2026 Health Law Seminar

July 21, 2026

Lathrop GPM

Health Regulatory Update

Year in Review

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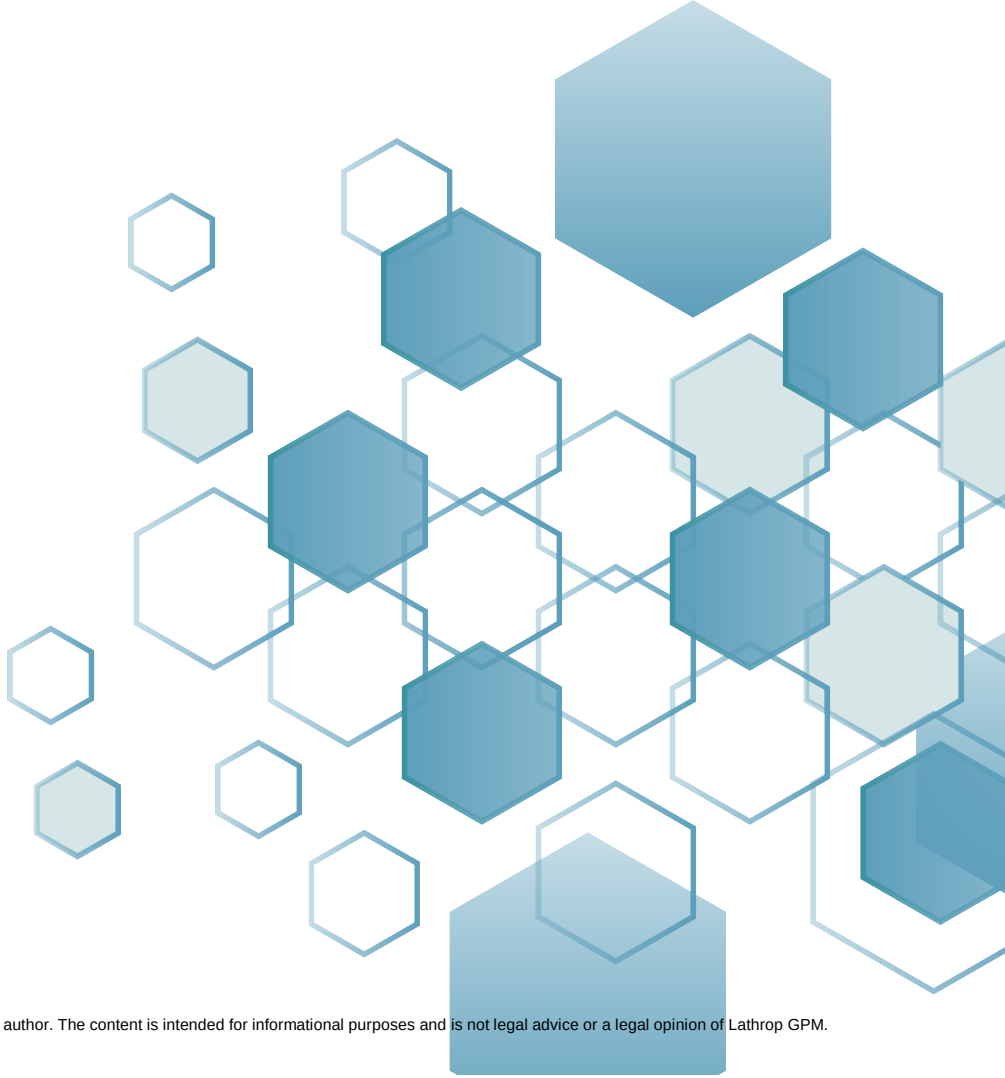


“There can be no doubt but that the statutes and provisions in question, involving the financing of Medicare and Medicaid, are among the most completely impenetrable texts within human experience. Indeed, one approaches them at the level of specificity herein demanded with dread, for not only are they dense reading of the most tortuous kind, but Congress also revisits the area frequently, generously cutting and pruning in the process and making any solid grasp of the matters addressed merely a passing phase.”

~ Rehabilitation Ass’n of Virginia v. Kozlowski, 42 F.3d 1444, 1450 (4th Cir. 1994)

Agenda

- Key 2025—2026 policy initiatives
- Developments in enforcement and program integrity
  - New tools, targets and enforcement theories
  - The old standbys
- Highlights from 2026 (final) and 2027 (proposed) payment rules
  - Hospitals, ASCs, SNFs, HHAs, DMEPOS, Physicians & NPPs
- New payment models
- Center for Medicare & Medicaid Innovation
- Many other things…

New & Expanded Policy Initiatives

Concepts of a Plan?

- Great Healthcare Plan (Jan. 2026- Updated)
  - Lowering drug prices
  - Lowering insurance premiums
  - Holding big insurance companies accountable
  - Maximize price transparency

THE WHITE HOUSE
WASHINGTON

JANUARY 2026

The *Great* Healthcare Plan

LOWER DRUG PRICES

Slash Prescription Drug Prices
Lower prescription drug prices for all Americans by codifying the Trump Administration's Most-Favored-Nation deals to get Americans the same low prices for prescription drugs that people in other countries pay. This would build off President Trump's landmark actions that made insulin more affordable in his first term and the successful voluntary negotiations following his recent executive order to lower drug prices. *Voluntarily negotiated deals with HHS/CMS will be grandfathered in.*

Allow More Over-the-Counter Medicines
Make more verified safe pharmaceutical drugs available for over-the-counter purchase. This will lower healthcare costs and increase consumer choice by strengthening price transparency, increasing competition, and reducing the need for costly and time-consuming doctor's visits.

LOWER INSURANCE PREMIUMS

Send the Money Directly to the American People
Stop sending big insurance companies billions in extra taxpayer-funded subsidy payments and instead send that money directly to eligible Americans to allow them to buy the health insurance of their choice.

Fund Cost-Sharing Reduction Program
Fund a cost-sharing reduction program for healthcare plans which would save taxpayers at least $36 billion and reduce the most common Obamacare plan premiums by over 10%.

Cut Kickback Costs
End kickbacks from pharmacy benefit managers to the large brokerage middlemen that deceptively raise the cost of health insurance.

OBBA: One Big Beautiful Bill Act (H.R.1)

- July 4, 2025 – 870 pages
- Medicaid
  - Redetermination requirements for expansion adults (ages 19–64)
  - Work or “qualifying activities” requirement for adults ages 19-64
  - Narrows eligible immigrant population
- Moratorium on certain CMS rules until September 30, 3034, including
  - CHIP eligibility and enrollment streamlining rule
  - MSSP final rule
  - Long-term care nursing home staffing standards
- *Commonwealth of Massachusetts et al. v. Oz et al*. (July 2026)
  - 25 states and the District of Columbia filed suit in federal court challenging CMS's interim final rule implementing the Medicaid work requirements.
  - Plaintiffs argue CMS unlawfully narrowed exemptions established by Congress, particularly the medical frailty exemption.
  - Plaintiffs simultaneously filed a motion for preliminary injunction seeking to block key provisions of the rule before implementation deadlines take effect.
  - As of July 10, 2026, the case remains pending in the U.S. District Court for the District of Massachusetts; no ruling on the preliminary injunction has been issued.

OBBA Implementation: Working Families Tax Cut Act

- CMS issued an Interim Final Rule with Comment Period (IFC) implementing nationwide Medicaid work requirements under the Working Families Tax Cut (WFTC) legislation (Public Law 119-21).
  - WFTC passed Jul. 4, 2025
- Certain Medicaid beneficiaries ages 19-64 must complete at least 80 hours per month of qualifying activities to maintain eligibility
  - States must generally implement this requirement no later than January 1, 2027
- CMS will provide:
  - $200 million in Government Efficiency Grants to support state implementation and system modernization.
  - More than $600 million in private-sector technology support for eligibility, enrollment, and outreach initiatives

State Directed Payments (SDPs)

- Medicaid Managed Care State Directed Payments and Medicaid Fee-For-Service Targeted Medicaid Practitioner Payments Proposed Rule (CMS-2449-P)
- Establishes new payment rate caps for certain Medicaid managed care SDPs:
  - 100% of Medicare rates in Medicaid expansion states
  - 110% of Medicare rates in non-expansion states
- Applies initially to:
  - Inpatient hospital services
  - Outpatient hospital services
  - Nursing facility services
  - Certain academic medical center practitioner services
- Extends payment limits to all SDPs beginning January 1, 2029.
- Grandfathered SDPs may continue temporarily but must be reduced by 10 percentage points annually beginning in 2028 until compliant with payment limits.
- Eliminates "uniform increase" SDPs beginning in 2028, except for certain grandfathered arrangements.

Fee-for-Service (FFS) Medicaid Payment Changes

- Establishes similar payment caps for targeted Medicaid practitioner payments:
  - 100% of Medicare rates (expansion states)
  - 110% of Medicare rates (non-expansion states)
- States with approved payment methodologies above the limits would be required to submit state plan amendments to comply by the first fiscal year beginning on or after January 1, 2029.
- Operational & Compliance Changes
  - Allows states to adopt Medicare-linked minimum or maximum fee schedules without prior CMS approval beginning in 2028.
  - Clarifies impermissible payment arrangements and "gray area" payment structures.
  - Requests stakeholder input on future revisions to SDP provider class definitions

A Busy Year

Press Releases Jul 01, 2026

CMS Proposes Updates to Strengthen Medicare Program Integrity, Combat Fraud, and Expand Access to Home Health Care

CMS Proposes Updates to Strengthen Medicare Program Integrity, Combat Fraud, and Expand Access to Home Health Care The Centers for Medicar...

Press Releases Jul 02, 2026

CMS Acts to Strengthen Care Quality, Cut Drug Costs, and Slash Out-of-Pocket Expenses for Medicare Beneficiaries

CMS Acts to Strengthen Care Quality, Cut Drug Costs, and Slash Out-of-Pocket Expenses for Medicare Beneficiaries In a move aimed at...

Press Releases Jun 12, 2026

CMS Proposed Rule Locks in Lower Prices and Fosters Innovation for the Medicare Drug Price Negotiation Program

CMS Proposed Rule Locks in Lower Prices and Fosters Innovation for the Medicare Drug Price Negotiation Program A new proposal from the...

Press Releases May 28, 2026

Federal Rule Takes Aim at Health Care Bureaucracy, Reducing Dispute Fees, and Boosting Transparency

Federal Rule Takes Aim at Health Care Bureaucracy, Reducing Dispute Fees, and Boosting Transparency Major reforms were finalized today to...

Fact Sheets May 20, 2026

Medicaid Managed Care State Directed Payments and Medicaid Fee-For-Service Targeted Medicaid Practitioner Payments Proposed Rule (CMS-2449-P)

Medicaid Managed Care State Directed Payments and Medicaid Fee-For-Service Targeted Medicaid Practitioner Payments Proposed Rule (CMS-2449...

Press Releases Jun 12, 2026

CMS Ensures Accrediting Organizations Uphold Trust in Standards and Oversight

CMS Ensures Accrediting Organizations Uphold Trust in Standards and Oversight Final Rule Reduces Burden and Strengthens...

Press Releases Jun 11, 2026

CMS Takes Bold New Approach to Stewarding Medicaid Demonstration Project Spending

CMS Takes Bold New Approach to Stewarding Medicaid Demonstration Project Spending Plans to Update Section 1115 Medicaid Demonstration...

Press Releases Jun 01, 2026

CMS Launches Nationwide Framework to Implement Medicaid Work Requirements

CMS Launches Nationwide Framework to Implement Medicaid Work Requirements The Centers for Medicare & Medicaid Services (CMS)...

Press Releases Jun 11, 2026

CMS Takes Bold New Approach to Stewarding Medicaid Demonstration Project Spending

Billing & payments Demonstration projects Medicaid & CHIP Policy

Share

CMS Takes Bold New Approach to Stewarding Medicaid Demonstration Project Spending

Plans to Update Section 1115 Medicaid Demonstration Budget Neutrality Policy Will Strengthen Accountability and Protect Federal Taxpayers

With nearly one-third of all federal Medicaid dollars flowing through demonstration projects, the Centers for Medicare & Medicaid Services (CMS) is issuing new guidance about its plans to strengthen budget neutrality standards for Medicaid section 1115 demonstrations. While states use demonstrations to test innovative ways to deliver care and improve health outcomes, the bounds of what is considered "budget neutral" have expanded over time to reflect evolving policy priorities and increased section 1115 demonstration spending. This new guidance previews CMS' plans to propose a rule that would ensure consistent oversight and clear budget neutrality requirements for proposed demonstration projects, which will help states cost-effectively enhance programs and ensure fiscal integrity, while lowering costs and improving outcomes.

Section 1115 Demonstrations

- July 17, 2025, CMS released two “dear colleague” letters:
  - Section 1115 Demonstration Authority for Continuous Eligibility Individuals
  - Section 1115 Demonstration Authority for Workforce Initiative

- Continuous eligibility
  - CMS will no longer approve new state proposals that allow for expanded continuous eligibility or extending existing 1115 demonstration authority for expanded continuous eligibility
  - States required to provide notification to beneficiaries if continuous eligibility periods will be ending

- Workforce initiatives
  - In the past, CMS has approved 1115 demonstrations permitting states to test workforce initiatives such as student loan repayment and workforce training programs to recruit / retain providers
  - CMS will no longer approve new programs or extend existing ones (current programs can run their course)

- 2026 update:
  - CMS tightening budget neutrality requirements for 1115 waivers
  - Expected to:
    - Restrict state flexibility
    - Reduce coverage expansions
  - CMS issued guidance (June 11, 2026) implementing new statutory requirements for Section 1115 demonstrations.
  - Beginning January 1, 2027, the CMS Chief Actuary must certify that all new, amended, or renewed demonstrations will not increase federal Medicaid spending.

WISeR Model

- Wasteful and Inappropriate Service Reduction Model
  - “will help protect American taxpayers by leveraging enhanced technologies, such as Artificial Intelligence (AI) and Machine Learning (ML), along with human clinical review, to ensure timely and appropriate Medicare payment for select items and services.”
- First Innovation Center Model in which technology innovators are only participants
- Tests use of enhanced technology to decrease certain wasteful (low-value) services shown to have little to no clinical, evidence-based benefit. Technology companies participating in the model will help streamline the review of medical necessity for select items and services earlier in the claims process to: (1) reduce inappropriate utilization, (2) lower spending in Original Medicare, (3) expedite decision making and (4) ease provider administrative burden.
- Non-exclusive examples: skin and tissue substitutes, electrical nerve stimulator implants, and knee arthroscopy for knee osteoarthritis.
- WISeR will run from Jan. 1, 2026—Dec. 31, 2031
- Model participants receive percentage of expenditures associated with “wasteful, inappropriate” care identified in their reviews
- Senate democrats introduced measure to repeal WISeR; defeated 46-50 in party line vote (July 16)

WISeR Model

- 6 participants in WISeR
  - Cohere Health, Inc, (Texas)
  - Genzeon Corp. (New Jersey)
  - Humata Health, Inc. (Oklahoma)
  - Innovaccer Inc. (Ohio)
  - Virtix Health LLC (Washington)
  - Zyer, Inc. (Arizona)
- Providers / suppliers have choice of submitting prior authorization request for selected services or going through post-service / pre-payment review
- While enhanced technology aims to expedite the prior authorization process, any recommendations that coverage should not be provisionally affirmed will be made by an appropriately licensed human clinician, not a machine.
- “Gold carding” exemption program slated to begin in 2026. Providers / suppliers that consistently meet coverage criteria will be exempt from pre authorization / pre-payment review. The first Gold Card exemption rollout is scheduled to begin July 6, 2026, starting in Washington, with phased expansion to the other WISeR states.
- To qualify, providers generally must:
  - Achieve a 90% affirmation rate
  - On a minimum of 10 prior authorization requests during the evaluation period

CRUSH Initiative

- Comprehensive Regulations to Uncover Suspicious Healthcare (CRUSH)
  - 91 Fed. Reg. 9803 (Feb. 27, 2026)
- Request for information seeking input from a broad range of stakeholders – including states, providers, suppliers, payers, technology companies, patient advocates, beneficiaries, and others – on ways to strengthen CMS' ability to prevent, detect, and respond to fraud, waste, and abuse, and program inefficiencies in Medicare, Medicaid, CHIP, and the ACA Health Insurance Marketplace.
- RFI input to be used by CMS to develop CRUSH proposed rule. Input sought on variety of topics, including:
  - Modifications to program integrity requirements
  - Enhanced identity proofing and ownership requirements
  - Preclusion list and Medicare Advantage enrollment requirements
  - Clinical lab fraud, including genetic tests and molecular diagnostic tests
  - Non-participating DMEPOS supplier risks in Medicare Advantage
  - Shortened period for providers / suppliers to bill Part A / B claims
  - Use of AI in coding oversight and hospital billing

Provider-Based Attestations

- Sec. 6225 of Consolidated Appropriations Act, 2026 made important changes related to Medicare provider-based regulation:
  - Each off-campus, provider-based hospital department will need to have its own NPI and be prepared to bill for services under that NPI after Jan. 1, 2028.
  - Hospitals required to submit attestations and accompanying documentation on behalf of each off-campus outpatient departments that is billed as provider-based.
- Initial provider-based attestation must be filed between Jan. 1, 2026 and Dec. 31, 2027
- Hospitals will be required to file subsequent attestations on a periodic basis
- Process by which attestations will be submitted and evaluated is presently unclear. However, CAA directs HHS to engage in notice and comment rulemaking to develop the process. In addition, Congress appropriated $20 million to CMS for purposes of carrying out its responsibilities under this part of the CAA.

