McDermott Will & Schulte

HEALTHCARE REGULATORY CHECK-UP

IN THIS JULY 2025 ISSUE

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JULY REGULATORY UPDATE SUMMARY

This issue of McDermott Will & Schulte's *Healthcare Regulatory Check-Up* highlights regulatory activity for July 2025, including the results of the US Department of Justice's (DOJ) 2025 National Health Care Fraud Takedown, DOJ and the US Department of Health and Human Services' (HHS) new False Claims Act (FCA) Working Group, and three Office of Inspector General (OIG) advisory opinions. We discuss a pharmaceutical company's challenge to the FCA *qui tam* provisions. This issue also reviews key proposals in the calendar year (CY) 2026 Physician Fee Schedule (PFS) proposed rule and the CY 2026 Hospital Outpatient Prospective Payment System (OPPS) and Ambulatory Surgical Center (ASC) Payment System proposed rule, as well as finalized policies in the fiscal year (FY) 2026 Medicare Hospital Inpatient Prospective Payment System (IPPS) final rule.

NOTABLE ENFORCEMENT RESOLUTIONS AND ACTIVITIES

DOJ ANNOUNCES 2025 NATIONAL HEALTH CARE FRAUD TAKEDOWN RESULTS

On June 30, 2025, DOJ announced the results of its 2025 National Health Care Fraud Takedown, which, in collaboration with 12 state attorneys general, resulted in criminal charges against 324 defendants in 50 federal districts. The takedown included charges in Arizona and Nevada against seven defendants in connection with approximately $1.1 billion in fraudulent claims to Medicare and other healthcare benefit programs for amniotic wound allografts that were applied unnecessarily, without proper treatment, and without coordination with the treating physician. The takedown also included 49 defendants charged with more than $1.7 billion in allegedly fraudulent claims to Medicare from telemedicine schemes using deceptive telemarketing campaigns for genetic testing, durable medical equipment, and COVID-19 tests.

DOJ ESTABLISHES FCA WORKING GROUP

On July 2, 2025, HHS and DOJ jointly announced the establishment of the False Claims Act Working Group. This new working group may indicate the government's intent to take a more active role in evaluating and potentially intervening in § 3730(c)(2)(A) dismissals, which pertain to *qui tam* actions under the FCA.

The FCA Working Group identified the following six priority areas of enforcement:

- Medicare Advantage.
- Drug, device, and biologics pricing, including arrangements for discounts, rebates, service fees, formulary placement, and price reporting.
- Barriers to patient access to care, including violations of network adequacy requirements.
- Kickbacks related to drugs, medical devices, durable medical equipment, and other products paid for by federal healthcare programs.
- Materially defective medical devices that impact patient safety.
- Manipulation of electronic health record systems to drive inappropriate utilization of Medicare covered products and services.

A key component of the FCA Working Group is the newly created Health Care Fraud Data Fusion Center, a collaboration between DOJ, the Federal Bureau of Investigation, OIG, and other federal agencies that aims to revolutionize the detection, investigation, and prosecution of healthcare fraud. The center will centralize and analyze data related to healthcare fraud and will leverage cloud computing, artificial intelligence (AI), and advanced analytics to increase efficiency, detection, and rapid prosecution of emerging healthcare fraud schemes. DOJ stated that the FCA Working Group will use AI tools to determine whether HHS should implement a payment suspension under 42 CFR § 405.370, *et seq.*, based on "credible allegation[s] of fraud" that may come from the data mined by such tools. For more information, read our *On the Subject*.

JANSSEN CHALLENGES CONSTITUTIONALITY OF THE FCA *QUI TAM* PROVISIONS

Earlier this year, Janssen Products LP received a monetary judgment in the US District Court for the District of New Jersey for conduct related to a 2012 whistleblower lawsuit filed by former Janssen sales representatives. The suit alleged that Janssen unlawfully marketed HIV drugs for off-label uses, causing false claims to be submitted to Medicare, Medicaid, and the AIDS Drug Assistance Program. The court ordered Janssen to pay $1.64 billion in damages and penalties after a jury found the company liable for submitting 159,574 false claims. The judgment included $360 million in treble damages and $1.28 billion in civil penalties.

