments) issued a joint request for information on how to improve prescription drug price transparency, specifically prescription drug price disclosure requirements, including information on existing prescription drug file data elements and information on implementation generally.

The departments also released updated guidance in the form of frequently asked questions (FAQs) for health plans and insurers related to the November 12, 2020, transparency in coverage final rules, which require non-grandfathered group health plans and health insurance issuers offering non-grandfathered group and individual health insurance coverage to disclose on a public website information regarding in-network provider rates for covered items and services, out-of-network (OON) allowed amounts and billed charges for covered items and services, and negotiated rates and historical net prices for covered prescription drugs in three separate machine-readable files. The FAQs set a clear applicability date for publishing an enhanced technical format for disclosures designed to eliminate meaningless or duplicative data and make cost information easier for consumers to understand and use. CMS also released new guidance to strengthen the hospital price transparency requirements, requiring hospitals to post the actual prices of items and services and not estimates. We discuss this guidance in detail in our *On the Subject*. Both efforts from the departments were effectuated in accordance with EO 14221, "Making America Healthy Again by Empowering Patients with Clear, Accurate, and Actionable Healthcare Pricing Information."

MAHA COMMISSION ISSUES MAKE OUR CHILDREN HEALTHY AGAIN REPORT

On May 22, 2025, the Make America Healthy Again (MAHA) Commission released its Make Our Children Healthy Again Assessment (also referred to as the MAHA report) as directed by EO 14212, released on February 13, 2025. That EO established the MAHA Commission and directed it to conduct and release the assessment within 100 days and to prepare a MAHA strategy based on the assessment within 180 days. The commission is chaired by HHS Secretary Robert F. Kennedy, Jr., and composed of other agency officials and is tasked with investigating childhood chronic illnesses and diseases.

The MAHA report identified four potential drivers of the rise in childhood chronic diseases: poor diet, aggregation of environmental chemicals, lack of physical activity and chronic stress, and overmedicalization. The MAHA report examines each driver and proposes 10 research initiatives to "close critical research gaps and guide efforts to better combat childhood chronic disease." The MAHA report states that the commission will begin developing the MAHA strategy in accordance with the EO.

Shortly after issuance of the MAHA report, a news outlet reported that certain studies cited in the MAHA report did not exist or were inaccurately cited. Several researchers identified in the report stated that the articles they allegedly authored either do not exist or were mischaracterized. White House Press Secretary Karoline Leavitt attributed the errors to "formatting issues," and HHS spokesperson Andrew Nixon staid that the MAHA report has since been updated to correct "minor citation and formatting errors," although the substance of the report remains the same.

> **The MAHA report identified four potential drivers of the rise in childhood chronic diseases: poor diet, aggregation of environmental chemicals, lack of physical activity and chronic stress, and overmedicalization.**

HHS ISSUES PROPOSED FY 2026 BUDGET

On May 2, 2025, the Trump administration, through the Office of Management and Budget (OMB), released its proposed fiscal year (FY) 2026 discretionary budget request, which seeks to cut $163 billion in nondefense discretionary funding across the federal government, including cuts to programs administered by HHS. This "skinny" budget proposal did not specify the funding requests for all programs and initiatives impacted by the proposal.

On May 30, 2025, OMB released supplemental documents providing additional details on the FY 2026 discretionary budget request. The request includes $94.7 billion for HHS, representing an aggregate $31.3 billion reduction in HHS funding from FY 2025.

That same day, HHS released a "Budget in Brief" document that provides additional details related to the proposed FY 2026 budget request for HHS. Among other proposals, the HHS budget proposes to slash National Institutes of Health funding nearly in half ($18 billion reduction) and to drastically cut funding for CMS ($661 million reduction), the Centers for Disease Control and Prevention ($3.9 billion reduction), and the US Food and Drug Administration ($409 million reduction). The HHS budget also proposes to allot $19 billion ($14 billion in discretionary funding and $4.8 billion from proposed mandatory sources) to establish the new Administration for a Healthy America, which would be responsible for overseeing HHS Secretary Kennedy's MAHA initiatives.