Gender Affirming Care

- Dec. 19, 2025, HHS made 5 significant announcements
  - HHS Declaration, Re: Safety, Effectiveness, and Professional Standards of Care for Sex Rejecting Procedures on Children and Adolescents
  - Proposed rule, Prohibition on Federal Medicaid and Children's Health Insurance Program Funding for Sex-Rejecting Procedures Furnished to Children (90 Fed. Reg. 59441)
  - Proposed Rule, Hospital Condition of Participation: Prohibiting Sex-Rejecting Procedures for Children (90 Fed. Reg. 59463)
  - FDA issued warning letters to 12 manufacturers and retailers related to marketing of breast binders to children for the purposes of treating gender dysphoria
  - Assistant Secretary for Health and Head of the United States Public Health Service Commissioned Corps Admiral Brian Christine, M.D. signed Public Health Message to inform health care providers, families, and policymakers that current evidence does not support claims that puberty blockers, cross-sex hormones, and surgeries are safe and effective treatments for pediatric gender dysphoria.

Gender Affirming Care: Medicaid / CHIP Proposed Rule

- Would prohibit state Medicaid agencies and Children's Health Insurance Program (CHIP) plans from paying for "sex rejecting procedures"
  - Through prohibiting federal financial participation from being used to cover these services
- Medicaid restriction applies to individuals under 18; CHIP restriction applies to individuals under 19
- Same definition of "sex rejecting procedures" and exceptions as in CoP rule
- No restriction on use of Medicaid / CHIP money to cover mental health treatments for gender dysphoria
- States not prohibited from covering services with state-only funds
- Approximately 23 states currently provide Medicaid coverage for services
- Comment period for Medicaid / CHIP and CoP proposed rules ended Feb. 16

Gender Affirming Care: CoP Proposed Rule

- Proposes adding a new hospital condition of participation (42 C.F.R. § 482.46)
- Hospitals would be prohibited under CoPs from providing “sex rejecting procedures” on a “child”
  - Defined to include any pharmaceutical or surgical intervention that attempts to align an individual's physical appearance or body with an asserted identity that differs from the individual's sex either by:
    - Intentionally disrupting or suppressing the development of biological functions, including primary or secondary sex-based traits; or
    - Intentionally altering an individual's physical appearance or body, including removing, minimizing, or permanently impairing the function of primary or secondary sex-based traits such as the sexual and reproductive organs.
  - Includes puberty blockers, sex hormones and gender-transition surgeries
- Limited exceptions (treating medically verifiable sexual development disorders or complications from prior procedures)

Gender Affirming Care: Kennedy Declaration

- Federal Court Blocks HHS Gender-Affirming Care Directive (Apr. 2026)
  - Oregon federal judge vacated HHS Secretary RFK Jr.’s Dec. 2025 directive that effectively threatened Medicare and Medicaid participation for providers offering gender-affirming care to minors.
  - Court held that HHS exceeded its statutory authority and failed to follow required federal rulemaking procedures.
  - Judge ruled that federal officials cannot unilaterally override state-established standards of care and prohibited HHS from enforcing the directive or a materially similar policy.
  - Lawsuit was brought by 21 states and the District of Columbia, arguing the directive unlawfully interfered with state regulation of healthcare and Medicaid programs.
  - HHS reported that more than 40 hospital systems had stopped providing gender-affirming care for minors following federal actions.

Gender Affirming Care: Other Developments

- Multiple lawsuits from health providers and patient groups related to DOJ subpoena in general and request for patient information in particular:
  - E.g., Children's Hospital of Philadelphia (*In re: Subpoena*, No. 25-39 (E.D. Pa. Nov. 21, 2025); QueerDoc (*QueerDoc PLLC v. U.S. Dep't of Justice*, No. 2:25-mc-00042-JNW (W.D. Wash. Oct. 27, 2026)); Boston Children's (*In Re: Administrative Subpoena*, No. 25-1431-019 (D. Mass. Sept. 9, 2025)); Children's National (*In re 2025 Subpoena to Children's Nat'l Hosp.*, No. 1:25-cv-03780-JRR (D. Md. Jan. 21, 2026)).

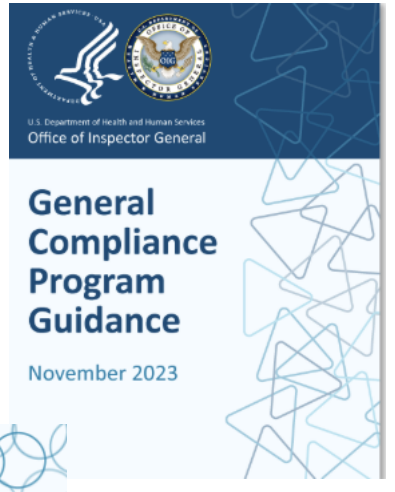
- FTC and Four States Challenge WPATH Standards of Care
  - In June 2026, FTC, Alaska, Iowa, Nebraska, and Texas sued WPATH, alleging its 2022 Standards of Care contained misleading and unsubstantiated claims regarding pediatric gender-transition services.
  - Complaint alleges WPATH removed age minimums for certain treatments without medical consensus and promoted coverage by insurers despite insufficient supporting evidence.
  - Lawsuit further alleges WPATH failed to adequately disclose potential risks and side effects and misrepresented the medical necessity of certain interventions.
  - FTC asserts the case falls within its longstanding authority to challenge deceptive health-related claims.
  - WPATH denies the allegations, calling the lawsuit "baseless," and argues the FTC lacks jurisdiction over its noncommercial medical guidance.

Gender Affirming Care: Other Developments

- At least three hospitals have received grand jury subpoenas for years of data on adolescent patients: NYU Langone Hospitals and the Mount Sinai Health System in New York City, plus the Lucile Packard Children's Hospital at Stanford.
  - Two federal judges have halted these efforts; most recently, a judge in early July halted the government from accessing private medical records of minors who received gender-affirming care at the Stanford children's hospital.
- Two hospitals have settled with the DOJ. The Cleveland Clinic in Ohio agreed to pay $308,000 to resolve allegations of false billing to insurance companies for minors' gender-affirming care. The clinic also committed $2 million to restorative care for people who sought a gender transition and then halted or reversed aspects of it.
- Texas Children's Hospital will pay $10 million to resolve false billing allegations and plans to open a clinic for individuals wanting to reverse transitions.

OIG Compliance Program Guidance

- GCPG issued Nov. 6, 2023
  - Applicable to all types of providers
  - Resource for developing or reviewing compliance programs
  - Promised Industry Compliance Program Guidance (ICPG)
- First ICPG: Nursing Facility issued Nov. 20, 2024
- Second ICPG: Medicare Advantage issued Feb. 3, 2026
- ICPGs yet to come:
  - Hospital
  - Clinical Laboratory
  - Pharmaceutical Manufacturer
  - Hospice



Medicare Advantage Compliance Program Guidance

- On Feb. 3, 2026, HHS OIG issued Industry Segment-Specific Compliance Program Guidance for Medicare Advantage. First update since 1999.

- Areas of focus include the following:
  - Marketing practices (including payments to providers for steering)
  - MA plan responsibility for oversight of First Tier, Downstream and Related Entities (e.g., conducting internal investigations and collaborating with regulators to ensure providers held accountable for MA-related fraud)
  - Implementation of rigorous data accuracy procedures (algorithmic and AI-driven analyses of provider-submitted data) to guard against risk adjustment fraud (e.g., submission of unsupported diagnosis codes; upcoding; incomplete / poor documentation; use of technology that results in incorrect diagnoses)
  - Obligations of MA plans to maintain adequate provider networks / accurate provider directories
  - Prior authorization
  - Quality of care
  - Compliance programs within vertically integrated organizations

Notable OIG Advisory Opinions (2026)

- 16 AOs issued so far in 2026 - 14 favorable, 2 unfavorable
- Certain Favorable AOs:
  - AO 26-07: proposal by an entity and its Medicare Advantage subsidiaries that offer Employer Group Waiver Plans to share a percentage of their savings with certain groups to which they provide coverage, in certain circumstances.
  - AO 26-11: a precision oncology company provides consenting patients a supplemental report at no cost in connection with a cancer screening test.
  - AO 26-03: medical technology manufacturer proposal to offer discounts on intraocular lenses and surgical supplies contingent on affiliated physician practices purchasing its software product.
  - AO 26-01: proposal by a manufacturer of a clinical laboratory test for colorectal cancer screening to waive any applicable cost sharing for certain commercially insured patients who receive its colorectal cancer screening test.

Notable OIG Advisory Opinions (2026)

- Unfavorable AOs:
  - AO 26-15: home health agency's payment of remuneration to a vendor for the use of an online referral management software.
  - AO 26-10: proposed arrangement whereby an orthopedic medical technology company would enter into agreements with individuals—often physicians—who would provide consulting services for its product lines.

Notable OIG Advisory Opinions (2025)

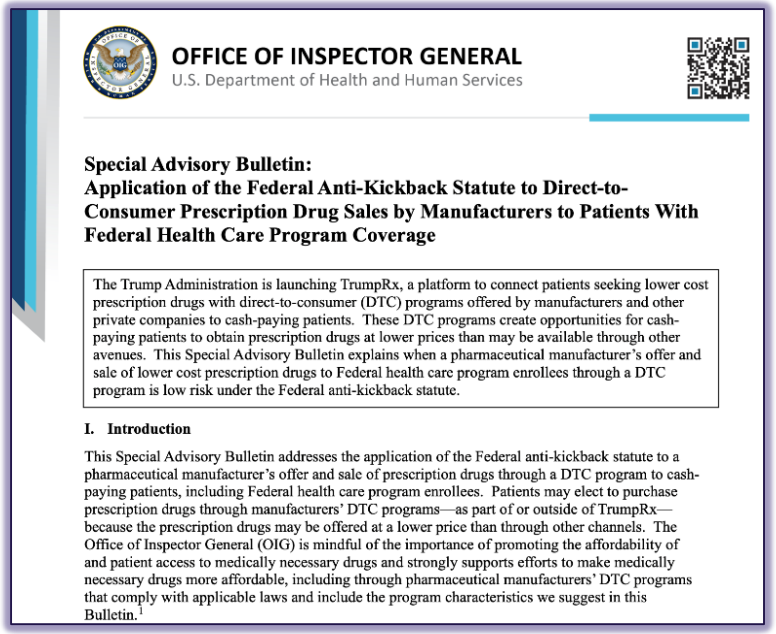
- 12 AOs issued in 2025 - 9 favorable, 3 unfavorable
- Certain Favorable AOs:
  - AO 25-09: physicians held passive investment interests in medical device company protected under AKS small entity investment safe harbor
  - AO 25-03: physician PC & MSO would lease telehealth clinicians from an independent telehealth platform from which they would receive administrative support services for a FMV fee
  - AO 25-11: biopharmaceutical manufacturer would offer certain discount and rebates on particular vaccines to certain customers
  - AO 25-05: medical device manufacturer would offer up to $2,500 to reimburse purchasers for actual costs incurred associated with a needle stick injury caused by the failure of a device that it manufacture

Notable OIG Advisory Opinions (2025)

- Unfavorable AOs:
  - AO 25-04: medical device company's proposal to pay the costs its customers otherwise would incur for a third-party company to screen and monitor the requestor for exclusion from Federal health care programs and to ensure compliance with certain other legal requirements
  - physicians held passive investment interests in medical device company protected under AKS small entity investment safe harbor
  - AO 25-08: medical device company's proposal to pay a third-party vendor to access an electronic billing system operated by the vendor that is used by some of the requestor's customers for certain billing operations
  - AO 25-12: home care agency to market sign-on bonuses to prospective employees with the intention of employing those individuals for the provision of services to other individuals, who most often would be family members of the prospective employees

OIG Pronouncements

- Special Advisory Bulletin on DTCs issued on Jan.26, 2026
- Enforcement Alert on Information Blocking issued on Sept. 4, 2025



OFFICE OF INSPECTOR GENERAL
U.S. Department of Health and Human Services

Special Advisory Bulletin:
Application of the Federal Anti-Kickback Statute to Direct-to-Consumer Prescription Drug Sales by Manufacturers to Patients With Federal Health Care Program Coverage

The Trump Administration is launching TrumpRx, a platform to connect patients seeking lower cost prescription drugs with direct-to-consumer (DTC) programs offered by manufacturers and other private companies to cash-paying patients. These DTC programs create opportunities for cash-paying patients to obtain prescription drugs at lower prices than may be available through other avenues. This Special Advisory Bulletin explains when a pharmaceutical manufacturer's offer and sale of lower cost prescription drugs to Federal health care program enrollees through a DTC program is low risk under the Federal anti-kickback statute.

I. Introduction

This Special Advisory Bulletin addresses the application of the Federal anti-kickback statute to a pharmaceutical manufacturer's offer and sale of prescription drugs through a DTC program to cash-paying patients, including Federal health care program enrollees. Patients may elect to purchase prescription drugs through manufacturers' DTC programs—as part of or outside of TrumpRx—because the prescription drugs may be offered at a lower price than through other channels. The Office of Inspector General (OIG) is mindful of the importance of promoting the affordability of and patient access to medically necessary drugs and strongly supports efforts to make medically necessary drugs more affordable, including through pharmaceutical manufacturers' DTC programs that comply with applicable laws and include the program characteristics we suggest in this Bulletin.[1]

ENFORCEMENT ALERT
Information Blocking

U.S. Department of Health and Human Services
U.S. Department of Health & Human Services
OFFICE OF INSPECTOR GENERAL
ASTP Assistant Secretary for Technology Policy

September 4, 2025

Stopping information blocking to unleash innovation and empower patients and their health care providers with friction-free information is a top priority for the Secretary of the Department of Health and Human Services and the Administration. The Office of Inspector General (OIG) and the Office of the Assistant Secretary for Technology Policy/Office of the National Coordinator for Health Information Technology (ASTP/ONC) are issuing this enforcement alert to signal our joint commitment to intensify enforcement activity, dedicate additional resources, and take decisive action to detect and end information blocking.

The availability of electronic health information when and where it is needed is a critical element of a high-functioning health care system. Information blocking threatens patient care and undermines efforts by providers, payers, and others to make the health system more efficient and to improve quality of care. It puts at risk the substantial taxpayer investments made to encourage and support the adoption and use of technologies such as electronic health records.

What Is Information Blocking?

The 21st Century Cures Act (Cures Act) defines information blocking as a practice by an individual or entity that is likely to interfere with, prevent, or materially discourage the access, exchange, or use of electronic health information except as required by law or as specified in an information blocking exception.

ASTP/ONC has issued regulations addressing information blocking, including identifying limited exceptions—such as to protect privacy or ensure security—where an entity will not be considered to have committed information blocking if its actions meet the conditions of the exceptions (45 CFR Part 171).

Medicare Reenrollment Bars

- Change Request 14019 (Sep. 18, 2025) would make updates to Medicare Program Integrity Manual addressing applicability of Medicare enrollment bar to specific bases for revocation of billing privileges
- Any reenrollment bar at a minimum applies to all enrollments under provider's / supplier's PECOS or legacy enrollment record at TIN level
- Following bases for revocation apply only to the specific enrollment that was the subject of the reenrollment bar:
  - Noncompliance with enrollment requirements (42 C.F.R. § 424.535(a)(1))
  - Onsite review / nonoperational (42 C.F.R. § 424.535(a)(5))
  - Application fee (42 C.F.R. § 424.535(a)(6))
  - Failure to meet reporting requirements (42 C.F.R. § 424.535(a)(9))
  - Failure to document or provide access to documentation (42 C.F.R. § 424.535(a)(10))
  - Failure to meet initial reserve operating funds requirement (42 C.F.R. § 424.535(a)(1))
  - Supplier standard or condition violations (if applicable) (42 C.F.R. § 424.535(a)(23))

Medicare Reenrollment Bars, cont.

