McDermott Will & Schulte

Healthcare Regulatory Check-Up

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November regulatory update summary

This issue of McDermott Will & Schulte's *Healthcare Regulatory Check-Up* highlights regulatory activity for November 2025. Regulators are signaling clear priorities: stronger enforcement, modernization of compliance standards, and expanded access to care. Recent enforcement actions underscore risks tied to billing accuracy, kickbacks, and Emergency Medical Treatment and Labor Act (EMTALA) compliance. The Centers for Medicare & Medicaid Services (CMS) advanced sweeping updates, including telehealth extensions and hospital and ambulatory surgical center (ASC) payment reforms, and pursued cost-control initiatives such as drug price negotiations and new Medicaid rebate models. Providers should focus on compliance readiness, digital infrastructure, and strategic planning to navigate these changes effectively.

Notable cases, settlements, and related agency activity

DRUGMAKER WINS DEFENSE VERDICT IN KICKBACK AND MEDICAID FRAUD TRIAL

After more than a decade of litigation, on November 7, 2025, a pharmaceutical manufacturer prevailed in a closely watched case involving allegations of kickbacks and Medicaid fraud tied to a hemophilia treatment. The state of Washington and a whistleblower claimed the company improperly promoted off-label and high-dose use of the drug and provided financial inducements to physicians and patients, allegedly resulting in false claims to government programs.

In closing arguments, plaintiffs urged jurors to "send a message" to the company, pointing to paid lectures, patient events, and assistance programs as evidence of unlawful inducement. However, following a two-week trial, the jury deliberated for less than four hours before returning a full defense verdict. The jury found no liability under the federal False Claims Act (FCA) or state statute, rejecting claims that the company's promotional activities constituted fraud or

kickbacks. The manufacturer maintained throughout the case that its conduct complied with regulatory standards and that there was no evidence linking its actions to improper remuneration.

The verdict underscores the evidentiary challenges in proving causation and intent in off-label promotion and Anti-Kickback Statute (AKS) cases. For pharmaceutical companies, the decision highlights the importance of robust compliance frameworks and documentation when engaging in patient support and educational initiatives.

MEDICAL DEVICE COMPANY TO PAY $38.5M TO SETTLE FCA ALLEGATIONS OVER FAULTY KNEE IMPLANT, KICKBACKS

On November 17, 2025, a medical device subsidiary of a global medical and pharmaceutical company agreed to pay $38.5 million to resolve allegations that it violated the FCA by marketing a knee implant that it allegedly knew would fail at a higher than acceptable rate and, as such, was not reasonable and necessary for use during knee replacement surgeries. The government alleged that the knee implant system was marketed despite concerns about its ability to properly adhere to bone cement, leading to loosening and, in some cases, revision surgeries. Prosecutors claimed these failures rendered the device neither reasonable nor necessary for knee replacement procedures, resulting in false claims to Medicare and Medicaid.

The settlement also addresses allegations that the company violated the AKS by providing unlawful inducements, including free international travel and entertainment, to an orthopedic surgeon who experienced problems with the implant. In addition to the civil settlement, the DOJ entered a nonprosecution agreement related to two devices sold without US Food and Drug Administration (FDA) clearance after a former employee forged clearance documents. Both devices were later recalled, purchasers reimbursed, and FDA clearance obtained.

The litigation, which began in 2017 as a whistleblower suit, underscores the enforcement risks tied to product performance issues and marketing practices. For medical device manufacturers, this case highlights the importance of promptly addressing adverse event reports, maintaining accurate regulatory submissions, and ensuring compliance with anti-kickback and FDA requirements to avoid significant liability. Both kickbacks related to drugs and devices, and "materially defective medical devices that impact patient safety" are on the priority list of the US Department of Health and Human Services (HHS)-US Department of Justice (DOJ) False Claims Act Working Group.

SENIOR LIVING OPERATOR COMMITS TO $7M IN STAFFING, FACILITY UPGRADES TO RESOLVE INVESTIGATION

On November 19, 2025, a senior living operator agreed to invest $7 million in staffing and upgrades to resolve an investigation by the Washington State Office of the Attorney General into the operator's practices at multiple facilities. From 2019 to 2024, the company allegedly failed to provide medication assistance, housekeeping, maintenance, dining, infection control, and resident care services in certain instances at 10 of its 15 facilities in Washington state. The attorney general's office asserted that this conduct likely violated the state's Consumer Protection Act.

