McDermott Will & Schulte

Healthcare Regulatory Check-Up

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February regulatory update summary

This issue of McDermott Will & Schulte's *Healthcare Regulatory Check-Up* highlights regulatory activity for February 2026, including two False Claims Act (FCA) settlements, a new Office of Inspector General (OIG) advisory opinion, and the US Department of Health and Human Services' (HHS's) 2027 Notice of Benefit and Payment Parameters proposed rule. We also discuss recent actions from the Centers for Medicare & Medicaid Services (CMS), including the agency's moratorium on certain Medicare durable medical equipment, prosthetics, orthotics, and supplies (DMEPOS) supplier enrollments; the deferment of millions in Medicaid funding to Minnesota over fraud, waste, and abuse concerns; and the agency's joint pledge with health plans to launch a new payment program aligned with CMS's ACCESS model. This issue also covers recent activity by the Health Resources and Services Administration (HRSA) and the US Food and Drug Administration (FDA).

Notable enforcement resolutions and activities

HHS TERMINATES 340B REBATE MODEL PILOT PROGRAM

Following a successful lawsuit filed by the American Hospital Association alleging that HRSA's 340B rebate model pilot program violated the Administrative Procedure Act, HRSA agreed to rescind the previously approved rebate models. These rebate models would have allowed HRSA-registered 340B covered entities to obtain certain drugs at the 340B price via post-purchase rebates, rather than through the upfront discounts that have been used since the program was established in 1992. Immediately following the cancelation of the 340B rebate model pilot program, HRSA issued a request for information (RFI) to gather stakeholder input for use in future rebate models.

DOJ AND SLEEP SPECIALIST SETTLE FCA ALLEGATIONS

A sleep specialist practice, two physicians, and a medical supply company agreed to pay more than $750,000 to resolve three sets of allegations stemming from a whistleblower lawsuit. The sleep practice and its two physician co-owners allegedly improperly billed federal healthcare programs for sleep studies conducted without certified sleep technicians, as required by federal regulations, and allegedly obtained nearly half a million dollars in Paycheck Protection Program loans while improperly billing. The medical supply company, owned by one of the two physicians involved in the

settlement, allegedly improperly billed Medicaid for positive airway pressure machine accessories. Medicaid regulations do not permit such machine accessories to be charged separately from the rental rate of the machine itself.

SURGICAL HOSPITAL AGREES TO PAY $5.6M TO RESOLVE FCA LIABILITY FOLLOWING SELF-DISCLOSURE

An Arizona surgical hospital agreed to pay $5.6 million to resolve FCA allegations that from 2011 through 2018, the hospital made improper financial contributions to a physician group that referred patients to the surgical hospital. The alleged improper financial contributions were in the form of interest payments on convertible bonds issued to the physician group by the surgical hospital. The surgical hospital disclosed the arrangement following an internal compliance review and investigation in 2019. The government alleged the arrangement violated both the physician self-referral law (Stark Law) and the Anti-Kickback Statute (AKS). The government credited the surgical hospital for its extensive cooperation in connection with the matter, including the provision of detailed and thorough written disclosures and the prompt implementation of remedial actions.

CMS regulatory updates

CMS DEFERS $259.5M IN MEDICAID FUNDING TO MINNESOTA OVER FRAUD CONCERNS

Following a review of Minnesota's Medicaid spending in the fourth quarter of fiscal year 2025, CMS announced it will defer nearly $259.5 million in federal matching funds to Minnesota's Medicaid program until the agency is satisfied with the state's corrective action plan to address ongoing program integrity concerns. CMS stated that the deferred payments include state expenditures of $243.8 million for potentially fraudulent or unsupported Medicaid claims and $15.4 million related to claims involving individuals without satisfactory immigration status. CMS stated that its review included both traditional financial management approaches and new program integrity oversight strategies to identify unusual spending and growth in several service areas, including personal care services and home- and community-based services. CMS alerted Minnesota that it intends to conduct further review of the state's Medicaid program and warned that it could defer up to $1 billion in payments over the next year.

CMS ANNOUNCES NATIONWIDE MORATORIUM ON CERTAIN MEDICARE DMEPOS ENROLLMENTS

On February 27, 2026, CMS published a notice in the *Federal Register* announcing a six-month moratorium on Medicare enrollments for certain DMEPOS suppliers, effective immediately. CMS stated that the moratorium is necessary to allow the agency to explore additional safeguards to mitigate fraud, waste, and abuse by DMEPOS suppliers. In the notice, CMS justified the moratorium by pointing to specific examples of medical supply companies involved in alleged fraud schemes, CMS's consultation with federal law enforcement agencies, and CMS's analysis of DMEPOS claims and reimbursement data.

The moratorium applies to "medical supply companies," defined as "business[es] whose principal function is to furnish DMEPOS supplies (regardless of supply type) directly to another party, such as, but not limited to: (1) beneficiaries with a medical order (for example, via mail order); (2) medical providers and suppliers; or (3) both." This definition includes medical supply companies with orthotics, pedorthics, and prosthetics personnel and those employing registered pharmacists and respiratory therapists. The moratorium does not apply to other types of DMEPOS suppliers that do not meet this definition, such as hospitals, home health agencies, pharmacies, physician groups, grocery stores, or other entities with DMEPOS enrollments, if their primary purpose is not the furnishing of DMEPOS.