- However, if “there is any effort to reestablish a revoked enrollment(s) under a different name, numerical identifier, or business identity”, the MACs are directed to contact CMS for guidance
- PIM gives following examples (non-exclusive) of scenarios where provider / supplier might be attempting to make an “effort to reestablish a revoked” enrollment:
  - SCENARIO 1 - Smith was the sole owner of XYZ Medical Supplies, Inc. XYZ’s lone location was at 1 Jones Street. XYZ’s billing privileges were revoked after it was determined that the site was nonoperational. Nine months later, the contractor receives an initial application from Johnson Supplies, LLC. The entity has one location at 1 Jones Street in the same city in which XYZ Medical Supplies is located. Smith is listed as a 75 percent owner.
  - SCENARIO 2 - Jones and Smith were 50 percent owners of World Home Health, a partnership. One year after World Home Health was revoked under § 424.535(a)(9), the contractor receives an initial application from XYZ Home Health, a corporation of which Jones is the sole owner/member.

Provider Enrollment: Other Updates

- 2026 HHA PPS final rule made a series of changes:
  - Effective date of revocation changed:
    - Had been 30 days after notice of determination. Now depends on the type of deficiency.
  - Expands reasons for which enrollment stays can be imposed (failure to furnish complete information / supporting documentation on revalidation of change of information that is rejected)
  - Expands deactivation authority to cover practitioners enrolled under 855O who have not been listed as ordering, certifying or referring individual under Part A or B claim during previous 12 months
    - Reactivation requires recertifying accuracy of enrollment record or CMS can require submission of complete 855O

Provider Enrollment: Other Updates

- 2026 HHA PPS final rule changes (continued):
  - Expands documentation that may be requested under enrollment application (42 C.F.R. 424.510(d)(2)(iii)) to include “any other documentation needed to verify and confirm the information furnished on the enrollment application. This includes, but is not limited to, documentation regarding [provider / supplier] ownership or management”
  - Providers / suppliers required to report adverse legal actions against them, owners, manages, etc., within 30 days (instead of 90 days)
  - Expands “improper prescribing practices” reasons for enrollment revocation to include “Medicare-covered drugs” (as opposed to “Part B or D drugs”)
    - Similar change to prescribing authority as basis for enrollment denials
  - Revises “abuse of billing privileges” (reasons for revocation of enrollment) to include situations where “beneficiary attests” items / services identified on claim was not rendered or furnished

Provider Enrollment: Moratorium on Medicare DMEPOS Enrollment

- On Feb. 25, 2026, CMS announced a nationwide temporary moratorium on Medicare enrollment of DMEPOS suppliers.
  - 91 Fed. Reg. 9855.
- Applies to newly enrolling suppliers of the following seven types (and new practice locations of these seven types):
  - Medical supply company
  - Medical supply company with orthotics personnel
  - Medical supply company with pedorthic personnel
  - Medical supply company with prosthetics personnel
  - Medical supply company with prosthetic and orthotic personnel
  - Medical supply company with registered pharmacist
  - Medical supply company with respiratory therapist
- States can decide whether to extend moratorium to Medicaid / CHIP

DMEPOS 36-Month Rule

- Effective Jan. 1, 2026, DMEPOS suppliers are subject to 36-month rule for changes in majority ownership. Change made in 2026 HHA PPS.
  - After that date, billing privileges will not transfer to new owners of DMEPOS suppliers if effect of transaction will be a change in majority ownership of the entity within 36 months after initial Medicare enrollment effective date or within 36-months of supplier's most recent change in majority ownership
  - Prospective owner would instead have to enroll in Medicare as new supplier
  - Same requirements that historically have applied to HHAs and hospices.
- Applies to changes of more than 50% direct ownership interest (including asset sale, stock transfer, merger and consolidation) and situations where there have been multiple ownership changes within the 36 months when added together exceed 50%
- Exceptions for following situations:
  - Parent company undergoes internal corporate restructuring (e.g., from LLC to corporation)
  - Changes in corporate form
  - Individual owner dies
- Rule applies to all DMEPOS supplier enrollments (e.g., physician practices, pharmacies are included)

Nationwide Hospice & Home Health Enrollment Moratoria

- On May 13, 2026, CMS announced a six-month nationwide moratorium on new Medicare enrollment for hospices and home health agencies (HHAs) as part of a coordinated federal effort to combat fraud, waste, and abuse.
- The moratoria apply to:
  - New Medicare enrollment applications
  - Certain majority ownership changes that may be used to obscure control of providers.
- Existing Medicare-certified providers may continue serving beneficiaries and billing Medicare
- CMS reported suspending payments to approximately 800 hospices and HHAs in Los Angeles suspected of fraud, representing roughly $1.4 billion in Medicare spending and $70 million in suspended payments.

Skin Substitutes: OIG

- Large increases in the number of enrollees with skin substitute claims and the amount of product billed for each enrollee, particularly in home care
- A massive gap in spending between Part B and Medicare Advantage.
- A steep rise in the cost of individual skin substitutes combined with providers' propensity to shift to more and more expensive products.
- Fraud schemes that allow bad actors to quickly get paid tens of millions of dollars when billing for just a small number of Part B enrollees.

Department of Health and Human Services
Office of Inspector General
Office of Evaluation and Inspections

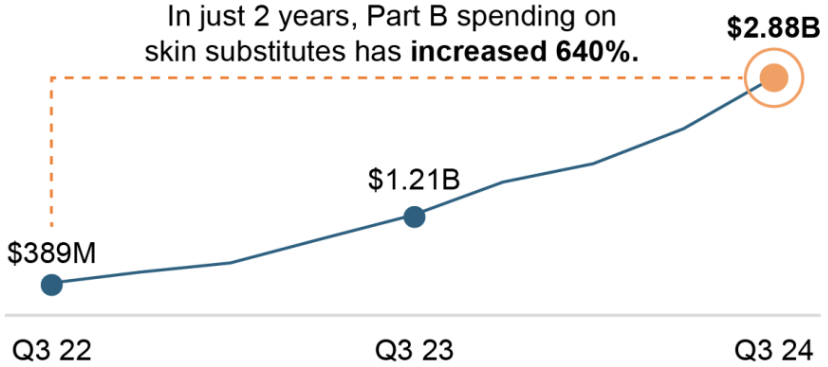
DATA SNAPSHOT

September 2025 | OEI-BL-24-00420

Medicare Part B Payment Trends for Skin Substitutes Raise Major Concerns About Fraud, Waste, and Abuse

Key Takeaways

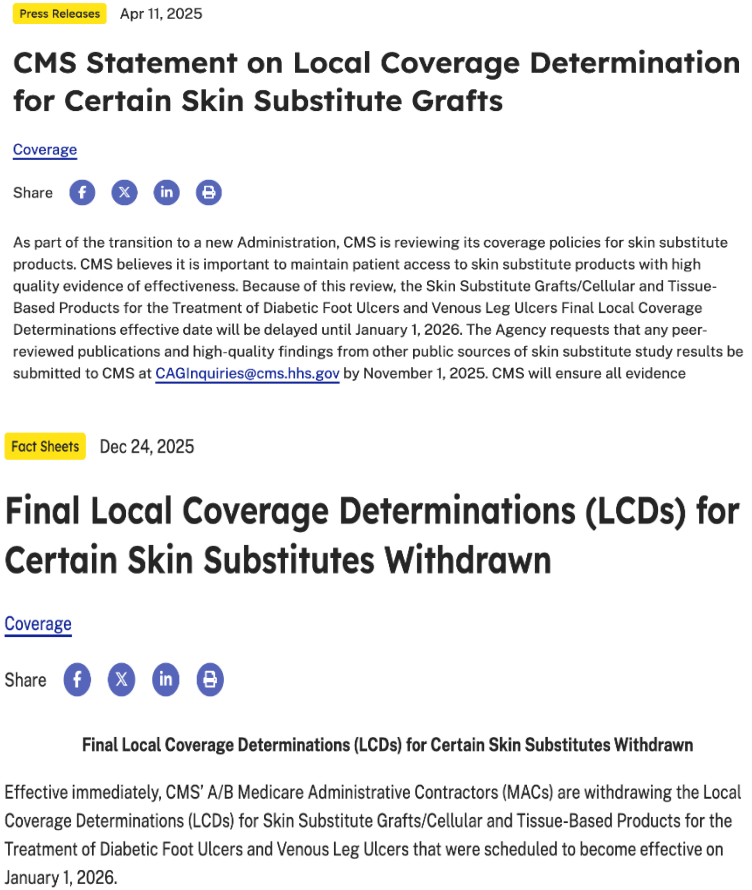
Part B expenditures for skin substitutes provided in non-institutional settings have skyrocketed over the last 2 years, surpassing $10 billion annually by the end of 2024.



Skin Substitutes: OIG

Certain MPFS Final Rules Changes:

- Biologics are now “incident-to supplies” when used during a covered application procedure paid under the PFS in the non-facility setting or under OPPS
  - In non-facility setting -> paid using the ASP methodology
    - Biologics license
  - In OPPS setting ->
- Reimbursement based on 3 categories of skin substitutes, based on FDA pathways: 510(k)-cleared devices; registered 361 HCT/Ps; and (3) PMA-approved devices



Press Releases Apr 11, 2025

CMS Statement on Local Coverage Determination for Certain Skin Substitute Grafts

Coverage

Share

As part of the transition to a new Administration, CMS is reviewing its coverage policies for skin substitute products. CMS believes it is important to maintain patient access to skin substitute products with high quality evidence of effectiveness. Because of this review, the Skin Substitute Grafts/Cellular and Tissue-Based Products for the Treatment of Diabetic Foot Ulcers and Venous Leg Ulcers Final Local Coverage Determinations effective date will be delayed until January 1, 2026. The Agency requests that any peer-reviewed publications and high-quality findings from other public sources of skin substitute study results be submitted to CMS at CAGInquiries@cms.hhs.gov by November 1, 2025. CMS will ensure all evidence

Fact Sheets Dec 24, 2025

Final Local Coverage Determinations (LCDs) for Certain Skin Substitutes Withdrawn

Coverage

Share

Final Local Coverage Determinations (LCDs) for Certain Skin Substitutes Withdrawn

Effective immediately, CMS’ A/B Medicare Administrative Contractors (MACs) are withdrawing the Local Coverage Determinations (LCDs) for Skin Substitute Grafts/Cellular and Tissue-Based Products for the Treatment of Diabetic Foot Ulcers and Venous Leg Ulcers that were scheduled to become effective on January 1, 2026.

Skin Substitutes/ Wound Care Enforcement Actions

Fraud Division Announces Massive Crackdown for Second Straight Week — Over $1 BILLION in Nationwide Fraud Enforcement Actions

Friday, May 15, 2026

Share

For Immediate Release

Office of Public Affairs

The Justice Department's National Fraud Enforcement Division announced numerous enforcement actions in the past week, as prosecutors across the country pursued the criminals stealing American taxpayer dollars. Notably, a jury in the Southern District of Florida found the founder and owner of HealthSplash guilty for his role in operating a platform that generated false doctors' orders and prescriptions to defraud Medicare and other federal health care benefit programs, billing more than $1 billion for unnecessary equipment.

"In the past week, prosecutors throughout the Department secured trial convictions of multiple defendants who ran fraud schemes totaling over a billion dollars," said Assistant Attorney General Colin M. McDonald of the National Fraud Enforcement Division. "I am proud of the fearless men and women of the Fraud Division who are fighting to protect the American people and hold fraudsters accountable."

Wound Graft Company Owners Sentenced for $1.2B Health Care Fraud and Agree to Pay $309M to Resolve Civil Liability Under the False Claims Act

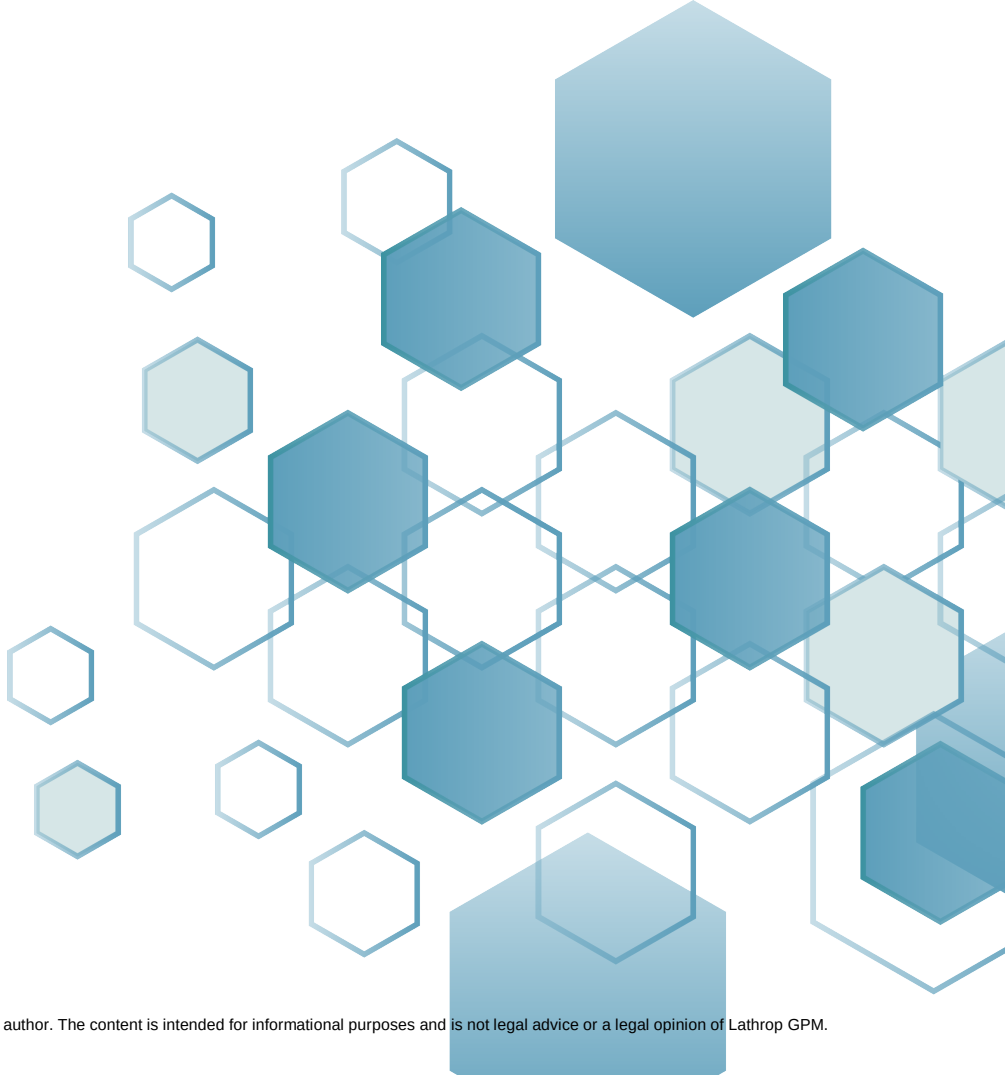
In the first prosecution of its kind, the owners of several Arizona wound graft companies were sentenced to significant terms of incarceration for causing over $1.2 billion of false and fraudulent claims to be submitted to Medicare and other health insurance programs for medically unnecessary wound grafts that were ordered as a result of illegal kickbacks and applied to elderly and terminally ill patients. On Oct.7 Alexandra Gehrke was sentenced to 15.5 years in prison, and on Oct. 10 her husband, Jeffrey King, was sentenced to 14 years in prison.

According to court documents, Gehrke, 39, and King, 46, both of Phoenix, orchestrated a large-scale wound-care scheme from 2022 through 2024. Gehrke solely owned and operated two companies that contracted with medically untrained "sales representatives" to find elderly Medicare beneficiaries throughout Arizona with wounds of any kind. Once the sales representatives identified these patients, many of whom were in hospice care, Gehrke directed the sales representatives to order expensive bioengineered skin substitutes — amniotic membrane allografts made from human placental tissue — to be placed on the wounds. To maximize profits, Gehrke required the sales representatives to order only the largest sizes of grafts available, even if the sizes of grafts — or the use of grafts as treatment — were not medically appropriate or reasonable.