The agreed order resolves the state's claims without further litigation or admission of liability, providing finality for both parties. It also reflects heightened regulatory scrutiny of senior living operators and their obligations to maintain consistent standards of care. For industry operators, this outcome highlights the importance of robust compliance programs, clear documentation, and proactive oversight of resident services to mitigate risk and ensure adherence to consumer protection requirements.

BEHAVIORAL HEALTH PROVIDER SUES PLAN OVER EARLY CONTRACT TERMINATION, TELEHEALTH TRANSITION

A behavioral health provider filed suit against a major health plan, alleging violations of state healthcare laws after the plan terminated its provider agreement early and transitioned patients to a telehealth-based model. The complaint

claims the termination disrupted care for more than 7,800 patients and violated state statutes governing notice and contracting requirements.

According to the lawsuit, the health plan moved to a telehealth-focused approach in 2024 to reduce costs, steering patients to a third-party provider and removing the behavioral health provider from directories while the agreement was still in effect. The provider alleges that the plan failed to provide required notice before termination, retroactively reduced reimbursement rates, and conducted an audit that violated state law by recalculating claims beyond the permissible adjustment window. The audit concluded that the provider owed nearly $5.4 million in overpayments, a figure the provider disputes.

The suit brings eight claims, including breach of contract and violations of consumer protection and fair contracting statutes. The provider seeks declaratory and injunctive relief, arguing that the plan's actions interfered with patient-provider decision-making and caused confusion and distress among thousands of patients.

CMS regulatory updates

CONGRESS EXTENDS KEY MEDICARE TELEHEALTH FLEXIBILITIES INTO 2026, MAKES BEHAVIORAL HEALTH PROVISIONS PERMANENT

Recent federal legislation extended many Medicare telehealth flexibilities originally adopted during the COVID-19 public health emergency (PHE). These extensions allow Medicare patients to receive non-behavioral telehealth services in their homes through January 30, 2026, with no geographic restrictions on originating sites. All eligible Medicare providers, including federally qualified health centers (FQHCs) and rural health clinics (RHCs), may serve as distant site providers for these services during the extension period. While there has generally been bipartisan support for extension of the telehealth flexibilities, the timing of an additional extension past January 30, 2026, is unknown.

Audio-only telehealth remains permitted for non-behavioral services through January 30, 2026, and certain payment provisions for FQHCs and RHCs will continue through December 31, 2026. For behavioral health, Congress made permanent several flexibilities patients can receive telehealth services at home without geographic limits, and audio-only platforms are allowed. Marriage and family therapists and mental health counselors are now permanently recognized as distant site providers. Congress also waived the in-person visit requirement for behavioral health telehealth services through January 30, 2026.

These updates reflect a consistent expansion of telehealth access, particularly for rural and behavioral healthcare, although waiver flexibilities remained in place through the PHE. Providers should review these changes to ensure compliance with extended timelines and leverage opportunities to improve patient access under the updated Medicare telehealth framework.

For more details, refer to CMS's telehealth FAQ. Congress has repeatedly addressed Medicare telehealth flexibilities through short-term extensions, included in government funding legislation, resulting in a series of temporary extensions rather than permanent statutory changes. This legislative approach has contributed to ongoing uncertainty regarding the long-term availability of certain telehealth waivers.

MODERNIZATION OF CLIA STANDARDS AND IMPACT ON LABORATORIES

The Centers for Medicare & Medicaid Services (CMS) finalized significant updates to CLIA in late 2024 (the first major overhaul in more than 30 years) with implementation continuing through 2025 and 2026. As part of CMS's digital modernization efforts, all CLIA-certified labs must transition to electronic communications and online fee payments by March 1, 2026. Additional changes cover emerging technologies such as molecular diagnostics and artificial intelligence (AI)-assisted tools, along with stronger enforcement measures, including civil penalties and public posting of deficiencies. Laboratories should act now to update staffing policies, review testing programs, prepare for digital

requirements, and validate new technologies to avoid penalties and reimbursement risks. For more information on CMS's CLIA updates and implementation dates, see our client alert.