On July 14, 2025, in a rare move, Janssen appealed the decision, challenging the constitutionality of the FCA's *qui tam* provisions and the excessive nature of the penalties. Janssen argued that "[v]esting relators with such sweeping and unchecked executive authority threatens to unsettle the government's reimbursement regime and frustrate patient care." *See U.S. ex rel. Penelow et al. v. Janssen Products LP*, No. 25-1818 (3d Cir. 2025). The US Chamber of Commerce filed an *amicus* brief supporting Janssen's position, arguing that the FCA's *qui tam* provisions violate Article II of the US Constitution by removing law enforcement authority from the president.

The US Court of Appeals for the Third Circuit is expected to hear oral arguments in the coming months.

CMS REGULATORY UPDATES

CMS RELEASES CY 2026 PHYSICIAN FEE SCHEDULE PROPOSED RULE

On July 14, 2025, the Centers for Medicare & Medicaid Services (CMS) released the CY 2026 Revisions to Payment Policies Under the Physician Fee Schedule and Other Revisions to Medicare Part B [CMS-13271] Proposed Rule, which includes proposals related to Medicare physician payment and the Quality Payment Program. For the first time, CMS proposes two separate PFS conversion factor updates: One for clinicians who participate in advanced alternative payment models (APMs) and are considered qualifying APM participants, and one for all other clinicians. Both proposed conversion factors for 2026 would incorporate a one-time 2.5% payment increase provided by the One Big Beautiful Bill Act.

CMS proposes to make significant changes to physician rate setting by incorporating an efficiency adjustment for codes not based on time and by adjusting the practice expense methodology. Other proposals include a new mandatory payment model related to heart failure and lower back pain, telehealth updates, changes to the Merit-based Incentive Payment System (MIPS) program, and movement toward the MIPS Value Pathways. For a more detailed analysis, see this McDermott+ article.

CMS PROPOSES RPM REIMBURSEMENT UPDATES, REQUESTS INFORMATION ON REIMBURSING FOR SAAS

In recent years, CMS has expanded payment for remote monitoring services in an effort to recognize and pay for non-face-to-face services that improve care management for Medicare beneficiaries. In connection with the CY 2026 PFS proposed rule, CMS proposes several payment policy changes for remote monitoring services, including modifications to the remote physiological monitoring (RPM) and remote therapeutic monitoring (RTM) codes. Most significantly, CMS proposes payment rates for new RPM and RTM codes established by the American Medical Association's CPT Editorial Panel last year.

The RPM code set currently includes CPT codes 99453, 99454, 99091, 99457, 99458, 99473, and 99474. For CY 2026, the CPT Editorial Panel created CPT codes 99XX4 and 99XX5 to describe RPM services that include fewer than 16 days of data transmission per 30-day period and fewer than 20 minutes of interactive communication per month, respectively. CMS proposes to accept these codes and establish payment rates effective January 1, 2026. CMS also proposes to adopt the CPT Editorial Panel's edits to specify the minimum days of data transmission per 30-day period for CPT code 99454.

CMS notes that many of the codes (99091, 99474, 99XX5, 99457, and 99458) will have to be resurveyed after one year of utilization data becomes available because the codes did not meet minimum survey requirements for the CPT Editorial Panel's January 2025 Relative Value Scale Update Committee meeting. CMS notes that all remote monitoring codes are expected to be reviewed at the CPT Editorial Panel's January 2028 meeting.

CMS also requests comments on how to establish pricing for software as a service (SaaS) under the PFS, which would have implications for the proposed reimbursement amounts for certain RPM and RTM codes. Comments on the proposed rule are due to CMS by 5:00 pm EDT on September 12, 2025. Learn more about the proposed rule in our *On the Subject*.