HIPAA and Related Matters

- HIPAA developments:
  - Feb. 16, 2026 compliance date for covered entities that create, receive, maintain or transmit SUD information
  - 2021 proposed modifications to Privacy Rule
    - 2026 HHS Regulatory Agenda says Privacy Rule will be released in Aug. 2026
  - 2024 proposed updates to Security Rule
    - Had been slated for May 2026 release; now shifted to Jul. 2027
  - OCR anticipates publishing industry reports summarizing audit findings (similar to OIG reports)
  - 2022 OCR RFI on how to share portion of financial recoveries for HIPAA violations with individuals harmed by those violations
  - “Voluntary” compliance with 2023 Healthcare Sector Cybersecurity strategy and 2024 HPH Sector Cybersecurity Performance Goals
- Other rules finalized and implemented
  - 2024 Final Rule aligning Part 2 confidentiality with HIPAA Privacy Rule. Feb. 16, 2026 compliance date
  - OCR has publicly said it is now receiving complaints / breach reports tied to Part 2 compliance

Enforcement



“The Social Security Act is among the most intricate ever drafted by Congress. Its Byzantine construction, as Judge Friendly has observed, makes the Act “almost unintelligible to the uninitiated.”

~Schweiker v. Gray Panthers, 453 U.S. 34, 43 (1981)

DOJ False Claims Act (Civil) Settlements and Judgments

FY	NEW MATTERS[4]		SETTLEMENTS AND JUDGMENTS[1]					RELATOR SHARE AWARDS[2]		
	NON QUI TAM	QUI TAM	NON[3] QUI TAM	QUI TAM			TOTAL QUI TAM AND NON QUI TAM	WHERE U.S. INTERVENED OR OTHERWISE PURSUED	WHERE U.S. DECLINED	TOTAL
			TOTAL	WHERE U.S. INTERVENED OR OTHERWISE PURSUED	WHERE U.S. DECLINED	TOTAL				
2006	76	385	1,712,459,257	1,491,105,499	22,711,363	1,513,816,862	3,226,276,119	219,976,072	5,647,836	225,623,908
2007	146	365	564,826,844	1,252,616,955	160,246,894	1,412,863,849	1,977,690,693	194,641,212	4,616,899	199,258,111
2008	166	379	312,193,480	1,105,288,516	12,678,936	1,117,967,452	1,430,160,932	208,686,037	2,997,615	211,683,652
2009	134	433	470,685,686	1,964,005,251	33,776,480	1,997,781,730	2,468,467,417	249,567,135	9,684,147	259,251,282
2010	144	576	649,300,368	2,279,140,248	109,778,613	2,388,918,862	3,038,219,230	379,518,436	30,915,991	410,434,427
2011	136	634	241,365,995	2,656,802,414	173,888,703	2,830,691,117	3,072,057,112	525,035,022	49,041,606	574,076,628
2012	158	655	1,612,212,862	3,379,683,169	90,248,343	3,469,931,512	5,082,144,374	440,672,456	24,861,743	465,534,199
2013	117	757	188,376,772	2,825,162,362	203,992,659	3,029,155,021	3,217,531,794	514,475,128	51,197,091	565,672,219
2014	119	716	1,677,608,226	4,390,679,739	91,136,701	4,481,816,440	6,159,424,665	703,127,381	17,615,475	720,742,857
2015	129	639	738,442,487	1,905,454,763	516,875,695	2,422,330,458	3,160,772,945	345,537,532	139,015,177	484,552,709
2016	184	710	1,929,806,062	2,929,387,222	108,298,069	3,037,685,292	4,967,491,353	525,546,823	29,658,600	555,205,423
2017	176	682	298,514,800	2,555,280,735	602,682,052	3,157,962,787	3,456,477,586	412,076,224	135,360,010	547,436,234
2018	133	650	783,996,453	1,999,330,585	210,796,053	2,210,126,638	2,994,123,091	328,352,091	37,505,357	365,857,449
2019	150	641	858,030,132	1,912,589,545	305,554,613	2,218,144,158	3,076,174,290	290,613,360	75,143,367	365,756,728
2020	261	679	544,724,942	1,566,964,401	193,883,475	1,760,847,877	2,305,572,819	285,973,891	51,274,154	337,248,044
2021	212	598	4,016,918,820	1,210,916,864	482,504,272	1,693,421,136	5,710,339,956	201,302,446	62,812,398	264,114,843
2022	305	660	250,337,200	807,419,063	1,199,211,531	2,006,630,594	2,256,967,793	149,231,533	350,990,454	500,221,987
2023	506	712	[illegible]	2,029,079,863	[illegible]	2,528,717,807	[illegible]	387,935,256	98,318,770	486,254,025
2024	425	[illegible]	504,097,394	2,317,992,077	311,728,929	2,629,721,006	3,133,818,400	393,046,308	86,158,558	479,204,866
2025	401	1,297	1,548,089,931	3,051,734,829	2,288,271,506	5,340,006,336	6,888,096,266	286,054,233	44,303,986	330,358,218

Fraud & Abuse: Proactive and Aggressive Enforcement

- Federal enforcement continuing shift from retrospective audits to real-time, data-driven intervention and from rulemaking to targeted enforcement
- Prepayment detection and analytics
  - CMS expanding use of predictive analytics to identify suspicious billing patterns before claims are paid
  - Increased reliance on automated screening and data modeling to flag risk-providers and services
- Targeted enforcement focus areas
  - Risk adjustment coding and Medicare Advantage audits (RADV expansion)
  - Third-party marketing and enrollment practices (TPMOs / DTC)
  - Information blocking and performance reporting integrity
- Regulatory direction
  - Greater emphasis on preventing improper payments rather than recovering them after the fact
  - Enforcement driven by data, patterns and system-level risk indicators

DTC Marketing and Sales

Under heightened scrutiny, especially third-party brokers (TPMOs), with new disclaimer requirements, call recording mandates, restrictions on benefit advertising and data-driven investigations into misleading enrollment practices

The United States Files False Claims Act Complaint Against Three National Health Insurance Companies and Three Brokers Alleging Unlawful Kickbacks and Discrimination Against Disabled Americans

Thursday, May 1, 2025

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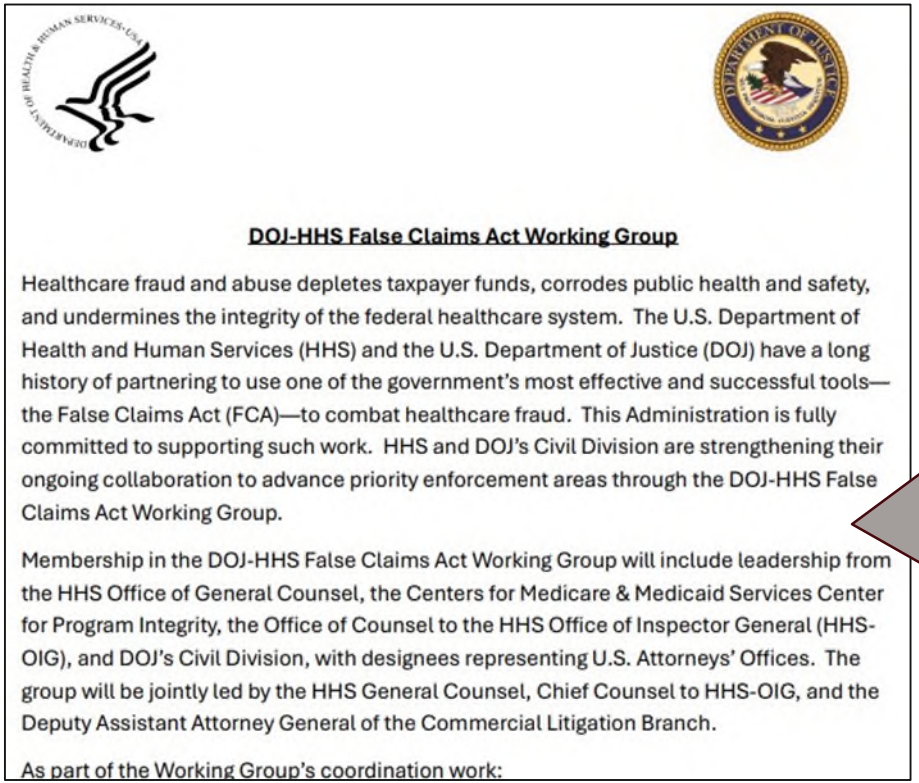
For Immediate Release

Office of Public Affairs

The United States filed a complaint today under the False Claims Act (FCA) against three of the nation's largest health insurance companies — Aetna Inc. and affiliates, Elevance Health Inc. (formerly known as Anthem), and Humana Inc. — and three large insurance broker organizations — eHealth, Inc. and an affiliate, GoHealth, Inc., and SelectQuote Inc. The United States alleges that from 2016 through at least 2021, the defendant insurers paid hundreds of millions of dollars in illegal kickbacks to the defendant brokers in exchange for enrollments into the insurers' Medicare Advantage plans.

Under the Medicare Advantage (MA) Program, also known as Medicare Part C, Medicare beneficiaries may choose to enroll in health care plans (MA plans) offered by private insurance companies, such as defendants Aetna, Anthem, and Humana. Many Medicare beneficiaries rely on insurance brokers to help them choose an MA plan that best meets their individual needs. Rather than acting as unbiased stewards, the defendant brokers allegedly directed Medicare beneficiaries to the plans offered by insurers that paid brokers the most in kickbacks, regardless of the suitability of the MA plans for the beneficiaries. According to the complaint, the broker organizations incentivized their employees and agents to sell plans based on the insurers' kickbacks, set up teams of insurance agents who could sell only those plans, and at times refused to sell MA plans of insurers who did not pay sufficient kickbacks.

DOJ / HHS False Claims Act Working Group



DOJ-HHS False Claims Act Working Group

Healthcare fraud and abuse depletes taxpayer funds, corrodes public health and safety, and undermines the integrity of the federal healthcare system. The U.S. Department of Health and Human Services (HHS) and the U.S. Department of Justice (DOJ) have a long history of partnering to use one of the government's most effective and successful tools—the False Claims Act (FCA)—to combat healthcare fraud. This Administration is fully committed to supporting such work. HHS and DOJ's Civil Division are strengthening their ongoing collaboration to advance priority enforcement areas through the DOJ-HHS False Claims Act Working Group.

Membership in the DOJ-HHS False Claims Act Working Group will include leadership from the HHS Office of General Counsel, the Centers for Medicare & Medicaid Services Center for Program Integrity, the Office of Counsel to the HHS Office of Inspector General (HHS-OIG), and DOJ's Civil Division, with designees representing U.S. Attorneys' Offices. The group will be jointly led by the HHS General Counsel, Chief Counsel to HHS-OIG, and the Deputy Assistant Attorney General of the Commercial Litigation Branch.

As part of the Working Group's coordination work:

Priority enforcement areas:

- Medicare Advantage
- Drug/device pricing
- Barriers to patient access to care, including network adequacy
- Kickbacks related to drugs, medical devices, durable medical equipment, and other products
- Defective medical devices that impact patient safety
- Manipulation of EHR systems to drive inappropriate utilization

2025: DOJ Health Care Fraud Takedown

- 2025 National Health Care Fraud Takedown resulted in charges against 324 defendants, including 96 doctors, nurse practitioners, pharmacists and other licensed professionals
- 50 federal districts and 12 State Attorneys General involved, along with HHS-OIG, Health Care Fraud Unit of DOJ Criminal Division, US Attorneys Offices, FBI and DEA
- Takedown alleges participants were involved in various health care fraud schemes involving more than $14.6 billion in intended losses (more than double previous record of $6 billion)
- Conduct alleged included:
  - Fraudulent DMEPOS billing
  - Fraudulent would care
  - Prescription opioid trafficking
  - Telehealth
  - Genetic testing fraud
  - Various kickback schemes

2026: Largest Health Care Fraud Takedown in History

- 2026: DOJ announced charges against 455 defendants, including 90 physicians and other licensed health care professionals, involving alleged health care fraud and opioid-related schemes totaling more than $6.5 billion in false claims.
- The effort involved 56 federal districts, 45 states and territories, and all 50 Medicaid Fraud Control Units, representing the broadest participation in Takedown history.
- Advanced data analytics and international law enforcement cooperation contributed to the investigation and recovery of assets valued at more than $182 million, including cash, luxury vehicles, and jewelry
- “Whole-of-government” approach
  - CMS suspended 1,079 providers and revoked billing privileges for 1,403 providers.
  - HHS-OIG secured 48 CMP settlements totaling more than $73 million, over 1,400 exclusions, and 25 additional enforcement actions.
  - DOJ pursued civil actions against 13 defendants involving $14.8 million in alleged fraud and obtained settlements with 31 defendants totaling $23 million.
  - DEA initiated 928 administrative actions to revoke controlled substance prescribing or handling authority since October 2025.

Crushing Fraud Chili Cook-Off Competition

- Market-based research challenge aimed at harnessing AI / ML to detect anomalies and trends in Medicare claims data that can be translated into novel indicators of fraud
- 2 Phases
  - Phase 1: Interested parties can submit proposals. 10 teams selected to advance to Phase 2
  - Phase 2: Finalists receive access to FFS Hospice, Part B and DME claims. Apply proposed AI / ML techniques to data and submit summary of findings and proposed scalable analytic and policy solutions
    - Final submissions due Dec. 1, 2025
    - Winner announced on Dec. 15, 2025: Milliman

OIG Enforcement Actions

U.S. Department of Health and Human Services
Office of Inspector General

- Employing Excluded Individuals:
  - 4 totaling $568,000; penalties ranged from $74,000 - $315,000
- Services Provided by an Unlicensed Individual:
  - 2 totaling $98,000; $33,000 and $65,000
- Claims for Incident-to Services w/o Proper Supervision:
  - 1 totaling $33,000
- Breach of:
  - Compliance Agreement: 1 totaling $7,500
  - Integrity Agreement: 3 totaling $97,600 (1 upheld by DAB)

Hot Off the Press: HHS OIG Spring 2026 Report

- Executive Summary
  - $5.56 billion total monetary impact generated.
  - 1,212 individuals and entities excluded from federal health care programs.
  - 317 criminal actions and 287 civil actions resulting from investigations.
  - $4.3 billion in investigative receivables.
  - OIG returns approximately $12.70 for every $1 invested in oversight activities.
- Preventing and Detecting Improper Payments
  - CMS estimated $95B+ in improper payments across major programs.
  - Medicare improperly paid $22.7M for DMEPOS during inpatient stays.
  - CMS contract closeout weaknesses exposed $11.2B to fraud, waste, and abuse risk.
  - OIG identified $447.6M in funds put to better use

HHS OIG Spring 2026 Report- Enforcement

- Major Fraud Enforcement Actions
  - CEO of Power Mobility Doctor Rx, LLC sentenced to 15 years in prison for a $1B telemedicine/DME fraud scheme; ordered to pay $452M restitution.
  - Wound graft company owners prosecuted in connection with $1.2B fraudulent claims and kickback scheme.
  - Insurance and marketing executives sentenced to 20 years for a $233M ACA enrollment fraud scheme.
  - Four hospice operators sentenced for submitting nearly $16M in false Medicare claims.
- Significant Managed Care Enforcement Settlements:
  - Kaiser Permanente affiliates: $556M settlement.
  - Aetna: $117.7M settlement.

HHS OIG Spring 2026 Report- Medicaid Fraud

- Medicaid Fraud Control Units (FY 2025 Results)
  - 1,185 convictions
  - 674 civil settlements/judgments
  - 900 exclusions
  - >$2 billion recovered
- Colorado: $77.8M improper Medicaid autism therapy payments.
- Maine: $45.6M improper Medicaid autism therapy payments.
- OIG found that Medicaid agencies in 35 States plus Puerto Rico and Washington, DC, made $207.5M in unallowable capitation payments for deceased Medicaid enrollees.

HHS OIG Spring 2026 Report- Nursing Homes

- Nursing Home Oversight
  - OIG identified inappropriate use of antipsychotic medications among nursing home residents with dementia.
  - Some facilities allegedly used schizophrenia diagnoses to mask inappropriate antipsychotic prescribing.
- Enforcement
  - Ten individuals and entities were excluded from Federal health care programs for an indefinite period based on their suspension and disqualification from participation in the New Jersey Medicaid program
  - Nursing facility Atrium Health and Senior Living and its CEO were sentenced after being convicted of health care fraud and tax conspiracy. The CEO was sentenced to 90 months in Federal prison, and both Atrium and the CEO were ordered to pay $146 million in restitution and $8.4 million in forfeiture.