CMS FINALIZES 2026 OPPS AND ASC RULE

CMS finalized the calendar year 2026 Outpatient Prospective Payment System (OPPS) and ASC Payment System rule, which includes several important changes that will take effect January 1, 2026. Payment rates for hospital outpatient departments and ASCs will increase by 2.6%, reflecting a 3.3% market basket update offset by a 0.7% productivity adjustment. CMS estimates these updates will result in about $101 billion in total OPPS payments and $9.2 billion for ASCs in 2026.

Beyond the rate increase, the rule includes significant policy shifts. For example, CMS expanded site-neutral payment policies, applying Physician Fee Schedule-equivalent rates to drug administration services in excepted off-campus hospital outpatient departments. This change is expected to reduce OPPS spending by about $290 million next year. The agency will also begin a three-year phase-out of the inpatient-only list, starting with the removal of 285 procedures, which will give patients more flexibility in choosing care settings and may lower out-of-pocket costs.

Hospitals should also prepare for enhanced price transparency requirements. Starting April 1, 2026, facilities must publish actual allowed amounts, adopt standardized reporting formats, and provide CEO attestations of compliance. Noncompliance will carry monetary penalties. CMS has made virtual direct supervision permanent for most outpatient therapeutic and diagnostic services, allowing real-time audio/video oversight to continue as a standard practice.

Other notable updates include separate payment for skin substitute products, changes to quality reporting programs, and the launch of a nationwide drug acquisition cost survey to inform future payment policy. CMS retained the previously codified 0.5% annual reduction to the OPPS conversion factor for non-drug items as part of the 340B remedy but signaled that it may consider larger offsets for 2027.

These changes will impact operational planning, compliance, and financial strategies for providers. Hospitals and ASCs should review service mix, site-of-care decisions, and reporting infrastructure to ensure readiness for the new requirements and mitigate potential revenue risks. For more information on the final rule, refer to the CMS fact sheet.

DC CIRCUIT TESTS AGENCY AUTHORITY OVER 340B PRICING STRUCTURE CHANGES

The US Court of Appeals for the District of Columbia Circuit is considering whether drug manufacturers can unilaterally shift from upfront discounts to a rebate-based system under the federal 340B drug pricing program, or whether they need approval from HHS. The program requires drugmakers to provide discounted outpatient drugs to certain healthcare entities serving low-income patients as a condition for Medicaid and Medicare Part B coverage.

Drug companies argue that rebates are standard business practice and should not require preapproval. They point to similar arrangements allowed under the AIDS drug assistance program. The government maintains that statutory defaults require agency oversight, and that a change to a rebate-based system could impose significant financial burdens on hospitals, which would need to pay full price upfront and wait for reimbursement.

The litigation, comprising five separate suits, raises fundamental questions about statutory interpretation and agency authority. The outcome will determine whether manufacturers can reshape discount structures without regulatory consent, a decision with broad implications for providers, patients, and the integrity of the 340B program.

MEDICAID GENEROUS MODEL AIMS TO LOWER DRUG COSTS, EXPAND ACCESS

CMS announced a new initiative called the GENErating cost Reductions for US Medicaid (GENEROUS) model. This voluntary program aims to address high prescription drug costs in the United States. Launching January 1, 2026, and running through December 31, 2030, the GENEROUS model introduces most favored nation (MFN) pricing principles to Medicaid. Under this approach, participating drug manufacturers will provide supplemental rebates to states so that

Medicaid pays prices comparable to those in other developed countries. The goal is to reduce Medicaid spending on prescription drugs while improving access to essential medications for vulnerable populations.

Participation is voluntary for both manufacturers and states. Manufacturers that join must already participate in the Medicaid drug rebate program and must agree to offer MFN-level pricing across their portfolio of covered outpatient drugs. States that opt in will gain access to CMS-negotiated supplemental rebate agreements with standardized coverage criteria and utilization management policies. Key features of the model include:

- **International benchmarking.** CMS will calculate MFN prices using a basket of countries that includes the other G-7 nations plus Denmark and Switzerland. The benchmark will be based on the second-lowest manufacturer-reported net price in these countries, adjusted for GDP per capita using purchasing power parity.

- **Supplemental rebates.** States will invoice manufacturers for rebates that bring net Medicaid prices in line with these international benchmarks. CMS will oversee the process and audit manufacturer-reported data to ensure accuracy.

- **No impact on best price or 340B.** CMS clarified that supplemental rebates under the GENEROUS model will not affect Medicaid best price calculations or 340B ceiling prices, reducing compliance concerns for manufacturers.

