HEALTHCARE REGULATORY CHECK-UP

IN THIS JUNE 2025 ISSUE

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JUNE REGULATORY UPDATE SUMMARY

This issue of McDermott's *Healthcare Regulatory Check-Up* highlights regulatory activity for June 2025, including a new Centers for Medicare & Medicaid Services (CMS) innovation model; proposed rules with significant implications for durable medical equipment, prosthetics, orthotics, and supplies (DMEPOS) suppliers and Medicare enrollment; and rescission of Biden-era Emergency Medical Treatment and Labor Act (EMTALA) guidance with respect to hospitals' obligation to provide emergency abortion care. This month's summary features landmark Supreme Court of the United States decisions on preventive care under the Affordable Care Act (ACA) and gender-affirming care. We also discuss enforcement actions focusing on allegations under the federal Anti-Kickback Statute (AKS), the False Claims Act (FCA), and other fraud and abuse laws. This issue examines three advisory opinions issued by the US Department of Health and Human Services (HHS) Office of Inspector General (OIG) regarding a telehealth employee lease agreement, a proposed arrangement for a medical device company to cover the cost of exclusion checks for its customers, and a proposed arrangement under which a manufacturer would pay up to $2,500 for actual injuries caused by device failure during a warranty period. We also discuss recent US Department of Justice (DOJ) enforcement priorities.

NOTABLE CASES, SETTLEMENTS, AND RELATED AGENCY ACTIVITY

SCOTUS UPHOLDS GENDER-AFFIRMING CARE BAN UNDER RATIONAL BASIS REVIEW

On June 18, 2025, in *United States v. Skrmetti*, the Supreme Court upheld Tennessee Senate Bill (SB) 1, which prohibits healthcare providers from administering certain gender-affirming care to individuals under 18 for the purpose of treating gender dysphoria or related conditions or to enable a minor to identify with, or live as, an identity inconsistent with the minor's biological sex. Applying rational basis review, the Court concluded that the law does not violate the Equal Protection Clause. Chief Justice John Roberts, writing for the majority, determined that SB 1 does not classify based on sex or transgender status but rather on age and medical purpose, and therefore is not subject to heightened scrutiny. The Court reasoned that a "mere reference" to sex is insufficient to trigger heightened scrutiny, particularly in the medical context, in which certain treatments are uniquely connected to sex. The Court also reaffirmed its holding in *Dobbs* that legislation regulating a medical procedure that only one sex can undergo does not automatically trigger heightened scrutiny. Under rational basis review, legislation is presumptively constitutional as long as it is

rationally related to a legitimate government interest and not motivated by animus. The Court found that Tennessee's interest in protecting minors from potentially irreversible medical treatments satisfies this requirement.

The *Skrmetti* decision marks the first time the Supreme Court has addressed the constitutionality of state bans on gender-affirming care for minors. Although the Court issued a narrow holding, by applying rational basis review, the Court's ruling previews how other states' laws will be evaluated if challenged. The decision also may pave the way for states to enact both protective and restrictive legislation if the laws can be viewed as classifying based on age or medical use.

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SCOTUS HOLDS PREVENTIVE TASK FORCE RECOMMENDATIONS REMAIN LEGALLY BINDING MANDATES

On June 27, 2025, the Supreme Court ruled in *Kennedy v. Braidwood Management* that members of the US Preventive Services Task Force (Task Force) were inferior officers that do not require Senate approval. This ruling upheld the constitutionality of an ACA provision that changed Task Force recommendations from mere advisory statements to legally binding mandates.

The Task Force, a panel of individuals within HHS who are appointed, supervised, and subject to without-cause removal by its Secretary, issues evidence-based recommendations regarding preventive healthcare services in the form of lettered ratings. After the enactment of the ACA, most health insurers and group plans are required to cover, without patient cost sharing, any preventive services that receive an A or B rating. The Court held that despite the Task Force's authority to issue mandates that impose requirements upon health insurers and group plans, the appointment of Task Force members complies with the Appointments Clause of the Constitution because the mandates are subject to review by the HHS secretary.

The Court issued this opinion after the plaintiffs challenged mandatory coverage for HPV vaccines, contraception, and HIV prevention drugs on the basis that coverage would violate their religious beliefs. The case highlights legal battles at the intersection of medical care and social and religious issues. Notably, the Court did not address the petitioners' claims under the Religious Freedom Restoration Act, which remain active in the US District Court for the Northern District of Texas and may result in fragmented benefit designs and coverage obligations despite the mandatory coverage nature of Task Force-recommended preventive services.