CMS RELEASES CY 2026 OPPS, ASC PAYMENT SYSTEM PROPOSED RULE

On July 15, 2025, CMS released the CY 2026 OPPS and ASC Payment System proposed rule [CMS-1834-P], which includes proposals to update payment rates and regulations affecting Medicare services furnished in hospital outpatient and ASC settings beginning in CY 2026.

CMS proposes to increase payment rates under the OPPS and the ASC Payment System by 2.4%. CMS continues to implement the statutory two percentage point reduction in payments for hospitals that fail to meet the hospital outpatient quality reporting requirements by applying a reporting factor of 0.9805 to the OPPS payments and copayments for all applicable services. CMS notes that payments for services at hospitals subject to the proposed 340B remedy offset will be reduced by two percentage points.

Based on the proposed policies, CMS estimates that total payments to OPPS and ASC providers (including beneficiary cost sharing and estimated changes in enrollment, utilization, and case mix) for CY 2026 will be about $100 billion and $9.2 billion, respectively. This represents an increase of about $8.1 billion and $480 million, respectively, from CY 2025 payment levels.

For more information, see this M+ article.

CMS PROPOSES EXPANDED SITE-NEUTRAL PAYMENT POLICY FOR DRUG ADMINISTRATION SERVICES

In the CY 2026 OPPS proposed rule, CMS proposes to reduce hospital payments for drug administration services furnished at all off-campus hospital outpatient departments, with a stated goal of reducing Medicare costs and addressing payment disparities between hospital and physician office settings. If this policy is finalized, it would significantly impact hospital reimbursement rates for drug administration services. CMS also requests information from stakeholders on additional future expansion of site-neutral payment policies.

Medicare pays for services furnished in a physician's office based on the PFS but pays for similar services furnished in hospital outpatient departments under the OPPS. When services are furnished in hospital outpatient departments, including provider-based departments (PBDs) of a hospital, Medicare typically makes a payment to the physician providing professional services in the hospital setting, and a payment to the hospital for the overhead and facility component of the services. In a physician office setting,

the payment to the physician includes both the professional component and the overhead associated with the services. The payment differential reflects the typically higher cost of furnishing care in hospital-based settings.

Consistent with Executive Order 14273, CMS proposes to use its authority under 42 U.S.C. § 1395l(t)(2)(F) to expand its existing site-neutral payment policies to include drug administration services furnished at all off-campus PBDs. Under this statutory authorization, CMS has the authority to "develop a method for controlling unnecessary increases in the volume of covered" outpatient services. CMS proposes to apply the PFS payment rate for any HCPCS codes covering drug administration ambulatory payment classifications when provided at excepted off-campus PBDs, rather than an OPPS rate. Off-campus PBDs that are not excepted are already subject to a PFS-equivalent payment rate for these services. CMS also proposes to exclude rural sole community hospitals from the proposed site-neutral policy for drug administration services.

CMS cites a substantial shift over time from drug administration in physician offices to administration in PBDs as the impetus for this change. The agency expresses concerns about higher costs both for beneficiaries who receive drugs administered in PBDs and for the Medicare trust fund due to higher reimbursement for those services under the OPPS.

CMS reasons that providing services in a PBD at a higher cost is unnecessary if a patient can safely receive those services in a physician office for a lower cost. To support this finding, the agency cites a study that found that 68% of drug administration services currently take place in physician offices, indicating that they are safely performed in multiple settings. CMS believes that because drug administration services are routinely and safely performed in physician offices, there is no reason to pay a higher OPPS rate for these services in a PBD setting. CMS points to the payment incentive as the primary motivator for the shift in care setting for these drug administration services, even though a minority of such services are provided in PBDs.

Stakeholders should review the proposed rule and consider submitting comments to CMS by the September 15, 2025, deadline to address potential operational and financial impacts. Learn more about these potential changes in our *On the Subject*.