Manufacturer applications are open now through March 31, 2026. Manufacturers and states must finalize participation agreements by August 31, 2026.

CMS FINALIZES SECOND ROUND OF MEDICARE DRUG PRICE NEGOTIATIONS

CMS announced the results of its second round of drug price negotiations under the Inflation Reduction Act, furthering efforts to reduce prescription drug costs for Medicare beneficiaries. These negotiations, finalized in late November 2025, set new prices for 15 high-cost medications (including diabetes and weight-loss drugs) that will take effect on January 1, 2027. CMS negotiated maximum fair prices for drugs that represent some of the highest spending under Medicare Part D. The new prices reflect an average 44% reduction compared to 2024 net spending, translating into $8.5 billion to $12 billion in projected annual savings for Medicare and taxpayers. CMS expects these savings to reduce out-of-pocket costs for beneficiaries by an estimated $685 million per year.

Ozempic and Wegovy, used for diabetes and weight management, will see a 71% discount, with negotiated monthly costs of $274 for Medicare-covered indications. Other widely used drugs for cancer, lung disease, and chronic conditions will receive discounts ranging from 38% to 85%.

These reductions are part of the Inflation Reduction Act's Medicare drug price negotiation program, which empowers CMS to negotiate directly with manufacturers. The first round of negotiations, announced in 2024, covered 10 drugs and takes effect in 2026. Combined, the two rounds will bring negotiated prices to 25 drugs, representing roughly one-third of Medicare Part D spending.

For manufacturers, these changes mean significant pricing pressure and compliance obligations. Failure to agree to negotiated prices could trigger steep excise taxes or termination from the Medicare and Medicaid programs. Medicare Advantage and Part D plans will need to incorporate new pricing into formularies and adjust cost-sharing structures, while providers and pharmacies should anticipate changes in reimbursement and patient affordability, particularly for high-demand drugs such as GLP-1 therapies.

CMS will select another 15 drugs for negotiation in 2026, with pricing effective in 2028, followed by 20 drugs in 2027. These actions signal continued momentum toward lower drug costs and greater transparency in pricing.

OIG updates

OIG FINDS MEDICARE OVERPAID $377M FOR CONTINUOUS GLUCOSE MONITORS

A recent Office of Inspector General (OIG) report determined that Medicare Part B payments for continuous glucose monitors (CGMs) and related supplies significantly exceeded both supplier costs and retail market prices from July 2022 to June 2023. During that period, Medicare spent $377 million (69%) more than suppliers' acquisition costs, and 8% above suppliers' total estimated costs (which include overhead, delivery, etc.). The discrepancy was especially pronounced for CGM-related supplies: Medicare payments surpassed supplier acquisition costs by $359 million and exceeded retail prices by $290 million in a single year. OIG identified about $7 million in overpayments attributed to billing errors, including suppliers submitting claims for higher-tier devices than were provided.

To address these concerns, OIG recommended that CMS employ its competitive bidding authority and "inherent reasonableness" power to reduce payment rates. OIG also recommended targeted efforts to prevent improper billing code usage. CMS has already taken initial steps in this direction, including proposing a rule to bundle CGMs and supplies into a monthly rental model and to leverage its authority to adjust payments.

OIG AUDIT OF SKILLED NURSING FACILITY UNCOVERS $31.2M IN IMPROPER PAYMENTS

OIG audited Medicare Part A skilled nursing claims at a large for-profit New York City skilled nursing facility that participates in both Medicare and Medicaid. In reviewing 2020 – 2021 claims, OIG found that 99 of 100 sampled claims were noncompliant, resulting in $1.1 million in overpayments in the sample and an extrapolated $31.2 million in improper payments. Identified errors included missing documentation to support Patient Driven Payment Model (PDPM) codes, failure to meet Medicare's definition of skilled nursing care, and insufficient justification of medical necessity.

OIG attributed these deficiencies to weak compliance controls, inadequate verification of medical necessity and coding accuracy, and inconsistent documentation practices. It recommended refunding the $31.2 million, performing internal audits of claims from the audit and post-audit periods, and training staff on PDPM coding and documentation.

The provider disputed all findings, citing COVID-19 PHE-era waivers and arguing that OIG applied coding standards retroactively. The provider warned that repayment could cause major operational disruptions.