SCOTUS REMANDS CHALLENGE TO NY REGULATION REQUIRING EMPLOYER-SPONSORED INSURANCE TO COVER ABORTIONS

In 2017, a New York state regulation required employer-sponsored health insurance plans to cover abortions but included a narrow exemption for employers whose primary purpose is the inculcation of religious values and that primarily employ and serve individuals of the same faith. *See* N.Y. Comp. Codes R. & Regs. tit. 11, § 52.16(o) & § 52.2(y). The Roman Catholic Diocese of Albany and others challenged the regulation as too restrictive and as an unconstitutional violation of their First Amendment rights.

The matter came before the Supreme Court twice, and in both instances the Court vacated the judgment of the New York Court of Appeals and remanded for further consideration. Most recently, on June 16, 2025, the Supreme Court remanded for consideration in light of the recently decided *Catholic Charities Bureau, Inc. v. Wisconsin Labor & Industry Review Comm'n*. 605 U. S. ___ (2025). In *Catholic Charities Bureau*, the Supreme Court affirmed that legislation that creates distinctions among religions based on specific

practices, rather than legislating neutrally for all religious groups, triggers strict scrutiny, and held the legislation at issue in that case to be unconstitutional. The challenge to New York's law will now return to the New York state courts for further proceedings.

JUDGE VACATES BIDEN-ERA RULE KEEPING ENTITIES FROM DISCLOSING ABORTION, GENDER-AFFIRMING CARE PHI UNDER MAJOR-QUESTIONS DOCTRINE

On June 18, 2025, Judge Kacsmaryk of the Northern District of Texas granted summary judgment to Carmen Purl, MD, owner of a walk-in clinic (Purl and the clinic, collectively the plaintiffs), in *Purl v. United States Dep't of Health and Hum. Servs.*, vacating a Biden-era HHS rule aimed at protecting the privacy of patients seeking abortion and certain gender-affirming care. The 2024 rule was a response to *Dobbs v. Jackson Women's Health Organization* and modified the Health Insurance Portability and Accountability Act (HIPAA) to keep regulated entities from using or disclosing individual protected health information (PHI) for the purpose of conducting an investigation or imposing criminal, civil, or administrative liability based on an individual's involvement in reproductive healthcare that was legal under the circumstances of its provision (*i.e.*, legal in the state and circumstances under which it was provided, or otherwise protected by federal law regardless of state in which care was provided).

In this case, the plaintiffs brought an action claiming that the rule was arbitrary and capricious and in excess of statutory authority in violation of the Administrative Procedure Act. The clinic is a HIPAA covered entity. The plaintiffs alleged that the rule caused harm by impairing Purl's and the clinic's employees' ability to report child abuse and participate in public health investigations, as well as imposing compliance-based costs on the clinic.

The court relied on three propositions in reaching its decision to grant summary judgment:

- The rule unlawfully limited state public health laws.
- The rule impermissibly contravened federal law in excess of statutory authority by redefining "person" and "public health."
- HHS lacked the authority to make this rule under the major-questions doctrine, which maintains that issues of certain importance cannot be delegated to agencies without explicit congressional approval.

The district court held that the US Court of Appeals for the Fifth Circuit's standard for triggering the major-questions doctrine was invoked for two reasons:

- By creating a "special protection" for a "politically favored" procedure, HHS resolved a matter of great political significance.
- Post-*Dobbs*, abortion is the sole province of state government, and by touching on the issue so explicitly, the rule created special political protections rather than merely addressing "private medical information."

On the matter of authority, the court held that Congress did not expressly delegate authority to HHS to distinguish between types of PHI for "political ends."

This case demonstrates judicial reluctance to uphold reproductive protections crafted by federal agencies post-*Dobbs*, suggesting a need to continue monitoring regulations that could be held to violate the major-questions doctrine, particularly those touching on controversial issues.

GEORGIA HOSPICE PAYS $9.2 MILLION TO SETTLE ALLEGED AKS AND FCA VIOLATIONS

In Georgia, a hospice and its affiliated companies paid $9.2 million to settle claims that they had violated the AKS and FCA by submitting claims after arranging for hospice patient referrals from medical directors. The alleged kickbacks included monthly stipends and signing bonuses paid to medical directors that increased with additional patient referrals and decreased in their absence.

According to the government, the investigation followed a complaint filed by a former hospice employee responsible for marketing hospice services, who claimed that kickbacks were paid to the medical directors to induce referrals.

This settlement is the latest in a long line of investigations and settlements related to medical director arrangements, highlighting the importance of close compliance review to manage AKS risks.