CMS RELEASES FY 2026 IPPS FINAL RULE

On July 31, 2025, CMS issued the FY 2026 IPPS and Long-Term Care Hospital (LTCH) Prospective Payment System final rule. The rule updates Medicare fee-for-service payment rates and policies for inpatient hospitals and LTCHs for FY 2026. Key highlights include the following:

- **Standardized amount.** CMS finalized a 2.6% increase to operating payment rates for general acute care hospitals paid under the IPPS that successfully participate in the hospital inpatient quality reporting program and are meaningful electronic health record users. This increase is based on a projected FY 2026 hospital market basket percentage increase of 3.3%, reduced by a 0.7 percentage point productivity adjustment.
- **Medicare severity diagnosis-related group (MS-DRG) updates.** CMS finalized its proposal to create new MS-DRG 209 for complex aortic arch procedures, MS-DRG 213 for endovascular abdominal aorta and iliac branch procedures, MS-DRGs 359 and 360 for percutaneous coronary atherectomy with intraluminal device, and MS-DRG 318 for percutaneous coronary atherectomy without intraluminal device. CMS also finalized its proposal to delete hypertensive encephalopathy MS-DRGs 077, 078, and 079.
- **Transforming Episode Accountability Model (TEAM).** Although CMS largely finalized the TEAM policies as proposed, the agency added a new low-volume hospital policy in response to extensive stakeholder feedback. The policy removes downside risk for any episode category in which a hospital had fewer than 31 episodes during the three-year baseline.
- **Special designations.** While Congress typically extends the Medicare-dependent hospital program and low-volume hospital payment adjustment, both are set to expire on September 30, 2025, and Congress has not yet acted to extend them further. CMS therefore could not assume these programs will continue for FY 2026, and the final rule reflects this.
- **New technology add-on payments.** For new technology add-on payment applications for FY 2027 onward, CMS finalized one minor policy change and broadened the application details that it will publicly post online (starting with FY 2027 applications).
- **Quality reporting programs.** CMS signaled future quality measure concepts supporting the Trump administration's Make America Healthy Again priorities of well-being and nutrition and finalized proposals to remove quality measures on health equity and social determinants of health.

- **HTI-4 and electronic prior authorization.** The IPPS rule includes the Health Data, Technology, and Interoperability: Electronic Prescribing, Real-Time Prescription Benefit and Electronic Prior Authorization Rule (HTI-4). This final rule from the Assistant Secretary for Technology Policy outlines new and revised standards and certification criteria for prescription benefit information and prior authorization.
- **Wage index.** CMS will discontinue the low wage index policy but will implement a transitional policy to phase out the low wage index adjustment for affected hospitals.
- **Disproportionate share hospital payments and uncompensated care payments.** Finalized uncompensated care payments and supplemental payments for FY 2026 total $7.8 billion, a 35.2% increase from the FY 2025 total of $5.78 billion.
- **Graduate medical education.** CMS finalized technical changes to the calculation of full-time-equivalent resident counts, caps, and three-year rolling averages for direct graduate medical education. CMS did not finalize proposed technical changes to the calculation of net nursing and allied health education costs.

For a more detailed analysis, check out this M+ article.

OIG UPDATES

OIG ISSUES FAVORABLE ADVISORY OPINION ON PHARMACEUTICAL MANUFACTURER'S TRAVEL AND LODGING ASSISTANCE PROPOSAL

OIG issued a favorable advisory opinion regarding a pharmaceutical manufacturer's proposal to provide assistance for certain travel, lodging, and associated expenses for qualifying patients receiving its autologous hematopoietic stem-cell based gene therapy. This product is the only US Food and Drug Administration (FDA)-approved treatment indicated for a deadly disease that is caused by a gene mutation and impacts fewer than 40 children annually in the US. The product is a one-time therapy shown to restore function and stop or slow the disease progression. Treatment involves multiple stages, including consultation, blood transfusions, mobilization and apheresis, creation of the product, conditioning, infusion, and recovery, which can span more than eight weeks. Requestor plans to qualify up to 10 treatment centers to provide the product, based on objective criteria.