The audit highlights heightened OIG scrutiny of PDPM compliance and the significant financial and operational risks for skilled nursing facilities that fail to ensure accurate coding, documentation, and internal controls.

PENNSYLVANIA'S MEDICAID DRUG REBATE PRACTICES: KEY TAKEAWAYS FROM OIG'S 2025 AUDIT

OIG released its audit of Pennsylvania's Medicaid drug rebate program, focusing on physician-administered drugs dispensed to enrollees of Medicaid managed care organizations. This program is a cornerstone of Medicaid cost control, requiring drug manufacturers to pay rebates to states for covered outpatient drugs. These rebates help reduce program expenditures and ensure compliance with federal requirements.

The audit found that Pennsylvania largely met its obligations to invoice manufacturers for rebates. However, gaps in the process resulted in about $488,051 in missed rebates, including $284,617 owed to the federal government. These missed amounts primarily involved single-source and top-tier multiple-source drugs administered by physicians. The

shortfall was linked to incomplete invoicing and insufficient review of exclusion reports, which identify drugs eligible for rebates. To address these issues, OIG recommended that Pennsylvania take three key steps:

- Invoice manufacturers for the missed rebates and return the federal share once collected.
- Strengthen its review process for exclusion reports to ensure all rebate-eligible drugs are captured.
- Update policies and procedures to prevent similar gaps going forward.

Pennsylvania agreed with all recommendations and plans to implement corrective actions by May 2026.

For manufacturers, additional rebate invoices may be forthcoming. Managed care organizations should anticipate heightened oversight and potentially more rigorous reporting requirements. Providers and compliance teams must ensure accurate coding and documentation for rebate-eligible drugs to avoid financial exposure and compliance risks. This audit reflects a broader national trend: OIG has repeatedly flagged states for failing to invoice all eligible rebates, resulting in millions of dollars in lost savings. As states tighten controls, stakeholders should expect more aggressive enforcement and follow-up audits.

Other notable developments

INTERSTATE MEDICAL LICENSURE COMPACT EXPANDS IN 2025

The Interstate Medical Licensure Compact continues to grow as a key tool for physician mobility and telehealth access. As of late 2025, the compact includes 42 states, the District of Columbia, and Guam, with recent implementations in Arkansas, North Carolina, and Rhode Island, and legislation introduced in Massachusetts. Additional states, including New Mexico and New York, are considering bills for 2026. Key updates include the following:

- **Membership growth.** 44 jurisdictions now participate, streamlining licensure for physicians practicing across state lines.
- **Faster processing.** Average turnaround for expedited licenses is about 19 days, with more than 150,000 licenses issued since inception.
- **Expanded eligibility.** Recent changes broaden eligibility to include more specialties and license types, supporting behavioral health and telemedicine.
- **Telehealth impact.** The compact facilitates multistate telehealth practice, improving access to care in rural and underserved areas.
- **Policy enhancements.** Revised conflict-of-interest and reporting rules, plus procurement policy updates, prioritize transparency and compliance.

The compact offers a pathway for physicians to obtain multiple state licenses quickly, reducing administrative burdens and enabling faster deployment of care, especially for telehealth and *locum tenens* roles. Healthcare organizations should review credentialing processes and confirm compliance with compact requirements.

NURSE LICENSURE COMPACT UPDATE

The Nurse Licensure Compact continues to grow, now covering 41 states and two US territories, with recent implementations in Connecticut and Pennsylvania. Massachusetts enacted the compact and is preparing for rollout, and Alaska, Hawaii, and the District of Columbia are considering legislation to join. The compact allows nurses holding a

multistate license to practice across member states, both in person and via telehealth, without obtaining additional licenses. Key updates include the following:

- **Uniform licensure requirements.** The compact requires federal/state fingerprint-based background checks, NCLEX passage, and a clean disciplinary record.
- **60-day relocation rule.** Nurses must apply for a new multistate license within 60 days of moving to another compact state.
- **Enhanced reporting.** Disciplinary actions are now shared across all compact states via Nursys.

These changes improve workforce mobility, support telehealth expansion, and help address nursing shortages. Employers should review onboarding and compliance processes for multistate nurses and confirm adherence to compact requirements. These changes improve workforce mobility and access to care but require continued attention to state-specific scope-of-practice rules.

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