DOJ, OIG ANNOUNCE LARGEST NATIONAL HEALTHCARE FRAUD TAKEDOWN

On June 30, 2025, the DOJ and OIG announced the results of the 2025 national healthcare fraud takedown. The takedown is the culmination of interagency cooperation among CMS, OIG, DOJ, the Federal Bureau of Investigation, and state attorneys general to investigate and prosecute healthcare fraud across the industry. The takedown resulted in criminal charges against 324 defendants across 12 states, and involved $14.6 billion in intended loss. The takedown included enforcement actions across many sectors of the healthcare industry, including wound care, prescription opioids, telemedicine, and genetic testing. The breadth of enforcement actions highlights increased coordination and cooperation between federal agencies and state law enforcement, and demonstrates an ongoing commitment to enforcement of fraud and abuse laws.

CMS REGULATORY UPDATES

WISeR MODEL WILL MONITOR FRAUD AND ABUSE, ENHANCE PRIOR AUTHORIZATIONS

On June 27, 2025, the CMS Center for Medicare and Medicaid Innovation (CMMI) announced the new Wasteful and Inappropriate Service Reduction (WISeR) Model and issued a request for participant applications.

CMS intends to partner with technology companies to improve and expedite the prior authorization process under Medicare fee-for-service. The WISeR Model is intended to test whether artificial intelligence, machine learning, and other technologies can enhance the prior authorization processes for specific items and services that CMS has identified as particularly susceptible to fraud, waste, and abuse, similar to existing programs already used by commercial insurers. WISeR contractors, referred to as model participants, will be compensated based on demonstrated reductions in spending for medically unnecessary or non-covered items that can be directly attributed to the prior authorization review process in the applicable participants' region. The WISeR Model will be implemented in certain states and Medicare Administrative Contractor (MAC) jurisdictions. The states selected for participation are Arizona (MAC Jurisdiction JF), New Jersey (JL), Ohio (J15), Oklahoma (JH), Texas (JH), and Washington (JF). CMS anticipates selecting one model participant per MAC jurisdiction initially.

WISeR Model participants must meet certain criteria and must have clinicians with expertise appropriate for conducting medical reviews and validating coverage determinations. CMS states that such clinicians will apply standardized, transparent, and evidence-based procedures to their review and in issuing decisions. Providers whose prior authorization requests are "non-affirmed" will have unlimited chances to resubmit a request for a future service. Alternatively, if a provider decides to deliver the service and submit a claim, a denial of such claim by the MAC will constitute an initial payment determination, which will be subject to the current administrative appeals process already in place.

The WISeR Model does not change any Medicare coverage or payment criteria. The CMS fact sheet states that WISeR Model review will not apply to inpatient only services, emergency services, or services that would pose a substantial risk to patients if substantially delayed. Providers in the covered geographic region will choose between submitting prior authorization requests for the identified items and services covered by the WISeR Model or having the claim subject to pre-payment review. If the provider chooses to submit a prior authorization request, the provider will be able to do so either directly to a WISeR Model participant or to the applicable MAC, which will then forward the request to a WISeR Model participant. CMS stated that it "may include" a future "gold carding" pathway for exemption from WISeR Model review if a provider or supplier has a strong record of compliance.

The WISeR Model will begin January 1, 2026, and run for two three-year agreement periods (six years in total) until December 31, 2031. Applications for interested model participants are due July 25, 2025.

Given the payment incentive for CMS contractors to reduce spending on the covered items and services, impacted organizations should closely follow this model and ensure appropriate preparation and availability of information necessary to support coverage and to support prior authorization requests. For further discussion of the WISeR Model, please see this Regs & Eggs blog post from our colleagues at McDermott+.

CMS ISSUES CY 2026 HOME HEALTH PROSPECTIVE PAYMENT PROPOSED RULE

On June 30, 2025, CMS issued the CY 2026 Home Health Prospective Payment System proposed rule, which was published in the *Federal Register* on July 2, 2025. To be considered by CMS, comments must be received by 5:00 pm EDT on September 2, 2025.

> **"A significant component of this proposed rule seeks to revise the regulatory scheme governing DMEPOS suppliers that participate in federal healthcare programs.**

A significant component of this proposed rule seeks to revise the regulatory scheme governing DMEPOS suppliers that participate in federal healthcare programs. The proposed rule looks to tighten DMEPOS supplier accreditation requirements, announces an intent to resume and improve the competitive bidding process for certain DMEPOS, and introduces a prior authorization exemption for suppliers that maintain a high level of accuracy when billing claims.

The proposed rule would set much stricter reporting and oversight obligations for accrediting organizations while also requiring DMEPOS supplier surveys to be conducted annually rather than every three years as currently mandated. This move reflects CMS's ongoing program integrity concerns in the DMEPOS space and represents the first major update to the accreditation regulations since their adoption in 2006.