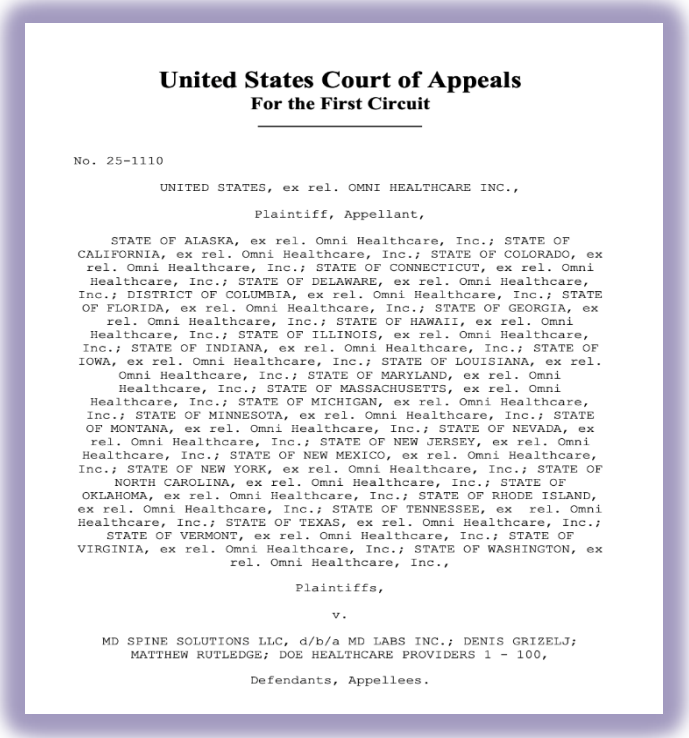
HHS OIG Spring 2026 Report- Opioid and Controlled Substance Fraud

- More than 70,000 overdose deaths occurred in FY 2025
- Enforcement
  - Louisiana physician excluded for 23 years for unlawfully distributing controlled substances, issuing pre-signed prescriptions, and participating in health care fraud.
  - Pharmacy owner excluded for 27 years after selling opioids directly to drug traffickers and engaging in related fraud offenses.
  - Two pharmacists and a narcotics dealer sentenced for illegally distributing high volumes of oxycodone while ignoring clear signs of diversion and misuse.
  - Mt. San Rafael Hospital and three physicians paid $650,000 to resolve allegations involving unsafe opioid prescribing, dangerous drug combinations, and improper billing to federal health care program

False Claims Act: Expansion and Pushback

- Expansion into:
  - Risk adjustment
  - Quality of care
  - Cybersecurity / data representations (DOJ Civil Cyber-Fraud Initiative)
- Courts are tightening:
  - Materiality
  - Causation
- Emerging issues:
  - Constitutional challenge to qui-tam (*Zafirov*-type challenge to qui tam in broader post *Loper Bright* environment)

FCA Enforcement: Medical Necessity & Labs



United States Court of Appeals
For the First Circuit

No. 25-1110

UNITED STATES, ex rel. OMNI HEALTHCARE INC.,

Plaintiff, Appellant,

STATE OF ALASKA, ex rel. Omni Healthcare, Inc.; STATE OF CALIFORNIA, ex rel. Omni Healthcare, Inc.; STATE OF COLORADO, ex rel. Omni Healthcare, Inc.; STATE OF CONNECTICUT, ex rel. Omni Healthcare, Inc.; STATE OF DELAWARE, ex rel. Omni Healthcare, Inc.; DISTRICT OF COLUMBIA, ex rel. Omni Healthcare, Inc.; STATE OF FLORIDA, ex rel. Omni Healthcare, Inc.; STATE OF GEORGIA, ex rel. Omni Healthcare, Inc.; STATE OF HAWAII, ex rel. Omni Healthcare, Inc.; STATE OF ILLINOIS, ex rel. Omni Healthcare, Inc.; STATE OF INDIANA, ex rel. Omni Healthcare, Inc.; STATE OF IOWA, ex rel. Omni Healthcare, Inc.; STATE OF LOUISIANA, ex rel. Omni Healthcare, Inc.; STATE OF MARYLAND, ex rel. Omni Healthcare, Inc.; STATE OF MASSACHUSETTS, ex rel. Omni Healthcare, Inc.; STATE OF MICHIGAN, ex rel. Omni Healthcare, Inc.; STATE OF MINNESOTA, ex rel. Omni Healthcare, Inc.; STATE OF MONTANA, ex rel. Omni Healthcare, Inc.; STATE OF NEVADA, ex rel. Omni Healthcare, Inc.; STATE OF NEW JERSEY, ex rel. Omni Healthcare, Inc.; STATE OF NEW MEXICO, ex rel. Omni Healthcare, Inc.; STATE OF NEW YORK, ex rel. Omni Healthcare, Inc.; STATE OF NORTH CAROLINA, ex rel. Omni Healthcare, Inc.; STATE OF OKLAHOMA, ex rel. Omni Healthcare, Inc.; STATE OF RHODE ISLAND, ex rel. Omni Healthcare, Inc.; STATE OF TENNESSEE, ex rel. Omni Healthcare, Inc.; STATE OF TEXAS, ex rel. Omni Healthcare, Inc.; STATE OF VERMONT, ex rel. Omni Healthcare, Inc.; STATE OF VIRGINIA, ex rel. Omni Healthcare, Inc.; STATE OF WASHINGTON, ex rel. Omni Healthcare, Inc.,

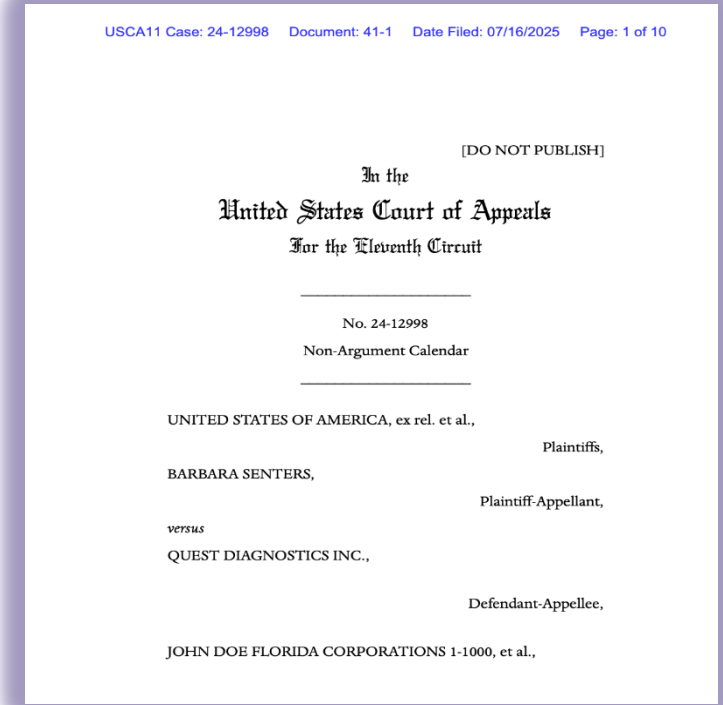
Plaintiffs,

v.

MD SPINE SOLUTIONS LLC, d/b/a MD LABS INC.; DENIS GRIZELJ; MATTHEW RUTLEDGE; DOE HEALTHCARE PROVIDERS 1 - 100,

Defendants, Appellees.

Omin: 1st Cir Dec. 1, 2025



USCA11 Case: 24-12998 Document: 41-1 Date Filed: 07/16/2025 Page: 1 of 10

[DO NOT PUBLISH]

In the
United States Court of Appeals
For the Eleventh Circuit

No. 24-12998
Non-Argument Calendar

UNITED STATES OF AMERICA, ex rel. et al.,

Plaintiffs,

BARBARA SENTERS,

Plaintiff-Appellant,

versus

QUEST DIAGNOSTICS INC.,

Defendant-Appellee,

JOHN DOE FLORIDA CORPORATIONS 1-1000, et al.,

Quest: 11th Cir. July 16, 2025

FCA Enforcement: Medical Necessity

Arkansas Pathology Laboratory and Its Owners Pay $30M to Settle Allegations of Kickbacks and Unnecessary Medical Testing

Wednesday, June 17, 2026

Share

For Immediate Release

Office of Public Affairs

Advanced Pathology Solutions PLLC (formerly known as Advanced Pathology Solutions LLC), ar anatomic pathology laboratory headquartered in North Little Rock, Arkansas, and its management services organization, APS MSO LLC (together, "APS"), along with current and former owners Kevin Hannah, Donell Burkett, and Daniel Hunter Pledger have agreed to pay a total of $30 million to the United States to resolve allegations that APS and its owners furnishec unlawful kickbacks and ordered medically unnecessary pathology testing services.

"Healthcare referrals must be based on the best decision for patients, not the influence of kickbacks," said Assistant Attorney General Brett A. Shumate of the Justice Department's Civil Division. "This settlement demonstrates the Department's commitment to hold accountable both corporations and individuals who profit from improper kickback arrangements and who burden federal healthcare programs with claims for medically unnecessary services."

Gastroenterology Practice Agrees to Pay $4.75M to Settle Allegations of Kickbacks and Unnecessary Medical Testing Services

Friday, February 27, 2026

Share

For Immediate Release

Office of Public Affairs

Atlanta Gastroenterology Associates resolves allegations that it received kickbacks for referrals and performed medically unnecessary gastrointestinal pathology testing services

Atlanta Gastroenterology Associates located in Atlanta, Georgia, has agreed to pay $4.75 million to resolve allegations that it violated the False Claims Act by receiving kickbacks in exchange for referrals of gastrointestinal pathology services and by performing certain gastrointestinal pathology services that were not medically reasonable or necessary.

The United States alleged that beginning in approximately May 2017, Atlanta Gastroenterology Associates contracted with Advanced Pathology Solutions (APS), a pathology laboratory located in Little Rock, Arkansas, to construct and operate a limited-capacity pathology laboratory in Atlanta Gastroenterology Associates' office. Atlanta Gastroenterology Associates received various benefits from APS in connection with the setup and ongoing operations of the in-house lab, in which histology technicians prepared and stained specimen sample slides and Atlanta Gastroenterology Associates billed Medicare and other insurers for the technical component of those services. In exchange, Atlanta Gastroenterology Associates agreed to exclusively refer patients to APS, which interpreted the slides and billed for the professional component of the services. The United States alleges that the benefits provided by APS to Atlanta Gastroenterology Associates were unlawful remuneration in exchange for patient referrals.

FCA Enforcement: Medical Necessity

Vascular Practice and Physician Agree to Pay More Than $6.73M to Settle False Claims Act Allegations of Unnecessary Vascular Interventional Procedures

Wednesday, May 6, 2026

Share

Serrano Kidney & Vascular Access Center, a physician practice based in Huntington Park, California, and physician Dr. Feliciano Serrano have agreed to pay more than $6.73 million to resolve allegations that they violated the False Claims Act by submitting false claims for medically unnecessary vascular interventional procedures on 20 Medicare beneficiaries.

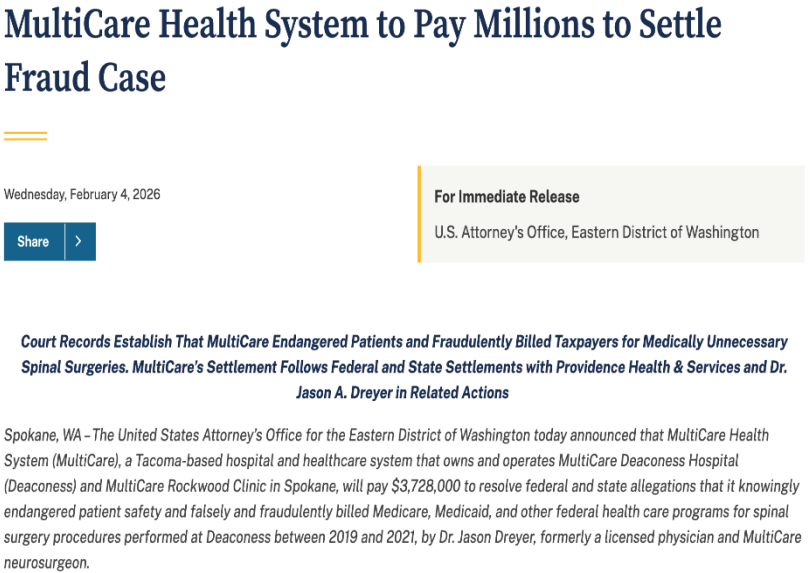
"Physicians should not be performing and billing for unnecessary and excessive medical interventions. False documentation of symptoms compromises the integrity of our federal health care programs and the well-being of beneficiaries," said Assistant Attorney General Brett A. Shumate of the Justice Department's Civil Division. "Physicians who place their own profit over patient needs will be held accountable."

"False claims to Medicare and Medicaid cause millions of dollars in losses to the government," said First Assistant U.S. Attorney Bill A. Essayli for the Central District of California. "This settlement sends a clear message to physicians that the United States will zealously pursue appropriate action against those who submit false claims for taxpayer funds."

FCA Enforcement: Medical Necessity

- Medically unnecessary spine surgery
- Other health system settled in 2022 for $22.7 M
- Dr. Dreyer settled in 2023 for $1.1M

“As the voluminous court records of this case demonstrate, MultiCare had direct knowledge of the danger Dr. Dreyer posed to patients, including through reports made by its own medical staff, and later from explicit warnings from federal investigators”



MultiCare Health System to Pay Millions to Settle Fraud Case

Wednesday, February 4, 2026

Share

For Immediate Release

U.S. Attorney's Office, Eastern District of Washington

Court Records Establish That MultiCare Endangered Patients and Fraudulently Billed Taxpayers for Medically Unnecessary Spinal Surgeries. MultiCare's Settlement Follows Federal and State Settlements with Providence Health & Services and Dr. Jason A. Dreyer in Related Actions

Spokane, WA – The United States Attorney's Office for the Eastern District of Washington today announced that MultiCare Health System (MultiCare), a Tacoma-based hospital and healthcare system that owns and operates MultiCare Deaconess Hospital (Deaconess) and MultiCare Rockwood Clinic in Spokane, will pay $3,728,000 to resolve federal and state allegations that it knowingly endangered patient safety and falsely and fraudulently billed Medicare, Medicaid, and other federal health care programs for spinal surgery procedures performed at Deaconess between 2019 and 2021, by Dr. Jason Dreyer, formerly a licensed physician and MultiCare neurosurgeon.

FCA Enforcement: Medical Necessity

Nurse Practitioner Sentenced to 87 Months in Prison for $12M Medicare Fraud

Wednesday, June 17, 2026

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For Immediate Release

Office of Public Affairs

A Louisiana nurse practitioner was sentenced today to 87 months in prison and three years of supervised release for causing over $12 million in false and fraudulent claims to Medicare for medically unnecessary cancer genetic tests. She was also ordered to pay $1,508,868.25 in restitution.

According to court documents and evidence presented at trial, Scharmaine Lawson Baker, 59, of Fulshear, Texas, a licensed nurse practitioner and Medicare provider, received tens of thousands of dollars in illegal kickbacks in exchange for ordering expensive cancer genetic tests. Lawson Baker held herself out as an expert in Medicare regulations — authoring books on medical necessity and patient-provider relationships — while actively violating those very standards.

FCA Enforcement: Substandard Care

PRESS RELEASE

Ohio Based Nonprofit and Affiliated Nursing Homes Agree to Pay $3.61M to Resolve False Claims Act Liability

Tuesday, June 3, 2025

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For Immediate Release

Office of Public Affairs

American Health Foundation (AHF), its affiliate AHF Management Corporation, and three affiliated nursing homes — Cheltenham Nursing & Rehabilitation Center (Cheltenham), The Sanctuary at Wilmington Place (Wilmington Place), and Samaritan Care Center and Villa (Samaritan) — have agreed to pay $3.61 million to resolve claims related to billing Medicare and Medicaid for grossly substandard skilled nursing services between 2016 and 2018. AHF is a nonprofit corporation that is headquartered in Dublin, Ohio, and owns and controls nursing homes in Ohio and Pennsylvania. Cheltenham is a 255-bed nursing home located in Philadelphia,

PRESS RELEASE

United States Intervenes and Sues ProMedica Health System, Inc. and Its Affiliates for Providing Grossly Substandard Nursing Home Services

Tuesday, September 2, 2025

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For Immediate Release

Office of Public Affairs

The United States has intervened and filed a complaint in the U.S. District Court for the Eastern District of Pennsylvania under the False Claims Act (FCA) against ProMedica Health System, Inc. (ProMedica) and various affiliated entities including HCR ManorCare Inc. and four nursing homes located in Pennsylvania, Ohio, South Carolina, and Virginia (the defendants). ProMedica is a nonprofit corporation that is headquartered in Toledo, Ohio. From 2018 to 2023, it owned and controlled the following four nursing homes: ProMedica Skilled Nursing and Rehabilitation - Pottstown (Pennsylvania), ProMedica Skilled Nursing and Rehabilitation - Riverview (Ohio), ProMedica Skilled Nursing, Rehabilitation - Greenville East (South Carolina), and ProMedica Skilled Nursing and Rehabilitation - Imperial (Virginia).