Building on Secretary Kennedy's March 2025 announcement of department-wide downsizing and reorganization, the HHS budget seeks to consolidate HHS's 28 operating divisions into 15, close five regional offices, reduce the HHS workforce to reflect 90% of pre-COVID staffing levels, and terminate more than 5,000 contracts. The budget proposes to create a new Office of the Assistant Secretary for Enforcement, which would consolidate several HHS units (including the Office for Civil Rights, the Departmental Appeals Board, the Office of Medicare Hearings and Appeals, and the Office for Human Research Protections) and shift new responsibilities to CMS, including oversight of the 340B Drug Pricing Program, despite the reduction to CMS's budget.

The Trump administration cannot implement the proposed FY 2026 budget without congressional approval. The release of the president's budget is the precursor to Congress's negotiations over federal funding levels for the upcoming FY, accomplished through its budget committees and the appropriations process. Read our +Insight to learn more about the proposed FY 2026 budget.

ONE BIG BEAUTIFUL BILL ACT PROCEEDS TO SENATE

On May 22, 2025, the US House of Representatives passed the One Big Beautiful Bill Act, which now is under US Senate review. The act seeks to cut billions of dollars in Medicaid spending by, for example, introducing new work requirements for otherwise eligible Medicaid recipients, requiring states to impose mandatory cost-sharing for certain services provided to individuals enrolled through the Medicaid expansion with incomes above the federal poverty line (and allowing providers to deny services to any individual who cannot pay the required co-payment), and blocking implementation of rules finalized by CMS in September 2023 and April 2024 intended to improve Medicaid and Children's Health Insurance Program eligibility and enrollment systems. The act also includes sweeping changes to health insurance marketplaces.

> **The US House of Representatives passed the One Big Beautiful Bill Act, which now is under US Senate review.**

For more information regarding the bill and its progression through Congress, visit the McDermott+ Reconciliation Roadmap Resource

Center.

NO SURPRISES ACT UPDATE: CMS PUBLISHES IDR PUBLIC USE FILES, SUPPLEMENTAL TABLES FOR Q3, Q4 2024

On May 28, 2025, the departments released NSA independent dispute resolution (IDR) public use files (PUFs) and federal IDR supplemental tables for the third and fourth quarters of 2024. According to a summary document, the last six months of 2024 saw "an increasingly large volume of disputes initiated through the Federal IDR portal, continuing complexity in determining whether disputes were eligible for the Federal IDR process, and continued changes to Federal IDR process operations as a result of multiple court orders in 2023." IDR entities increased the number of payment determinations made each calendar quarter throughout the 12-month period of January 1, 2024, through December 31, 2024.

The NSA, enacted under the first Trump administration as part of the Consolidated Appropriations Act, 2021, prohibits OON providers from balance billing patients for certain services furnished at an OON facility (in the case of emergency services) or an in-network facility (in the case of non-emergency services provided by OON providers). The NSA sets forth a methodology by which plans or issuers must calculate the OON rate for OON providers or facilities that rendered items or services subject to the NSA. Plans and issuers must pay the provider or facility an amount determined by an applicable all-payer model agreement, and if none exists, an amount determined by applicable state law. If state law does not set forth a mechanism by which the OON rate should be determined, the plan or issuer may negotiate the rate with the provider or facility through a 30-day "open negotiation" process. If the parties are unable to agree to an OON rate by the expiration of the open negotiation period, either party may initiate a dispute under the federal IDR process.

The NSA required the departments to establish a federal IDR portal through which parties may initiate disputes, and to publish certain information about the IDR process for each calendar quarter on a public website. To facilitate the departments' reporting obligations, CMS and the Center for Consumer Information & Insurance Oversight publish IDR PUFs and IDR supplemental tables. IDR PUFs include detailed information for each payment determination, such as outcomes and offer amounts, while IDR supplemental tables include summary information, such as the number of payment disputes initiated, the number of payment disputes closed, and the reasons for closure.

AUTHORS & CONTACT

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

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

SARAH KITCHELL
PARTNER
skitchell@mwe.com
Tel +1 617 535 3929

JAMIE GELFMAN
PARTNER
jgelfman@mwe.com
Tel +1 305 507 2306

SARAH REIS
ASSOCIATE
sreis@mwe.com
Tel +1 617 535 5983

KELSEY REINHARDT
ASSOCIATE
kreinhardt@mwe.com
Tel +1 310 788 4173

CHRISTOPHER WHALEN
ASSOCIATE
chwhalen@mwe.com
Tel +1 212 547 5573

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