CMS also announced its intention to resume and improve the competitive bidding program, although the agency did not detail the expected timeframe for resumption or the product categories to be included. CMS proposes that all continuous glucose monitors and insulin infusion pumps be reclassified under the frequent and substantial servicing payment category, which would eliminate the need to wait five years to replace equipment. CMS seeks to establish a prior authorization exemption for DMEPOS suppliers that achieve and maintain a claim approval rate of 90% or higher.

This proposed rule also includes proposed changes to Medicare provider enrollment revocation effective dates and additional bases under which CMS may revoke or deactivate an enrollment. CMS proposes to add seven grounds under which a CMS revocation decision would take effect retroactively. The retroactive effective date of such a revocation would be the date indicated in the following scenarios:

- For revocations based on a lapse in an independent diagnostic testing facility's comprehensive liability insurance under 42 C.F.R. § 410.33(g)(6), the date the insurance lapsed.
- For revocations based on the provider's or supplier's submission of false or misleading information on the enrollment application, the date the application certification statement was signed.
- For revocations based on the provider's or supplier's failure to timely report a change of ownership or adverse legal action, or change, addition, or deletion of a practice location, the day after the date by which the provider or supplier was required to report the change, addition, or deletion.
- For revocations based on the surrender of the provider's or supplier's failure US Drug Enforcement Administration certificate of registration in response to a show cause order, the date the certificate was surrendered.
- For revocations based on the state's suspension or revocation of the physician's or supplier's ability to prescribe one or more drugs, the date of the suspension or revocation.
- For revocations of any of the provider's or supplier's other enrollments under 42 C.F.R § 424.535(i), the effective date of the revocation that triggered the revocations of the other enrollments.

- For revocations based on a DMEPOS supplier's noncompliance with a condition or standard in 42 C.F.R. § 424.57(b) or (c), the date on which the noncompliance began.

CMS believes each of these scenarios represent instances of action or inaction resulting in noncompliance or "otherwise concerning conduct."

CMS also proposes a clarification to amend its regulations to include revocation in situations where a beneficiary attests that a provider did not in fact furnish the services claimed by the provider, and to include deactivation for enrolled ordering and referring physicians and non-physician practitioners (enrolled via the Form CMS-855O) who have not ordered or certified services for 12 consecutive months.

CMS ISSUES CY 2026 END-STAGE RENAL DISEASE PROSPECTIVE PAYMENT SYSTEM PROPOSED RULE

On June 30, 2025, CMS issued the CY 2026 End-Stage Renal disease (ESRD) Prospective Payment System (PPS) proposed rule to update payment rates and policies for CY 2026. The ESRD PPS proposed rule was published in the *Federal Register* on July 2, 2025. Interested parties may submit comments through August 29, 2025.

The ESRD PPS proposed rule focuses on updating rates and payment methodologies for ESRD facilities. CMS proposes a 1.9% increase in the base rate for freestanding and hospital-based ESRD facilities. The rule also proposes changes to the ESRD Quality Incentive Program, which assesses facilities' total performance based on quality measures established for a specific payment year. Facilities that do not meet a minimum total performance score are assessed a payment deduction. CMS proposes to remove three reporting measures beginning in payment year 2027: facility commitment to health equity, screening for social drivers of health, and screen positive rate for social drivers of health. CMS concluded that the costs of such measures may outweigh the benefits to providers and patients.

CMS also proposes to terminate the ESRD Treatment Choices Model effective December 21, 2025, because the model has not shown the quality results initially projected for home dialysis and transplant waitlisting and expenditure savings.

CMS FINAL RULE ALLOWS ISSUERS TO REQUIRE INITIAL AND PAST DUE PREMIUM PAYMENTS, EXCLUDES DACA RECIPIENTS

On June 20, 2025, CMS issued a final rule creating new standards for Health Insurance Marketplaces and adding guardrails to the ACA access process. The rule finalizes the repeal of a past rule prohibiting issuers from denying health insurance coverage based on unpaid past-due premiums, permitting an issuer to require both initial and past-due premium payments to effectuate new coverage. The rule also amends the definition of "lawfully present" to exclude DACA recipients, making them ineligible to enroll in qualified health plans through the Marketplace. Beginning in 2026, issuers subject to essential health benefit requirements may not cover specified "sex trait modification procedures" as an essential health benefit. Beginning in 2027, the rule standardizes the open enrollment period for all individual market exchanges operating on both State and Federal platforms. These regulations become effective on August 25, 2025.