Notable Court Decisions – Anti-kickback Statute

- US v. Regeneron Pharma., Inc., 23-2086 (1st Cir. 2025)
  - Allegation: Regeneron's co-payment rebate program was a kickback to patients that resulted in false claims to Medicare
  - DOJ claim: if there was a rebate, then the claim was false "whether or not those claims would have been made" absent the co-payment rebate program
  - Context: claims "resulting from" kickbacks are false for purposes of civil liability
  - The First Circuit held that the phase, "resulting from" means "but for" causation, i.e., if doctor would have billed for the drug absent the rebate program, then claim not result from the program
  - Joins the Sixth and Eight Circuits, Third Circuit requires only some "causal link"

Notable Court Decisions – Stark Law & AKS

ex Rel. Terpening v. Fresno Community Hospital and Medical Center, 1:19-CV-01699 (E.D. Cal.)

- Community Health System (CHS) and affiliate Physician Network Advantage (PNA) agreed to pay $31.5 million to resolve AKS and Stark Law allegations
- Allegations included:
  - CHS gave various extravagant benefits to induce referrals from physicians in Fresno area
  - CHS built lounge on PNA premises where expensive wine, liquor, cigars and meals given to referring physicians
  - CHS / PNA provided financial subsidies for EHR technology / equipment
  - Paid referral bonuses to physicians, disguised as payment for participation in clinical integration activities

Notable Settlements – Stark Law & AKS

Traditions Health LLC

- Traditions agreed to pay $34 million to resolve allegations it violated FCA by billing for medically unnecessary home health claims and providing financial benefits to referring physicians
- Settlement resulted from self-disclosure. DOJ press release cited Traditions taking “significant steps entitling it to credit for cooperating with the government”
  - Removed individuals responsible for the conduct, improved compliance program and provided additional training to employees

ex rel. Tucker v. Catholic Health System 20-cv-1482 (W.D.N.Y.)

- Catholic Health System agreed to pay $3.3 million to resolve allegations that it knowingly submitted false claims to Medicare that resulted from Stark Law violations
- Government alleged that CHS and its affiliated hospitals had financial relationships with non-employee physicians, who referred health services, such as laboratory testing, hospital services, or medical supplies, to CHS and its affiliated hospitals.

Notable Enforcement Actions– Stark Law & AKS

Priority Hospital Group

- On Jan. 16, DOJ filed FCA complaint against Priority Hospital Group (PHG), a hospital management company, three PHG-managed long term care hospitals and a physician
- Alleges FCA violations based on medically unnecessary care and referrals made in violation of AKS and Stark Law, including following:
  - Patients held in hospital longer than necessary in order to increase payments
  - Medical director arrangement with referring physician. Paid $450,000 to induce referrals. Payments were in excess FMV and physician not required to work hours specified in contract

Gulf Coast Eye

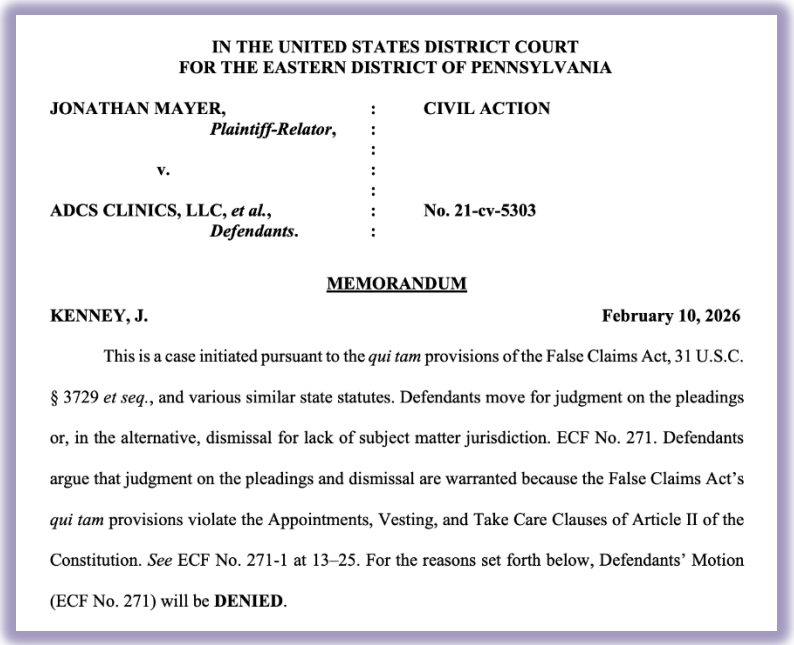
- Pinellas Eye Care (d/b/a Gulf Coast Eye) agreed to pay $615,000 to resolve FCA claims based on Stark Law and AKS
- Allegations were that Gulfcoast Eye paid the third-party trans-cranial ultrasound (TCD) provider based on the volume / value of tests ordered and referred the patients to the TCD provider's preferred radiology group for the TCD's professional component.
- Before patients received test results, patients identified as having received diagnosis of occlusion and stenosis of their cerebral arteries in order to qualify for reimbursement of TCDs
- Nearly all patients who received TCDs never had occlusion and stenosis of cerebral arteries, and that diagnosis was accordingly not reflected in the patient's medical history or in the TCD results.

False Claims Act: Is it Constitutional??

- **The Origin**: U.S. ex rel. Polansky v. Exec. Health Res., Inc. 599 U.S. 419 (2023)
  - Justice Thomas's dissent raised "serious constitutional questions" regarding the qui tam provisions of the FCA, including their potential inconsistency with Article II of the Constitution.
- **Florida Court**: U.S. ex rel. Zafirov v. Florida Med. Assocs., 751 F. Supp.3d 1293 (M.D. Fla. Sept. 30, 2024)
  - Court held that the qui tam provisions of the FCA violated Article II and the Appointments Clause
  - Appealed to 11th Circuit
  - Oral argument held Dec 12, 2025

False Claims Act: Is it Constitutional??

- *Penelow, et al. v. Janssen Prods. LP*
- *U.S. ex rel. Murphy v. TriHealth Inc.*
- Fifth Circuit:
  - *U.S. ex rel. Montcrief v. Peripheral Vascular Assocs*., P.A. (March 2025)
  - *U.S. ex rel. Gentry v. Encompass Health Rehab. Hosp. of Pearland, L.L.C.* (Nov 2025)



IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF PENNSYLVANIA

JONATHAN MAYER, ***Plaintiff-Relator,***	:	**CIVIL ACTION**
v.	:	
ADCS CLINICS, LLC, *et al.*, ***Defendants.***	:	**No. 21-cv-5303**

MEMORANDUM

KENNEY, J. **February 10, 2026**

This is a case initiated pursuant to the *qui tam* provisions of the False Claims Act, 31 U.S.C. § 3729 *et seq.*, and various similar state statutes. Defendants move for judgment on the pleadings or, in the alternative, dismissal for lack of subject matter jurisdiction. ECF No. 271. Defendants argue that judgment on the pleadings and dismissal are warranted because the False Claims Act's *qui tam* provisions violate the Appointments, Vesting, and Take Care Clauses of Article II of the Constitution. *See* ECF No. 271-1 at 13–25. For the reasons set forth below, Defendants' Motion (ECF No. 271) will be **DENIED**.

Jonathan Meyer v ADS Clinics, LLC, Feb. 10, 2026

More False Claims Act Developments

- May 27, 2026: DOJ announced a new initiative to accelerate review of FCA qui tam complaints alleging fraud in federally funded, state-administered benefit programs
  - DOJ aims to complete initial case assessments within 60–120 days.
- *United States v. Ma* (Feb 2026)
  - The Fifth Circuit upheld enforcement of a $2.3 million FCA settlement between the US and an acupuncture practice accused of submitting inflated reimbursement claims to the Department of Veterans Affairs.
- *United States ex rel. LaBenne v. Koninklijke Ahold Delhaize N.V.* (May 2026)
  - Ahold Delhaize USA Inc. agreed to pay $40 million to the US and participating states to resolve FCA allegations related to reporting inflated prescription drug prices to federal health care programs
- *United States ex rel. Lieberman v. Modern Nuclear, Inc.* (May 2026)
  - Modern Nuclear Inc. (MNI) agreed to pay more than $8.3 million to resolve allegations that it violated the FCA and Anti-Kickback Statute (AKS) through compensation arrangements with referring cardiologist

COVID Enforcement

PRESS RELEASE

Florida Businessman Patrick Walsh and Affiliated Companies Agree to $20M Consent Judgment to Settle False Claims Act Liability Relating to Fraudulent Pandemic Relief Loans

Wednesday, March 12, 2025

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For Immediate Release

Office of Public Affairs

Patrick Walsh and 10 companies he owned or operated have agreed to enter into a consent judgment totaling $20,074,458.70 to resolve allegations that they violated the False Claims Act by knowingly providing false information in support of Paycheck Protection Program (PPP) and Economic Injury Disaster Loan (EIDL) loan applications. The 10 companies for which Walsh

"The Department's enforcement efforts in this area have included the pursuit of cases involving improper payments under the Paycheck Protection Program (PPP), administered …, and alleged fraud affecting Medicare and other federal healthcare programs for services related to COVID-19 testing and treatment."

"During fiscal year 2025, the Department obtained more than 200 False Claims Act settlements and judgments, which collectively exceeded more than $230 million, resolving allegations of pandemic-related fraud."

- Fact Sheet False Claims Act Settlements and Judgments FY2025 -

COVID Enforcement

Brooklyn Woman Sentenced in $600 Million Covid Tax Credit Scheme

Wednesday, May 13, 2026

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For Immediate Release
Office of Public Affairs

A Brooklyn tax preparer was sentenced on Friday to 36 months in prison for her role in a fraud scheme that fraudulently claimed more than $600 million in COVID-19-related employment tax credits.

According to court documents and statements made in court, Tiffany Williams, 43, of Brooklyn, conspired with others to file tax returns seeking fraudulent refunds based on the employee retention credit and paid sick and family leave credit, credits passed by Congress to aid struggling businesses during the COVID-19 global pandemic. From November 2021 to June 2023, Williams and her co-conspirators filed more than 8,000 false tax returns seeking COVID-19 related tax credits.

In total, Tiffany Williams and her co-conspirators sought more than $600 million in credits they and their clients were not entitled to receive, which caused a loss to the United States of approximately $45 million.

Justice Department Prosecutes a Half-Billion Dollars in Healthcare and COVID Fraud Schemes Exploiting Taxpayer Funded Programs

Tuesday, April 7, 2026

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For Immediate Release
Office of Public Affairs

Actions support the Administration's Task Force to Eliminate Fraud

The Justice Department announced today three separate civil and criminal actions to hold two companies and two individual defendants accountable for schemes that attempted to fraudulently bill taxpayer-funded programs of over $500 million.

Department of Justice efforts support President Trump's Task Force to Eliminate Fraud, a whole-of-government effort chaired by Vice President J.D. Vance to eliminate fraud, waste, and abuse within Federal benefit programs.

"Thanks to the leadership of President Donald Trump, the Department, working closely with the Task Force to Eliminate Fraud, is supercharging efforts to take down every fraudster and bring them to justice," said Acting Attorney General Todd Blanche. "In one day, the Department prosecuted the theft of a half-billion in taxpayer dollars. All those ripping off the American people are on notice."

“The Medicaid statute (as is true of other parts of the Social Security Act) is an aggravated assault on the English language, resistant to attempts to understand it. The statute is complicated and murky, not only difficult to administer and to interpret but a poor example to those who would like to use plain and simple expressions.”

~ Friedman v. Berger, 409 F. Supp. 1225 (S.D.N.Y. 1976)

Hospital Developments

CMS 2026 IPPS Final Rule

- Final Rule: July 31, 2025 (Aug. 4, 2025) (90 Fed. Reg. 36536)
  - Most provisions go into effect on October 1, 2026
  - Hospital payments increased by net 2.6%
  - LTCH PPS standard payment rate increased by 2.7%
  - DSH and UCC payments increased by $2B
- CMS discontinued it low wage index policy for FY2026 +
  - Bridgeport Hospital, et al. v. Becerra
- Changes were made to:
  - Hospital Inpatient Quality Reporting
  - Promoting Interoperability Program
  - Hospital Readmissions Program
  - Health Equity
  - Transforming Episode Accountability Model or “TEAM” program

18002 Federal Register / Vol. 90, No. 82 / Wednesday, April 30, 2025 / Proposed Rules

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

42 CFR Parts 412, 413, 495, and 512

[CMS–1833–P]

RIN 0938–AV45

Medicare Program; Hospital Inpatient Prospective Payment Systems for Acute Care Hospitals and the Long-Term Care Hospital Prospective Payment System and Policy Changes and Fiscal Year 2026 Rates; Requirements for Quality Programs; and Other Policy Changes

AGENCY: Centers for Medicare & Medicaid Services (CMS), Department of Health and Human Services (HHS).

ACTION: Proposed rule.

SUMMARY: This proposed rule would revise the Medicare hospital inpatient prospective payment systems (IPPS) for operating and capital-related costs of acute care hospitals; make changes relating to Medicare graduate medical education (GME) for teaching hospitals; update the payment policies and the annual payment rates for the Medicare prospective payment system (PPS) for inpatient hospital services provided by long-term care hospitals (LTCHs); update and make changes to requirements for certain quality programs; and make other policy-related changes.

DATES: To be assured consideration, comments must be received at one of the addresses provided in the **ADDRESSES** section, no later than 5 p.m. EDT on June 10, 2025.

ADDRESSES: In commenting, please refer to file code CMS–1833–P. Because of staff and resource limitations, we cannot accept comments by facsimile (FAX) transmission.

Comments, including mass comment submissions, must be submitted in one of the following three ways (please choose only one of the ways listed):

1. *Electronically.* You may (and we encourage you to) submit electronic comments on this regulation to *https://www.regulations.gov.* Follow the instructions under the ''submit a comment'' tab.

2. *By regular mail.* You may mail written comments to the following address ONLY: Centers for Medicare & Medicaid Services, Department of Health and Human Services, Attention: CMS–1833–P, P.O. Box 8013, Baltimore, MD 21244–8013.

Please allow sufficient time for mailed comments to be received before the close of the comment period.

3. *By express or overnight mail.* You may send written comments via express or overnight mail to the following address ONLY: Centers for Medicare & Medicaid Services, Department of Health and Human Services, Attention: CMS–1833–P, Mail Stop C4–26–05, 7500 Security Boulevard, Baltimore, MD 21244–1850.

For information on viewing public comments, we refer readers to the beginning of the **SUPPLEMENTARY INFORMATION** section.

FOR FURTHER INFORMATION CONTACT: Donald Thompson, and Michele Hudson, (410) 786–4487 or *DAC@cms.hhs.gov*, Operating Prospective Payment, MS–DRG Relative Weights, Wage Index, Hospital Geographic Reclassifications, Graduate Medical Education, Capital Prospective Payment, Excluded Hospitals, Medicare Disproportionate Share Hospital (DSH) Payment Adjustment, Sole Community Hospitals (SCHs), Medicare-Dependent Small Rural Hospital (MDH) Program, Low-Volume Hospital Payment Adjustment, and inpatient Critical Access Hospital (CAH) issues.

Emily Lipkin, Jim Mildenberger and Hyoyoung Kim, *DAC@cms.hhs.gov*, Long-Term Care Hospital Prospective Payment System and MS–LTC–DRG Relative Weights issues.

Lily Yuan, *NewTech@cms.hhs.gov*, New Technology Add-On Payments issues.

Mady Hue, *marilu.hue@cms.hhs.gov*, and Andrea Hazeley, *andrea.hazeley@cms.hhs.gov*, MS–DRG Classifications issues.

Radhika Puri, *Radhika.puri@cms.hhs.gov*, Rural Community Hospital Demonstration Program Issues.

Joris Smith, *joris.smith@cms.hhs.gov*, Frontier Community Health Integration Project (FCHIP) Demonstration Issues.

Lang Le, *lang.le@cms.hhs.gov*, Hospital Readmissions Reduction Program—Administration Issues.

Ngozi Uzokwe, *ngozi.uzokwe@cms.hhs.gov*, Hospital Readmissions Reduction Program—Measures Issues.