The moratorium applies to initial enrollments or changes in majority ownership that require an initial enrollment. The moratorium generally prevents affected DMEPOS suppliers from enrolling new locations at a different address since these typically require initial enrollments. It also affects changes in ownership that trigger initial enrollments, including certain changes in majority ownership of a DMEPOS supplier that occur with 36 months of the supplier's initial enrollment or the supplier's most recent change in majority ownership. The moratorium does not affect changes in

practice location, changes in provider or supplier information (*e.g.*, phone number or address), or changes in ownership that do not require an initial enrollment.

CMS encouraged states to consider implementing their own moratoriums on Medicaid and Children's Health Insurance Program (CHIP) DMEPOS enrollments. However, since most states require suppliers to be enrolled as Medicare DMEPOS suppliers before enrolling in a state program, the moratorium on Medicare enrollments may effectively extend to Medicaid and CHIP enrollments, unless states waive this requirement. CMS also stated that it intends to publish information on providers and suppliers whose participation in Medicare has been revoked and the reason for the revocation.

CMS RELEASES UPDATED MEDICARE OUTPATIENT OBSERVATION NOTICE

On February 20, 2026, CMS released an updated Medicare Outpatient Observation Notice (MOON), which hospitals and critical access hospitals are required to provide to Medicare beneficiaries who receive observation services as outpatients for more than 24 hours. The MOON is intended to inform these patients that their hospital stay is outpatient, not inpatient, and to inform them of the implications of that outpatient status. CMS said the MOON was updated to improve readability and design. The newly released MOON is effective through February 28, 2029, and hospitals are required to begin using the new MOON starting April 21, 2026. Delivery of the MOON is a condition of participation for Medicare providers and failure to deliver the MOON as required can result in penalties such as a deficiency citation for noncompliance.

HHS PROPOSES SWEEPING CHANGES TO ACA EXCHANGE POLICIES

In the 2027 Notice of Benefit and Payment Parameters proposed rule, published in the *Federal Register* on February 11, 2026, HHS pitched an expansive set of changes to the standards that qualified health plans participating in the Affordable Care Act (ACA) marketplace must comply with and new requirements for state-based exchanges, brokers, and agents. The proposed changes include expanding the availability of catastrophic plans, adding examples of prohibited marketing practices for agents and brokers, and increasing required income verification checks during special enrollment periods.

OIG updates

OIG ISSUES FAVORABLE ADVISORY OPINION 26-02 ON LAB SERVICES ARRANGEMENT

On February 12, 2026, OIG issued Advisory Opinion 26-02, concluding that a proposed arrangement in which an urgent care management entity would provide laboratory services to its affiliated urgent care centers would not generate prohibited remuneration under the AKS.

The requestor is a management entity affiliated with four urgent care centers operated through various management companies and one affiliated professional corporation. Because of state corporate practice of medicine restrictions, the requestor does not own the professional corporation that holds the urgent care licenses. However, the requestor oversees and manages all four centers and holds ownership interests in the management companies associated with each site.

Under the proposed arrangement, the requestor would own and operate an independent clinical laboratory through a separate legal entity. The laboratory would perform clinical testing for the affiliated urgent care centers but would be located offsite and would not be owned or operated by any individuals or entities in a position to refer specimens.

OIG ultimately determined that the AKS would not be implicated because neither the requestor nor the laboratory would provide any remuneration to induce referrals. OIG highlighted several key safeguards:

- The laboratory would directly bill federal healthcare programs and other payors and would not bill the urgent care centers or other providers for services furnished.
- Patients of the urgent care centers would receive written notice of the affiliation and would retain the option to have their tests sent to an unaffiliated laboratory.
- Urgent care center personnel would not be required to send specimens to the laboratory.
- The requestor would not track referrals from the urgent care centers.
- The urgent care centers' electronic health record system would allow ordering from multiple laboratories without preference.
- The laboratory would accept specimens only when consistent with payor contracts and patient insurance coverage.
- Compensation for urgent care center providers and suppliers would not be tied to the volume or value of tests ordered from the laboratory.
- No remuneration would flow from the laboratory to the urgent care centers.
- The requestor would not share laboratory-related revenue, directly or indirectly, with the urgent care centers.

This opinion provides a roadmap for management companies of urgent care centers seeking to structure affiliated laboratory arrangements to mitigate AKS risks. OIG concluded that management entities may own and operate clinical laboratories serving affiliated sites as long as referral influence is sufficiently separated from ownership. Key compliance considerations include maintaining a distinct physical location for the laboratory, implementing direct billing to payors, disclosing the affiliation to patients, preserving patient choice, and ensuring no remuneration is based on referrals of specimens to the laboratory. However, the opinion does not address management companies with physician practices and physician ownership in the management company. Additional analysis may be needed for these arrangements.