CMS RESCINDS REQUIREMENT THAT HOSPITALS PROVIDE EMERGENCY ABORTIONS TO STABILIZE PREGNANT PATIENTS

On June 3, 2025, HHS and CMS rescinded Biden-era guidance that required hospitals to provide emergency abortions when necessary to stabilize pregnant patients. The guidance, published in the wake of *Dobbs v. Jackson Women's Health Organization*, restated existing guidance for hospital staff and physicians regarding their obligations under EMTALA.

The EMTALA statute is a federal law that imposes certain obligations on Medicare-participating hospitals that offer emergency services. Under EMTALA, anyone coming to an emergency department requesting evaluation or treatment of a medical condition must receive a medical screening examination to determine whether an emergency medical condition exists. If such a condition exists, the hospital must provide either stabilizing treatment or an appropriate transfer. The now-rescinded guidance provided that if a physician believed that a pregnant patient presenting at an emergency department was experiencing an emergency medical

condition and that abortion was the necessary stabilizing treatment, EMTALA preempted any directly conflicting state law or mandate. In its statement accompanying the rescission, CMS indicated that the guidance does not reflect the policy of the current administration, but that CMS will continue to enforce EMTALA.

OIG UPDATES

OIG ISSUES FAVORABLE AO FOR EMPLOYEE LEASE AND ADMINISTRATIVE SERVICES AGREEMENT

OIG issued a favorable advisory opinion (AO), 25-03, regarding an agreement between a management services organization (requestor MSO) and a physician professional corporation (requestor PC) (collectively, the requestors) to lease employees and provide certain administrative services, and with various platform MSOs and other PCs to provide telehealth and other support services.

Requestor PC receives nonclinical management services from requestor MSO. Requestor PC is a physician practice owned by a physician shareholder that holds significant national payor contracts, including commercial health plans, Medicare Advantage plans, and Medicaid managed care plans. Requestor PC does not directly employ or otherwise contract with providers to provide clinical services.

Independent of the requestors, certain other third-party MSOs (each a platform) provide management services to certain telehealth providers (platform PCs). Each platform PC provides various professional telehealth services to patients via the platform's website (platform patients), including services that are reimbursable by federal healthcare programs. The requestors believe that platform patients have reduced access to in-network telehealth services and may face out-of-pocket costs for healthcare services that may otherwise be covered by other health insurance plans because the platform PCs do not have sufficiently broad payor contracts. In the requestors' view, this issue is particularly prevalent in rural and underserved areas. In some cases, a platform PC and requestor PC each hold contracts with the same payor. This creates certain situations in which certain platform patients covered under both contracts will be referred to requestor PC.

Under the proposed arrangement, the requestors would enter into an agreement with the platforms and platform PCs pursuant to which requestor PC would lease certain healthcare providers (HCPs) from a platform PC that would provide telehealth services to platform patients covered by insurance plans with which requestor PC holds contracts, and the associated platform would provide certain administrative services to the requestor PC. The requestors would credential the leased HCPs, facilitate enrollment of the leased HCPs under requestor PC's existing payor contracts, and submit claims for the telehealth services provided by the leased HCPs under requestor PC's payor contracts. The platform would provide the following administrative services: accounting services, marketing services, administrative support, and information technology services. Although there are other contracts between the parties, OIG's AO only addresses the employee lease and administrative services agreement. The requestors certified that they would not control or influence decisions regarding how to allocate platform patients when they are covered by payor contracts held by both a platform PC and requestor PC. Each of the platform PCs employs or contracts with various HCPs.

The requestor PC would pay the platform PC an hourly rate based on HCP license type (*e.g.*, physicians, nurse practitioners, physician assistants), and the requestor MSO would pay the platform an administrative fee for the administrative services. The requestors certified that both the hourly rates and the administrative services fee would be consistent with fair market value as determined by a reputable independent third-party valuator. Requestor PC also certified that it would pay the hourly rate for HCPs regardless of whether requestor PC was ultimately reimbursed by payors for the telehealth services provided by the HCPs. The requestors certified that the methodology for determining the fees under the agreement would be set in advance and consistent with fair market value in arm's length transactions and would not be determined in a manner that takes into account the volume or value of referrals or any business generated between the parties for which payment is made under federal healthcare programs. The requestors further certified that the agreement would meet all elements of the personal services and management contracts safe harbor (42 C.F.R. 1001.952(d)(1)).