Jennifer Tate, *jennifer.tate@cms.hhs.gov*, Hospital-Acquired Condition Reduction Program—Administration Issues.

Ngozi Uzokwe, *ngozi.uzokwe@cms.hhs.gov*, Hospital-Acquired Condition Reduction Program—Measures Issues.

Julia Venanzi, *julia.venanzi@cms.hhs.gov*, Hospital Inpatient Quality Reporting Program and Hospital Value-Based Purchasing Program—Administration Issues.

Melissa Hager, *melissa.hager@cms.hhs.gov*, and Ngozi Uzokwe, *ngozi.uzokwe@cms.hhs.gov*—Hospital Inpatient Quality Reporting Program and Hospital Value-Based Purchasing Program—Measures Issues Except Hospital Consumer Assessment of Healthcare Providers and Systems Issues.

Elizabeth Goldstein, *elizabeth.goldstein@cms.hhs.gov*, Hospital Inpatient Quality Reporting and Hospital Value-Based Purchasing—Hospital Consumer Assessment of Healthcare Providers and Systems Measures Issues.

Jennifer Tate, *jennifer.tate@cms.hhs.gov*, PPS-Exempt Cancer Hospital Quality Reporting—Administration Issues.

Kristina Rabarison, *Kristina.Rabarison@cms.hhs.gov*, PPS-Exempt Cancer Hospital Quality Reporting Program-Measure Issues.

Ariel Cress, *Ariel.Cress@cms.hhs.gov*, Long-Term Care Hospital Quality Reporting Program—Administration Issues.

Jessica Warren, *jessica.warren@cms.hhs.gov*, and Lisa Marie Gomez, *LisaMarie.Gomez1@cms.hhs.gov*, Medicare Promoting Interoperability Program.

Bridget Dickensheets, *bridget.dickensheets@cms.hhs.gov* and Mollie Knight, *mollie.knight@cms.hhs.gov*, IPPS Market Basket Rebasing.

CMMI_TEAM@cms.hhs.gov, Transforming Episode Accountability Model (TEAM).

SUPPLEMENTARY INFORMATION:

Inspection of Public Comments: All comments received before the close of the comment period are available for viewing by the public, including any personally identifiable or confidential business information that is included in a comment. We post all comments received before the close of the comment period on the following website as soon as possible after they have been received: *https://www.regulations.gov.* Follow the search instructions on that website to view public comments. CMS will not post on *Regulations.gov* public comments that make threats to individuals or institutions or suggest that the commenter will take actions to harm an individual. CMS continues to encourage individuals not to submit duplicative comments. We will post acceptable comments from multiple unique commenters even if the content is identical or nearly identical to other comments.

Plain Language Summary: In accordance with 5 U.S.C. 553(b)(4), a

2027 IPPS / LTCH Proposed Rule

- CMS-1849-P, 91 Fed. Reg. 19312 (Apr. 14, 2026)
- Proposed changes include:
  - Increase in IPPS / LTCH payments (2.4%)
  - Approved medical residency training programs must not discriminate, or promote or encourage discrimination, on the basis of race, color, national origin, sex, age, disability, or religion (including use of those characteristics or intentional proxies for those characteristics as a selection criterion for employment, program participation, resource allocation, or similar activities, opportunities, or benefits)
  - Changes to organ acquisition and reasonable cost reimbursement and appeals policies
  - Hospital quality reporting measures (new measures adopted; several removed; modifications made to others)
  - Modifications to hospital value-based reporting measures
  - New quality measures for TEAM
  - Expand Comprehensive Care for Joint Replacement Model to all acute care hospitals

2027 OPPS / ASC Proposed Rule

- CMS-1850-P (July 2, 2026)
- OPPS
  - CMS proposed a 2.4% OPPS payment increase for hospitals meeting quality reporting requirements
    - Based on: 3.2% hospital market basket increase minus 0.8 percentage point productivity adjustment.
- ASC
  - CMS proposed a 2.4% ASC payment update for ASCs meeting quality reporting requirements.
- 340B Drug Payment Policy
  - CMS conducted a 2026 hospital acquisition cost survey and found average 340B drug acquisition costs were approximately 33.4% below ASP.
  - CY 2027 Proposal: Pay 340B-acquired drugs at ASP - 33.4%
- 340B Remedy Adjustment
  - Increase annual adjustment from 0.5% to 3.0%.
  - Applies to hospitals enrolled before January 1, 2018.
  - CMS estimates full recovery of prior 340B remedy payments by CY 2029 rather than CY 2041

2027 OPPS / ASC Proposed Rule

- Inpatient Only (IPO)
  - CMS proposes removing approximately 637 additional procedures from the IPO list in CY 2027.
  - Represents roughly half of the remaining IPO procedures.
  - Remaining procedures would be removed in CY 2028 under the 3-year transition.
- ASC Covered Procedures List
  - CMS proposes adding 618 procedures to the ASC CPL.
  - Continued focus on shifting care to outpatient and lower-cost settings
- Imaging Services
  - CMS proposes applying Physician Fee Schedule-equivalent rates for imaging services without contrast furnished in excepted off-campus provider-based departments.
  - Rural Sole Community Hospitals would be exempt
  - Builds off of previous efforts to equalize payment between freestanding and provider-based locations

Hospital Price Transparency

- CMS notes changes are being made consistent with EO 14221 (“Making America Healthy Again by Empowering Patients with Clear, Accurate, and Actionable Healthcare Pricing Information”)
- Revisions made to 45 C.F.R. § 180.50
- Hospitals must make public actual dollar amounts in their machine readable files (MRFs):
  - Replace estimated allowed amount with median allowed amount and add 10th and 90th percentile allowed amounts
  - Where payer-specific amount is based on a percentage or algorithm, hospital must calculate and encode the media allowed amount (and 10th / 90th percentile amounts)
  - Also required to calculate and encode the count of allowed amounts that were used to calculate the 10th, median and 90th percentiles
- Must use EDI 835 or an alternative, equivalent source of remittance data for calculations
- Must apply lookback period of no less than 12 months and no longer than 15 months prior to posting MRF
- CY 2027 Proposed Rule Update
  - CMS issued a Request for Information (RFI) seeking additional ways to strengthen Hospital Price Transparency requirements and improve standardization and comparability of pricing information across hospitals

Hospital Price Transparency, cont.

- New MRF attestation requirement:
  - To the best of its knowledge and belief, this hospital has included all applicable standard charge information in accordance with the requirements of 45 CFR 180.50, and the information encoded is true, accurate, and complete as of the date in the file. This hospital has included all payer-specific negotiated charges in dollars that can be expressed as a dollar amount. For payer-specific negotiated charges that cannot be expressed as a dollar amount in the machine-readable file or not knowable in advance, the hospital attests that the payer-specific negotiated charge is based on a contractual algorithm, percentage or formula that precludes the provision of a dollar amount and has provided all necessary information available to the hospital for the public to be able to derive the dollar amount, including, but not limited to, the specific fee schedule or components referenced in such percentage, algorithm or formula.
- Hospitals required to encode in MRF the name of hospital's CEO, president or senior official to oversee the encoding of true, accurate and complete data
- Hospitals must encode any organizational NPIs associated with primary taxonomy code 28 (hospital) or 27 (hospital unit) in MRF
- Eligible for 35% reduction in CMPs if hospital waives right to ALJ hearing
- Elements were effective as of Jan. 1, 2026 (but enforcement was delayed to Apr. 1, 2026)

Hospital and CAH CoP Changes

- 2025 OPPS Rule (89 Fed. Reg. 93912) established new CoP requirements for hospitals and critical access hospitals related to emergency services and obstetrical care. Rationale for changes described as needed to address high maternal mortality rate. Phased-in effective dates as follows:

- Effective Jul. 1. 2025
  - Emergency Services Readiness: must adopt written protocols based on nationally recognized and evidence-based guidelines (42 C.F.R. §§ 482.55(c); 485.618(e))
  - Transfer Protocols: policies / procedures / training for transfers (42 C.F.R. §§ 482.43(c))

- Effective Jul. 1, 2026
  - Obstetrical Services Organization and Staffing: requirements for organization and staffing, delivery of services and training (42 C.F.R. §§ 482.59(a) and (b); 485.649(a) and (b))

- Effective Jan. 1, 2027
  - Staff Training (42 C.F.R. §§ 482.59(c); 485.649(c))
  - Quality Assessment and Performance Improvement: apply QAPI to obstetrical services (42 C.F.R. §§ 482.21; 485.641)

Physicians & NPPs

CMS 2026 PFS Final Rule

- 90 Fed. Reg. 49266 (Nov. 5, 2025)
- One-time 2.5% increase to Medicare Part B services
  - RVU conversion rates increased by 3.77% for APM clinicians and by 3.26% to $33.4009 for other clinicians
  - Efficiency adjustment reduction of 2.5% for certain codes
  - Changes made to practice expense methodology
- MSSP changes:
  - BASIC glide path applies only to first agreement period
  - Mid-year modifications to participant and SNF lists OK if change of ownership
  - Revised certain definitions and modified certain quality reporting
- Additional issues (discussed below):
  - Telehealth, Skin Substitutes, and ASM

49266 Federal Register / Vol. 90, No. 212 / Wednesday, November 5, 2025 / Rules and Regulations

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

42 CFR Parts 405, 410, 414, 424, 425, 427, 428, 495, and 512

[CMS–1832–F]

RIN 0938–AV90

Medicare and Medicaid Programs; CY 2026 Payment Policies Under the Physician Fee Schedule and Other Changes to Part B Payment and Coverage Policies; Medicare Shared Savings Program Requirements; and Medicare Prescription Drug Inflation Rebate Program

AGENCY: Centers for Medicare & Medicaid Services (CMS), Department of Health and Human Services (HHS).

ACTION: Final rule.

SUMMARY: This major final rule addresses: changes to the physician fee schedule (PFS); other changes to Medicare Part B payment policies to ensure that payment systems are updated to reflect changes in medical practice, relative value of services, and changes in the statute; codification of establishment of new policies for: the Medicare Prescription Drug Inflation Rebate Program under the Inflation Reduction Act of 2022; the Ambulatory Specialty Model; updates to the Medicare Diabetes Prevention Program expanded model; updates to drugs and biological products paid under Part B; Medicare Shared Savings Program requirements; updates to the Quality Payment Program; updates to policies for Rural Health Clinics and Federally Qualified Health Centers; update to the Ambulance Fee Schedule regulations; codification of the Inflation Reduction Act and Consolidated Appropriations Act, 2023 provisions; updates to the Medicare Promoting Interoperability Program.

DATES: These regulations are effective on January 1, 2026.

FOR FURTHER INFORMATION CONTACT: *MedicarePhysicianFeeSchedule@cms.hhs.gov*, for any issues not identified below. Please indicate the specific issue in the subject line of the email. For all questions related to reporting a service on a claim, please contact your Medicare Administrative Contractor.

Michael Soracco, Morgan Kitzmiller, or *MedicarePhysicianFeeSchedule@cms.hhs.gov*, for issues related to practice expense, work RVUs, conversion factor, and PFS specialty-specific impacts.

Hannah Ahn, or *MedicarePhysicianFeeSchedule@cms.hhs.gov*, for issues related to potentially misvalued services under the PFS.

Julie Rauch, or *MedicarePhysicianFeeSchedule@cms.hhs.gov*, for issues related to Malpractice RVUs.

Morgan Kitzmiller, Terry Simananda, or *MedicarePhysicianFeeSchedule@cms.hhs.gov*, for issues related to Geographic Practice Cost Indices.

Mikayla Murphy, or *MedicarePhysicianFeeSchedule@cms.hhs.gov*, for issues related to direct supervision using two-way audio/video communication technology, telehealth, and other services involving communications technology.

Erick Carrera, or *MedicarePhysicianFeeSchedule@cms.hhs.gov*, for issues related to office/outpatient evaluation and management visit inherent complexity add-on and Digital Mental Health Treatment services.

Maya Peterson, Terry Simananda, or *MedicarePhysicianFeeSchedule@cms.hhs.gov*, for issues related to payment for advanced primary care management services.

Sarah Lelpnik, or *MedicarePhysicianFeeSchedule@cms.hhs.gov*, for issues related to global surgery payment accuracy.

Patsela West, or *MedicarePhysicianFeeSchedule@cms.hhs.gov*, for issues related to outpatient therapy services and KX modifier thresholds.

Michelle Cruse, Erick Carrera, Zehra Hussain, or Hannah Ahn *MedicarePhysicianFeeSchedule@cms.hhs.gov*, for issues related to dental services inextricably linked to other covered medical services.

Zehra Hussain, or *MedicarePhysicianFeeSchedule@cms.hhs.gov*, for issues related to payment of skin substitutes.

Laura Kennedy, (410) 786–3377, Rebecca Ray, (667) 414–0879, and Jae Ryu, (667) 414–0765 for issues related to Drugs and Biological Products Paid Under Medicare Part B.

MedicarePhysicianFeeSchedule@cms.hhs.gov, for issues related to complex drug administration.

Allison Cipro, (667) 414–0756, for issues related to Medicare Diabetes Prevention Program.

Sabrina Ahmed, (410) 786–7499, or *SharedSavingsProgram@cms.hhs.gov*, for issues related to the Medicare Shared Savings Program (Shared Savings Program) quality performance standard and other quality reporting requirements.

Janae James, (410) 786–0801, or *SharedSavingsProgram@cms.hhs.gov*, for issues related to Shared Savings Program beneficiary assignment and benchmarking methodology and shared losses mitigation.

Kari Vandegrift, (410) 786–4008, or *SharedSavingsProgram@cms.hhs.gov*, for issues related to Shared Savings Program participation options, and ACO participant and SNF affiliate change of ownership requirements.

Elisabeth Daniel, (667) 290–8793, for issues related to the Medicare Prescription Drug Inflation Rebate Program.

Benjamin Picillo or Genevieve Kohoe, *AmbulatorySpecialtyModel@cms.hhs.gov*, or 1–844–711–2664 (Option 4) for issues related to the Ambulatory Specialty Model.

Amy Gruber, (410) 786–1542, for issues related to Ambulance Extender provisions.

Kati Moore, (410) 786–5471, for inquiries related to the Merit-based Incentive Payment System (MIPS) track of the Quality Payment Program (QPP).

Trevey Davis, (410) 786–6600, for inquiries related to the Advanced Alternative Payment Models (APMs) track of QPP.

Jessica Warren, (410) 786–7519, and Lisa Marie Gomez, (410) 786–1175, for inquiries related to the Medicare Promoting Interoperability Program.

Lisa Parker, (410) 786–4949, or *FQHC-PPS@cms.hhs.gov*, for issues related to FQHC payments.

Michele Franklin, (410) 786–0226, or *RHC@cms.hhs.gov*, for issues related to RHC payments.

SUPPLEMENTARY INFORMATION: *Addenda Available Only Through the Internet on the CMS Website:* The PFS Addenda along with other supporting documents and tables referenced in this final rule are available on the CMS website at *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/PhysicianFeeSched/index.html*. Click on the link on the left side of the screen titled, ''PFS Federal Regulations Notice'' for a chronological list of PFS **Federal Register** and other related documents. For the CY 2026 PFS final rule, refer to item CMS–1832–F. Readers with questions related to accessing any of the Addenda or other supporting documents referenced in this final rule and posted on the CMS website identified above should contact *MedicarePhysicianFeeSchedule@cms.hhs.gov*.

CPT (Current Procedural Terminology) Copyright Notice:

Physician Fee Schedule Proposed Rule

- In mid-July, CMS released the CY 2027 PFS proposed rule, which proposed policy changes for Medicare payments under the Physician Fee Schedule (PFS), and other Medicare Part B issues, effective on or after January 1, 2027.
  - CMS-1848-P (July 14, 2026)
- Physician Payment Updates
  - Proposed 2027 Conversion Factors:
    - APM Participants: $33.17 (-1.19%)
    - Non-APM Participants: $32.84 (-1.68%)
    - Reduction largely reflects expiration of the temporary 2.5% increase enacted for CY 2026
- Change in how practice expense is calculated
  - Phase out of portion of old methodology
  - Seeks comment on whether site of service differential between facility & non-facility locations is appropriate

Physician Fee Schedule Proposed Rule

- Same-Day E/M and Procedure Reduction
  - When an E/M visit and global procedure occur on the same day:
    - Highest-valued service paid at 100%
    - Additional E/M visit(s) or procedures paid at 50%
- G2211 Complexity Add-On Reform
  - Convert G2211 from a stand-alone HCPCS code into a modifier.
  - Modifier would increase associated E/M payment by 16%.
- New ACO Care Coordination Modifier
  - Available for MSSP ACO and LEAD Model participants.
  - Would increase associated E/M payment by 32%.