Under the proposed arrangement, requestor would offer patients and up to two caregivers assistance to cover airfare or ground transportation, lodging, and other support (*e.g.*, daily meals and incidentals) during the treatment center stay. The support would be limited to patients who are residents of the US or a US territory; whose income is below 600% of the federal poverty level; and who meet program distance requirements, do not receive any other assistance, and have an on-label prescription for the product. Requestor would not promote the arrangement and would use a vendor to determine a patient's eligibility for the arrangement.

OIG concluded that while the proposed arrangement does not satisfy an AKS safe harbor, it does not present a material risk under the AKS for the following reasons:

- The arrangement removes a barrier to accessing medically necessary care furnished by treatment centers, as patients may live a significant distance from the closest center.
- The arrangement facilitates compliance with the instructions of the healthcare provider for the patient to remain at the treatment center for the duration of the treatment.
- The product is a one-time treatment, which differs from other arrangements that may pose problematic seeding issues.
- The requestor certifies that it will not authorize the arrangement for expenses covered by other means (*e.g.*, insurance, third-party charitable assistance) and that it will not promote the arrangement.

OIG concluded that the arrangement satisfies the promotes access to care exception to the beneficiary inducements civil monetary penalty law because there are a limited number of treatment centers, an extended inpatient stay is necessary for treatment, and the arrangement poses a low risk of harm to Medicare and Medicaid beneficiaries.

OIG ISSUES FAVORABLE ADVISORY OPINION ON PHARMACEUTICAL MANUFACTURER'S COMPANION LABORATORY TEST PROPOSAL

OIG issued a favorable advisory opinion regarding a pharmaceutical manufacturer's proposal to sponsor a companion laboratory test for eligible patients before a provider can prescribe a certain prescription drug manufactured by the requestor. The drug is an enzyme inhibitor that impacts certain tumor cells with a particular gene mutation. The drug is FDA-approved for treatment of adult patients with the gene mutation. A laboratory test was developed to test for the gene mutation as an FDA-approved companion diagnostic for the drug and is typically covered by federal healthcare programs and private insurance. A positive test result indicates treatment with the drug may be appropriate, whereas a negative result would indicate treatment with the drug is not appropriate. Notably, the competitor drug product is indicated regardless of gene mutation. Requester asserted that the test has no independent value as it is only used to identify whether a patient has the gene mutation.

Under the proposed arrangement, requestor would offer the laboratory test to eligible patients for free. Patients would be eligible if they have a negative test result from a prior genetic test for the mutation, a previously collected tumor tissue sample is available to be tested, use of the test is consistent with the FDA labeling, and the patient has not previously received the laboratory test. The arrangement would be open to all eligible patients in the US regardless of income or insurance status. The provider must order the test after attesting to the patient's eligibility, clinical appropriateness of the test, that the provider is not seeking reimbursement for the test, and that the provider has obtained the necessary informed consent. Requestor would contract with a laboratory to perform the tests for a fixed fee and would not provide the test outside of the arrangement. Requestor certified that providers lack awareness of the gene mutation. Accordingly, the requestor's field personnel undertake passive, nonpromotional disease-awareness activities through leave-behind pamphlets discussing the gene mutation without reference to brand or drug.

OIG concluded that while the proposed arrangement does not satisfy an AKS safe harbor, it does not present a material risk under the AKS for the following reasons:

- The arrangement is unlikely to result in overutilization or inappropriate utilization, skew clinical decision-making, or result in unfair competition as the competitor drug is indicated regardless of gene mutation and requestor does not require providers who order the test to prescribe requestor's drug product. Indeed, in half the cases, the test may result in the prescribing of the competitor drug.
- The distributed materials do not take into account a provider's usage of the arrangement or history prescribing the drug, and the partner laboratory does not provide requestor with any individually identifiable health information.

OIG also concluded that the arrangement satisfies the promotes access to care exception to the beneficiary inducements civil monetary penalty law because the free test could improve a beneficiary's ability to obtain items and services, and the arrangement poses a low risk of harm to Medicare and Medicaid beneficiaries.