Analyzing the employee lease and administrative services agreement, OIG observed that the AKS would be implicated when a platform PC refers platform patients to requestor PC for services that are reimbursable by federal healthcare programs. OIG

concluded that based on the requestors' certifications, the agreement would satisfy the personal services and management contracts safe harbor. OIG found it significant that the requestors would pay the hourly HCP rates regardless of the requestor PC's receipt of reimbursement for the telehealth services provided by the HCPs. OIG stated that this factor decreases the likelihood that the service fee paid under the agreement would be determined in a manner that takes into account the volume or value of referral or business otherwise generated between the parties that is reimbursable by a federal healthcare program.

OIG ISSUES UNFAVORABLE AO ON MEDICAL DEVICE COMPANY PROPOSAL TO PAY CUSTOMERS' EXCLUSION SCREENING COSTS

OIG issued an unfavorable AO, 25-04, regarding a medical device company's proposal to pay the costs that would otherwise be paid by its customers (*e.g.*, hospitals, health systems, and ambulatory surgery centers) for a third-party vendor to screen and monitor the medical device company for exclusion from federal healthcare programs and to ensure compliance with certain other legal requirements. Under the proposed arrangement, the third-party vendor would request information from the device company that would allow the vendor to perform initial and continual screenings of the device company for exclusion from federal healthcare programs. The vendor might also request other information to ensure compliance with other legal requirements, including those imposed by specific Medicare Advantage plans. The vendor would charge the device company an annual subscription fee for each of its customers receiving screening and monitoring reports from the device company. The device company would pay this per-customer fee directly to the vendor. The device company estimated that the fees would equal about $450,000 per year and that such fees would be paid on an annual basis during the recredentialing process for existing customers or during the onboarding process for new customers. The device company certified that it would not be party to any contract between the customer and the vendor and that, upon request for information from certain customers regarding their arrangements with the vendor, the customers denied such requests.

OIG analyzed the proposed arrangement and observed that it would implicate the AKS because the device company would pay the vendor fees for screening and monitoring the device company that would otherwise be incurred by the customer directly. Such payments could induce customers to purchase items or services from the device company that are reimbursed under federal healthcare programs.

Because no safe harbor applies to the proposed arrangement, OIG analyzed the proposed arrangement under a facts and circumstances analysis and concluded that it was not sufficiently low risk to issue a favorable AO. OIG stated that the device company would be paying for a valuable service that its referral sources would otherwise have to pay for themselves, which presents both anticompetitive risks and risk of inappropriate steering. OIG noted its longstanding and continuing concerns regarding the provision of free items or services to referral sources that could lead to ordering of an item or service payable by federal healthcare programs. Here, the medical device company would take on a financial burden that would otherwise be borne by its customers, resulting in a payment that could inappropriately steer customers to the device company over other device companies that are not willing or able to pay the vendor fees. OIG noted that there are many ways in which the parties could structure an arrangement to allocate responsibility for vendor checks, and that there may be certain fact patterns under which OIG might reach a favorable conclusion. However, under the particular arrangement before it, OIG could not approve the proposed per-customer fee because of the risk that the vendor "would serve as a gatekeeper of referrals" between customers and the medical device company. Because some customers might condition their business on the device company paying the vendor fee, OIG determined that the proposed arrangement was not sufficiently low risk to warrant a favorable AO.

OIG ISSUES FAVORABLE AO UNDER WARRANTIES SAFE HARBOR

OIG issued a favorable AO, 25-05, regarding a device manufacturer and distributor's proposal to offer up to $2,500 to reimburse purchasers of a particular device for actual costs incurred from needle stick injuries caused by failure of the manufacturer's device. Purchasers of the device include pharmacies, hospitals, clinics, and laboratories. The device is used by healthcare practitioners employed by the purchasers to administer immunizations and other drugs to patients via injections. The device has a safety mechanism that covers a needle except when the needle penetrates patient tissue during an injection. The safety mechanism is designed to protect the users of the device from accidental needle contact. However, users may still experience an unintended needle stick injury due to failure of the safety mechanism.

When a needle stick injury occurs due to device failure, the user's employer (*i.e.*, the device purchaser) typically covers the costs of services required as a result of the injury. The requester certified that these costs may include retraining staff, expenses incurred due

to staff absence and replacement, counseling for injured workers, and certain legal expenses (*e.g.*, litigation and settlement expenses if the employee sues the purchaser). The proposed reimbursement would only be available to cover costs incurred by a device failure, not user error. The arrangement would only apply when the device purchaser acknowledges and agrees to the device's warranty, which provides:

- The proposed arrangement benefits only the purchaser and not third parties.
- The manufacturer warrants that the device, if used in accordance with the descriptions and intended purpose, will not cause a needle stick injury to an authorized user (*i.e.*, healthcare practitioners).
- The manufacturer's sole obligation, and the purchaser's sole remedy, is a payment to the purchaser equal to the amount of documented actual costs incurred by the purchaser because of the failure of the device and resulting needle stick injury to an authorized user up to the $2,500 limit.
- The manufacturer will not be liable to the purchaser or any third party for needle stick injury nor will the manufacturer indemnify any purchaser or third party related to a needle stick injury.
- The "warranty period" (*i.e.*, the period of time during which the manufacturer will cover actual costs for needle stick injuries due to failure of the device) lasts for one year and applies only to the device (not services).