OIG ISSUES AUDIT REPORTS FOR MISSOURI, WEST VIRGINIA ON FAILURE TO OBTAIN REBATES FOR MEDICAID OUTPATIENT DRUGS

Two recent OIG audits conducted in Missouri and West Virginia resulted in recommendations that the states refund the federal government for their failure to obtain rebates from manufacturers for certain Medicaid physician-administered drugs. States are required to collect these rebates from manufacturers for covered outpatient drugs to be eligible for federal reimbursement. An audit report issued on February 11, 2026, found that Missouri did not invoice for or receive $9.7 million in manufacturer rebates for physician-administered drugs and $2.5 million for pharmacy drugs. OIG also found that Missouri failed to invoice manufacturers for rebates totaling $165,783 for other physician-administered drugs that may have been eligible for rebates. A separate audit report issued on February 10, 2026, found that West Virginia did not invoice for or receive an estimated $6.1 million in manufacturer rebates for physician-administered drugs dispensed to Medicaid managed care organization enrollees.

In both audit reports, OIG recommended that the states refund the federal government for the value of the rebates they should have obtained from the manufacturers of the physician-administered or pharmacy drugs. OIG additionally recommended that Missouri work with CMS to determine how much of the $165,783 for other physician-administered drugs may have been required to be rebated. In a response to the report, Missouri agreed to this recommendation but did not indicate concurrence or nonconcurrence with OIG's other recommendations. West Virginia indicated nonconcurrence with OIG's recommendations in its response. Both states included a description of corrective actions they had taken and planned to take with regard to future rebates.

Other notable developments

HRSA REQUESTS INFORMATION ON 340B REBATE PROGRAM

After withdrawing the previously approved 340B rebate models earlier this month, the HRSA issued an RFI seeking stakeholder input on the potential use of rebates to "effectuate the ceiling price under the 340B Program, including the standards and procedures that should govern the approval of manufacturer rebate plans and the impacts on all stakeholders." HRSA aims to gather information that will help the agency assess how a rebate-based model might affect manufacturers, covered entities, and other participants across the drug supply chain operationally, financially, and with respect to patient access to drugs. HRSA requests feedback on potential cash-flow implications, data supporting the use of rebates to effectuate the ceiling price, and possible alternatives or scope-limiting measures to inform a future rebate pilot. The deadline for submitting comments has been extended to April 20, 2026.

FDA TO DROP TWO-STUDY REQUIREMENT FOR NEW DRUG APPROVALS

On February 18, 2026, FDA Commissioner Marty Makary and a top deputy, Vinay Prasad, published an article in the *New England Journal of Medicine* announcing FDA's plan to drop its two-study requirement for new drug approval with the goal of reducing sponsor costs and speeding drugs to market. Moving forward, FDA will require only one clinical trial in combination with confirmatory evidence, such as clinical evidence from a trial for a related indication, evidence from a relevant animal model, or real-world data. The piece clarifies that two studies may still be required for interventions with a "nebulous, pluripotent, or nonspecific mechanism of action," or if there is an "underlying limitation or deficiency" in the trial.

FDA ISSUES UNTITLED LETTER TO JANSSEN BIOTECH FOR FALSE OR MISLEADING ADVERTISING

On February 6, 2026, FDA sent an untitled letter to Johnson & Johnson's Janssen Biotech unit regarding its advertising of the ulcerative colitis drug Tremfya. According to the letter, Janssen's direct-to-consumer television advertisement "is false or misleading" because it made multiple claims that "many people" or "~1 out of 2 patients" treated with Tremfya would achieve clinical remission at one year and maintain their remission through two years despite clinical evidence to the contrary. FDA further took issue with the advertisement's claim that "healing is possible" with Tremfya. The letter asserted that the claim of a curative effect was misleading because it overstated Tremfya's efficacy. FDA also flagged as misleading the advertisement's omission of material risk information pertaining to infection. The letter concluded by declaring that the TV ad misbrands Tremfya and makes its distribution in violation of the Food, Drug, and Cosmetic Act, and requested a response within 15 working days to address the violations and Janssen's plan to remediate them.

CMS ANNOUNCES PLEDGE BY HEALTH PLANS TO LAUNCH DIGITAL PAYMENT MODELS

Health plans representing 165 million beneficiaries across Medicare Advantage, Medicaid managed care, and private insurance signed a pledge with CMS to adopt an outcomes-based payment model aligned with CMS's Advancing Chronic Care with Effective, Scalable Solutions (ACCESS) model, according to an announcement from CMS. The ACCESS model ties Medicare digital health reimbursement payments to the impact of technology-supported care on patient outcomes and is intended to incentivize flexibility in care delivery and payer coordination with primary care clinicians. Participation in the ACCESS model is limited to Medicare Part B-enrolled providers, but payers that join the pledge commit to offering their own payment arrangements aligned with the ACCESS model's core principles by January 1, 2028. CMS stated that it is developing a series of optional alignment resources for health plans that take the pledge, to be released later this year.

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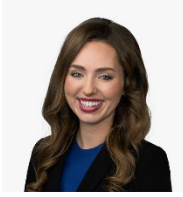

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