OIG ISSUES NEGATIVE ADVISORY OPINION ON MEDICAL DEVICE COMPANY'S VENDOR PORTAL PROPOSAL

OIG issued a negative advisory opinion regarding a medical device company's proposal to pay to access an electronic billing system operated by a third-party vendor that some of the company's customers use for billing operations. Requestor provides "bill-only" surgical medical devices that are not part of a customer's regularly purchased inventory but rather purchased in real time as the surgeon selects the size or component to use during a surgery. Typically, bill-only items are delivered to a customer the day before a procedure, and the customer's staff records the used items to generate a purchase order that requester uses to generate an invoice for the customer to pay. Requestor certified that this process does not require a third-party vendor.

Under the proposed arrangement, requestor would pay the vendor an annual per-user licensing fee to access the vendor's bill-only portal to process the bill-only items for customers that selected the vendor's software. The requestor certified it has no access to vendor's agreements with customers and that vendor's advertising is directed toward providing services to customers, not medical device companies. Requestor certified that it has not identified any benefits or services it would receive from the portal because it has its own well-established team and process.

OIG concluded that the arrangement does not satisfy an AKS safe harbor and, based on the totality of the facts and circumstances, would pose enough risk to issue a negative opinion for the following reasons:

- Requestor would pay substantial fees to access the portal as part of an effort to retain business from customers despite the redundancy in services.

- The arrangement presents anticompetitive risks of inappropriate steering because customers find value in the portal and payments made by requestor to the vendor could incentivize the vendor to steer customers to requestor over competitors that do not pay the fee.

OTHER NOTABLE DEVELOPMENTS

$1.55 MILLION CCPA SETTLEMENT CONTINUES COOKIE FOCUS, SIGNALS INCREASING ENFORCEMENT

The California attorney general proposed a $1.55 million settlement with Healthline Media LLC for alleged violations of the California Consumer Privacy Act (CCPA) and the state's Unfair Competition Law. The case centers on the use of cookies that disclose sensitive health information. This marks the third cookie-related CCPA settlement in recent months, highlighting regulators' growing scrutiny of web-based consumer rights and online data collection disclosures. The attorney general's complaint reflects a broader interpretation of sensitive health data and stricter expectations for vendor due diligence. For more information, check out our *On the Subject*.

FDA FOOD DYE PHASE-OUT CONTINUES

On July 14, 2025, the FDA announced its approval of gardenia blue for use in various beverages and candies. This follows the May 2025 approval of three other natural color additives: galdieria extract blue, calcium phosphate (white), and butterfly pea flower extract (blue, purple, and green). The FDA also encouraged a faster phase-out of Red No. 3 and is moving to revoke authorization for Citrus Red No. 2 and Orange B. These actions align with the Make America Healthy Again Commission's priorities.

HDHP TELEHEALTH SAFE HARBOR PERMANENTLY REINSTATED

On July 4, 2025, the president signed the One Big Beautiful Bill Act (H.R. 1), which permanently reinstates the telehealth safe harbor for high-deductible health plans (HDHPs) starting in 2025. This provision allows HDHPs to offer telehealth services at low or no cost, expanding access for millions of individuals and dependents. The safe harbor is a major win for telehealth providers, health plans, and participants who advocated for its return. Explore more in this M+ article.

WHITE HOUSE RELEASES AI ACTION PLAN

On July 23, 2025, the White House released "Winning the Race: America's AI Action Plan," a document outlining nonbinding policy goals for federal regulation and support of AI. The plan emphasizes US manufacturing, deregulation, and trade, in alignment with existing administration priorities. While not legally binding, the document sets forth specific objectives that AI developers and deployers should monitor closely, especially as agencies are directed to accelerate innovation through reduced regulation. Dive deeper in our recent

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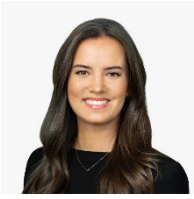

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