The proposal would not condition the potential payment for needle stick injuries due to the failure of the device on purchaser's exclusive use of or minimum purchases of the device. The manufacturer also certified that if the authorized user is a federal healthcare program enrollee, it would not pay any remuneration to any entity or individual, including the purchaser, for any medical, surgical, or hospital expense incurred by the authorized user.

OIG stated that the AKS would be implicated by the proposed arrangement because the manufacturer would offer purchasers something of value (the payment), which could induce purchasers to buy the device. In its analysis, OIG noted that the proposed arrangement may qualify for protection under the warranties safe harbor. As a threshold matter, OIG concluded that the proposed payment satisfied the definition of a warranty under the safe harbor. It then analyzed each element of the safe harbor applicable to manufacturers and buyers. OIG concluded that the element applicable to buyers (that they fully and accurately report any price reduction of an item that was obtained as part of the warranty in the applicable cost report or claim for payment) did not apply to the proposed arrangement because there would be no price reduction offered on the device as a part of the warranty. OIG then analyzed the elements of the warranties safe harbor applicable to the manufacturer based on the facts discussed above. Applying these facts against the safe harbor elements, OIG concluded that the proposed arrangement would be protected by the AKS warranties safe harbor.

OIG RELEASES SPRING 2025 SEMIANNUAL REPORT TO CONGRESS

On June 2, 2025, OIG published its Spring 2025 Semiannual Report to Congress, summarizing OIG's activities for the six-month period ending March 31, 2025. As described in the report, OIG's total monetary impact during the reporting period was $16.61 billion, $3.51 billion of which is categorized as investigative receivables (*i.e.*, funds owed to the federal government). Highlights from the report include the following:

- OIG's enforcement efforts resulted in 744 civil and criminal actions during the reporting period. This represents a 4.49% increase over the 712 actions that occurred during the spring 2024 reporting period, and an 11.21% increase over the 669 actions that occurred during the spring 2023 reporting period.
- An OIG evaluation found that in 2023, diagnoses reported only on health risk assessments (HRAs) and HRA-linked chart reviews generated a total of $7.5 billion in Medicare Advantage risk-adjusted payments. The evaluation also found that in-home HRAs and the subset of HRA-linked chart reviews that relied on in-home HRAs generated an estimated $4.2 billion of this total. OIG recommended that CMS impose additional restrictions on the use of diagnoses reported only on in-home HRAs or chart reviews that are linked to in-home HRAs for risk-adjusted payments.

- OIG found that Medicaid gross spending on 10 selected diabetes drugs and two selected weight loss drugs totaled more than $9 billion in 2023, an increase of 540% from 2019. It also found that Medicare Part D spending for 10 selected diabetes drugs totaled $35.8 billion in 2023, an increase of 364% from 2019. OIG seemed to express concern over both increases, noting that Medicaid and Medicare Part D could potentially spend a collective $131 billion on the selected drugs in 2026 if spending continues to grow at similar rates.

OTHER NOTABLE DEVELOPMENTS

DOJ REVIVES FCPA ENFORCEMENT WITH NARROWER SCOPE

Following a temporary pause earlier this year, the DOJ resumed enforcement of the Foreign Corrupt Practices Act (FCPA). On June 9, 2025, Deputy Attorney General Todd Blanche issued new Guidelines for Investigations and Enforcement of the FCPA, outlining the DOJ's updated enforcement priorities. While the guidelines emphasize increased focus on sectors tied to national security – such as defense, intelligence, critical minerals, and strategic infrastructure – they also confirm that enforcement will continue across other industries. For healthcare companies with global operations, FCPA risk remains elevated because of frequent interactions with foreign officials, including those at state-run hospitals, national health systems, and regulatory agencies. These touchpoints continue to attract DOJ scrutiny, and companies should ensure their compliance programs are structured to address evolving enforcement priorities and cross-border risks.

OREGON ENACTS EXPANSIVE CORPORATE PRACTICE OF MEDICINE BILL

On June 9, 2025, the Oregon legislature enacted SB 951, which prohibits certain ownership of, and actions related to, professional medical entities and aims to modernize Oregon's corporate practice of medicine doctrine. The salient prohibitions included in SB 951 will become effective on January 1, 2026, for all MSO-PC structures created after June 9, 2025, with a three-year grace period ending on January 1, 2029, for currently existing MSO-PCs.

On June 20, 2025, the Oregon legislature passed House Bill (HB) 3410, which amends portions of SB 951. If signed into law by the governor, HB 3410 would allow greater structural flexibility for management structures but would not amend the central prohibitions on MSOs interfering in the clinical operations of professional medical entities. More information is available in McDermott's article on these most recent developments.

> **"If signed into law by the governor, HB 3410 would allow greater structural flexibility for management structures but would not amend the central prohibitions on MSOs interfering in the clinical operations of professional medical entities.**

DOJ CIVIL DIVISION PUBLISHES ENFORCEMENT PRIORITIES

On June 11, 2025, the assistant attorney general for the DOJ's Civil Division issued a memorandum directing Civil Division lawyers to prioritize investigations and enforcement actions advancing the following five priorities:

Combating discriminatory practices and policies. The memorandum's first priority is rooted in one of US President Donald Trump's executive orders (EOs) from January 2025. The EO, titled "Ending Illegal Discrimination and Restoring Merit-Based Opportunity," orders all agencies "to enforce our longstanding civil-rights laws and to combat illegal private-sector DEI preferences, mandates, policies, programs, and activities." According to the memorandum, consistent with the EO, "the Civil Division will use all available resources to pursue affirmative litigation combatting unlawful discriminatory practices in the private sector." The memorandum specifically notes that the Civil Division is authorized to bring suit under the FCA against any person who knowingly submits or causes the submission of false claims to the government. It also references the Civil Rights Fraud

Initiative, which the DOJ recently announced will use the FCA to investigate and pursue claims against any recipient of federal funds that knowingly violates federal civil rights laws.

Ending anti-Semitism. The memorandum's second priority is also rooted in a January 2025 EO. According to the memorandum, EO 14188, "Additional Measures to Combat Anti-Semitism," established the policy of the United States to combat anti-Semitism vigorously and encouraged the attorney general to employ appropriate civil rights enforcement authorities to do so. To assist enforcement efforts specified by Attorney General Bondi, the Civil Division will prioritize investigations and enforcement actions against entities that make claims for federal funds but knowingly violate federal civil rights laws by participating in or allowing anti-Semitism. This priority signals that DOJ also intends to leverage the FCA to investigate and pursue claims related to this enforcement priority.

Protecting women and children. The memorandum's third priority specifically references two additional EOs from January 2025, both of which take aim at transgender rights. The memorandum also references a pair of directives from Attorney General Bondi. The first directive calls for the investigation of any violations of the Food, Drug, and Cosmetic Act (FDCA) related to "false claims about the on- or off-label use of puberty blockers, sex hormones, or any other drug used to facilitate a child's so-called 'gender transition.'" The second directive calls for the investigation of FCA violations related to the submission of false claims to federal healthcare programs "for any non-covered services related to radical gender experimentation." The memorandum specifically states that the Civil Division will use all available resources to prioritize investigations of doctors, hospitals, pharmaceutical companies, and other appropriate entities consistent with these directives. These investigation efforts will target possible violations by drug manufacturers and online pharmacies.

Ending sanctuary jurisdictions. The memorandum's fourth priority references several of President Trump's directives to enforce immigration laws. It also references Attorney General Bondi's directive regarding sanctuary jurisdiction, stating that "[c]onsistent with this directive, the Civil Division shall prioritize affirmative litigation to invalidate any State or local laws preempted by Federal law." This priority signals that the DOJ intends to continue bringing lawsuits against jurisdictions that implement sanctuary policies.

Prioritizing denaturalization. The memorandum's fifth and final policy states that "[t]he Civil Division shall prioritize and maximally pursue denaturalization proceedings in all cases permitted by law and supported by the evidence." The memorandum lays out 10 categories of priorities for denaturalization cases, including cases against individuals who engaged in various forms of financial fraud against the US, including Medicaid and Medicare fraud.

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

AMANDA ENYEART
PARTNER
aenyeart@mwe.com
Tel +1 312 984 5488

DEXTER GOLINGHORST
ASSOCIATE
dgolinghorst@mwe.com
Tel +1 312 984 6866

ALAN LEBLANG
ASSOCIATE
aleblang@mwe.com
Tel +1 312 899 8465

McDermott Will & Emery

MATTHEW GIBSON
ASSOCIATE
mgibson@mwe.com
Tel +1 212 547 5590

Quinn Kopelman, a summer associate in the Chicago office, also contributed to this newsletter.

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