Physician Fee Schedule Proposed Rule

- Remote Physiologic Monitoring (RPM) / Remote Therapeutic Monitoring (RTM)
  - CMS proposes:
    - RTM limited to established patients.
    - Required initiating visit before RPM/RTM services begin.
    - RPM/RTM clinical staff services payable only when furnished by practice employees—not contractors.
    - Updated valuation reflecting lower device costs
  - Primary Care Reform
    - CMS seeks comments on:
      - Increasing primary care valuation.
      - Incorporating technology into primary care payment.
      - Moving toward prospective primary care payments.

Physician Fee Schedule Proposed Rule

- New Shared Medical Appointment Payments
  - Proposes separate coding and payment for group-based shared medical appointments.
  - Designed to improve:
    - Chronic disease management
    - Patient engagement
    - Lifestyle modification support
    - Social connectedness
- Behavioral Health
  - Proposes to expand behavioral health payment increases to tobacco cessation services and SBIRT (Screening, Brief Intervention, and Referral to Treatment) services
- Advanced Care Planning
  - Create two new HCPCS codes for ACP services provided by clinical staff under physician supervision.
  - Existing ACP CPT codes would be reserved for practitioner time personally spent providing ACP services.

Physician Fee Schedule Proposed Rule

- Rural Health Clinics (RHCs)
  - CMS proposes allowing Diabetes Self-Management Training (DSMT) and Medical Nutrition Therapy (MNT) as stand-alone preventive visits paid under the Rural Health Clinic benefit
- Telehealth
  - Proposal to extend telehealth flexibilities for RHCs and Federally Qualified Health Centers (FQHCs) through December 31, 2027
- Medicare Drug Inflation Rebate Program
  - CMS proposes technical updates to implementation of Inflation Reduction Act drug rebate requirements
- New 340B Reporting Requirement
  - Beginning January 1, 2027, 340B covered entities and contract pharmacies would be required to submit claim-level information for covered Part D drugs to CMS's Medicare Part D Claims Data 340B Repository

Physician Fee Schedule Proposed Rule

- Clinical Laboratory Fee Schedule
  - Updates reporting and payment rules required by the Consolidated Appropriations Act, 2026.
  - Payment reductions for laboratory tests would continue to be phased in through CY 2029.
  - See PAMA slides later
- Global Surgery Review
  - CMS proposes pausing MACRA-required post-operative visit data collection.
- Medicare Eligibility Changes
  - CMS proposes implementing statutory eligibility restrictions limiting Medicare eligibility to specified categories of lawful residents and citizens.

HHS/DEA Telehealth Prescribing

- Dec 31, 2025
- HHS & DEA
- 4th temporary extension of flexibilities for telehealth providers prescribing controlled substances
- Extension is through Dec 31, 2026
- Allows prescribing of Schedule II-V controlled substances via telemedicine w/o an initial in-person exam IF prescription if for legit medical purpose & complies w/ all other federal & state laws
- Extension allows DEA more time to finalize permanent regulations and acts as a “bridge” to avoid the “telemedicine cliff”

DEPARTMENT OF JUSTICE

Drug Enforcement Administration

21 CFR Part 1307

[Docket No. DEA–407]

RIN 1117–AB40, 1117–AB78, and 1117–ZA07

DEPARTMENT OF HEALTH AND HUMAN SERVICES

42 CFR Part 12

Fourth Temporary Extension of COVID–19 Telemedicine Flexibilities for Prescription of Controlled Medications

AGENCY: Drug Enforcement Administration, Department of Justice; Substance Abuse and Mental Health Services Administration, Department of Health and Human Services.

ACTION: Temporary rule.

SUMMARY: The Drug Enforcement Administration (DEA) jointly with the Department of Health and Human Services (HHS) is issuing a fourth extension of telemedicine flexibilities for the prescribing of controlled medications through December 31, 2026.

DATES: This rule is effective January 1, 2026 through December 31, 2026.

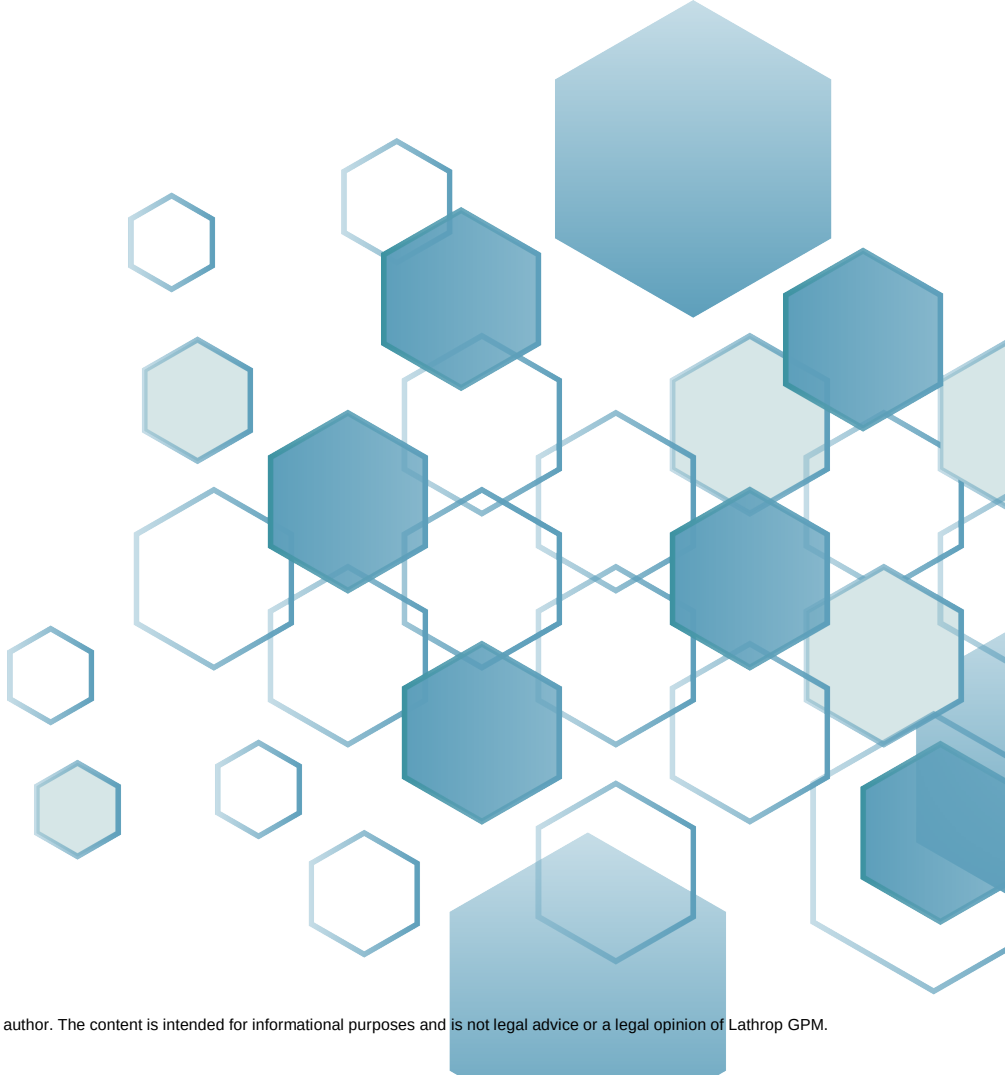
Clinical Lab Fee Schedule: PAMA

- Absent changes, CLFS payment faced cuts of up to 15% effective Jan. 1, 2026
- CAA, 2026 continued trend of putting reimbursement cuts slated to go into effect under PAMA (2014)
- Sec. 6226 of CAA updated data reporting requirements for clinical diagnostic lab tests (CDLTs) that are not advanced diagnostic lab tests (ADLTs). Also delayed payment reductions under CLFS.
- Next data reporting period will be from May 1, 2026—Jul. 31, 2026 and based on updated data collection period of Jan. 1, 2025—Jun. 30, 2025
- No phase-in reduction in CLFS reimbursement in 2026. Beginning Jan. 1, 2027—2029, payment may not be reduced by more than 15% per year compared to payment amount established for test the preceding year
- 2027 MPFS proposes conforming regulatory changes

Current Status of PAMA Reporting

Year	Data Collection Period	Data Reporting Period	Reduction Cap
2020	January 1, 2016 – June 30, 2016	January 1, 2017 – May 30, 2017	10%
2021	January 1, 2016 – June 30, 2016	January 1, 2017 – May 30, 2017	0.0%
2022	January 1, 2016 – June 30, 2016	January 1, 2017 – May 30, 2017	0.0%
2023	January 1, 2016 – June 30, 2016	January 1, 2017 – May 30, 2017	0.0%
2024	January 1, 2016 – June 30, 2016	January 1, 2017 – May 30, 2017	0.0%
2025	January 1, 2016 – June 30, 2016	January 1, 2017 – May 30, 2017	0.0%
2026	January 1, 2016 – June 30, 2016	January 1, 2017 – May 30, 2017	0.0%
2027	January 1, 2025 – June 30, 2025	May 1, 2026 – July 31, 2026	15%

Skilled Nursing Facilities



Provider Enrollment: CMS-855A and SNF Attachment

- Revamped CMS-855A issued in Sep. 2024
  - Contains new “Attachment 1” to 855A. Replaces parts of sections 5 and 6 (for SNFs).
  - Obligates provider to address “additional disclosable parties”
  - ADPs defined broadly and triggered extensive disclosure requirements
- Initially required off-cycle revalidation for all SNFs between Oct.—Dec. 2024
- CMS issued several versions of accompanying guidance document (“Guidance for SNF Attachment on Form-855A”). Updated periodically during 2024 and 2025.
  - Last updated Feb. 24, 2026
- Revalidation deadline extended three times:
  - May 1, 2025, Aug. 1, 2025, Jan. 1, 2026
- Due date has now been “indefinitely suspended”

Nursing Home Staffing Mandate

- CMS released a final rule establishing minimum staffing standards designed to address the quality of care in long term care facilities.
  - "Minimum Staffing Standards for Long-Term Care Facilities and Medicaid Institutional Payment Transparency Reporting"
  - 89 Fed. Reg. 40876 (May 10, 2024); Added to 42 C.F.R. § 483.35
- CMS' final rule contains three core staffing requirements:

  (1) Minimum nurse staffing requirements
    - Facilities must have total nurse staffing of 3.48 hours per resident day. This includes: (i) at least 0.55 HPRD of direct RN care, and (ii) 2.45 HPRD of direct nurse aide care
    - Facilities can use any combination of nurse staff (e.g., RN, LPN, etc.) to account for the additional hours requirement

  (2) RN onsite 24 hours per day, seven days per week

  (3) enhanced facility assessment requirements
- Compliance deadline phased-in depending on rural v. non-rural status

Nursing Home Staffing Mandate

- Staffing mandate vacated in multiple federal court decisions
  - On June 18, 2025, Iowa federal court vacated the Biden administration's nursing home staffing mandate that required a registered nurse (RN) be on-site 24/7 and set a minimum number of nursing hours per resident per day. The court found that the Centers for Medicare & Medicaid Services (CMS) exceeded its legal authority with these requirements, stating that only Congress—not CMS—can impose such rigid staffing floors.
    - Did keep in place the enhanced facility assessments (EFA) and Medicaid institutional reporting requirements that are in the staffing mandate, while stating the federal government lacked authority to dictate the number of hours a nursing home needs to provide every day.
    - *Kansas v. Kennedy*, No. C24-110-LTS-KEM (N.D. Iowa June 18, 2025).
  - Follows earlier (April 2025) decision by U.S. District Court of Northern Texas vacating staffing mandate (*Am. Health Care Ass'n v. Kennedy*, Nos. 2:24-CV-114-Z-BR (lead) 2:24-CV-171-Z (N.D. Tex. Apr. 7, 2025)).
- OBBBA included provision prohibiting CMS from implementing mandate until Sep. 30, 2034
- Interim Final Rule issued on Dec. 3, 2024 (90 Fed. Reg. 44587) that withdraws minimum staffing mandate

SNF Payment Rate Updates for CY 2026 / 2027

- SNF PPS (2026 Final Rule)
  - 90 Fed. Reg. 37310 (Aug. 4, 2025)
  - 3.2% increase in PPS rates (final SNF market basket of 3.3%, plus 0.6% market basket forecast error adjustment and negative 0.7% productivity adjustment). Translates to increase in SNF PPS payments of $1.16 billion.
  - PPS change does not incorporate SNF VBP reductions (pay-for-performance)
  - Changes to SNF VBP include:
    - Applies SNF Within-Stay Potentially Preventive Readmission measure for 2028 PY
    - Adopts new reconsideration process that allows SNFs to appeal CMS' initial decisions for Review and Correction requests prior to CMS making any affected data publicly available
    - Removes Health Equity Adjustment from VBP's scoring methodology

Other Changes from 2026-2027 SNF PPS

- Patient-Driven Payment Model (PDPM) ICD-10 Code Mappings
  - Finalizes 34 changes to PDPM ICD-10 code mappings intended to maintain consistency with latest ICD-10-CM coding guidance
- SNF Quality Reporting
  - Pay-for-reporting program
  - Removes 4 standardized patient assessment data elements under SDOH category from MDS (one item for “living situation”; two items for “food”; one item for “utilities”
  - Changes to reconsideration process: SNFs permitted to request extension to file request for reconsideration; CMS updates bases on which reconsiderations can be granted
- 2027 SNF Proposed Rule (CMS 1843-P)
  - CMS proposed a 2.8% net increase in SNF PPS payments for FY 2027 (approximately $750 million in increased payments nationally). This proposal is based on:
    - the proposed SNF market basket of 3.2%,
    - and a negative 0.8% productivity adjustment.

Risk-Based SNF Surveys

- CMS adopting new “risk-based survey” approach. To be implemented nationwide, beginning on Sep. 2026
  - Announced in QSO-26-14-NH (Jul. 16, 2026)
  - Based on 2023 demonstration under which facilities with higher quality results subject to more focused survey (takes less time, involves smaller survey team
- Higher quality facility? Indicated by factors such as a history of fewer citations, higher staffing levels, fewer hospitalizations, and other similar indicators of quality
  - Does facility have “qualifying criteria” (see next slide)?
- Disqualifying criteria can take facility out of RBS
  - Citations at Actual Harm, Immediate Jeopardy, Abuse or Substandard Quality of Care
  - Pending intake investigations triaged at Immediate Jeopardy
  - More than 3 pending Non-IJ active intakes
  - CMS-approved nursing waivers
  - CHOW since the last survey
- CMS will provide state agencies with lost of RBS qualified facilities each quarter
- Approximately 12% of nursing facilities nationwide will qualify (14.2% in MN (48 of 338) qualify for the RBS

Risk-Based SNF Surveys

To qualify, facility must not have any of the following:

- Less than a 5-Star Overall Rating
- Less than 3-star Staffing Rating
- Any citation(s) for Actual Harm, or Immediate Jeopardy (IJ) or Substandard Quality of Care (SQC) in the last survey cycle
- More than 18 months without a standard survey
- Any staffing waivers in effect
- Failed Payroll-Based Journal (PBJ) staffing data audit
- Failed resident assessment Minimum Data Set audit (MDS)
- Health Inspection Score higher than the 50th percentile in the state (lower scores indicate better performance)
- Two or more residents aged 65 or older that are coded with diagnosis of schizophrenia after being admitted without this diagnosis.
- A change in ownership since the last standard survey
- Special Focused Facility Candidate

New Payment Models & CMS Innovation Center

“Congress has, throughout the various Medicare and Medicaid statutory provisions, consistently used the words “eligible” to refer to potential Medicaid beneficiaries and “entitled” to refer to potential Medicare beneficiaries for no reason whatever that anyone (including the Secretary, who is intimately familiar with the statutes at issue) has been able to divine.”

~Caball Huntington Hospital, Inc. v. Shalala, 101 F.3d 984 1450 (4th Cir. 2011)

Snapshot of Current Value-Based Programs

- ACOs
  - 2026 Participation:
    - 511 ACOs (increase from 480 in 2024)
    - 687,700 providers (up from 634,000 in 2024)
    - 14.3M+ assigned patients (increase from 10.8M in 2024)
  - For PY 2024, ACOs earned shared savings totaling $4.1 billion and saved Medicare $2.5 billion
  - ACO REACH expires at end of 2026 (responsible for $2.5 billion of total ACO savings, up from just $70.4 million in savings in 2021)
- Guiding an Improved Dementia Experience (GUIDE) Model: a voluntary nationwide model test to support people with dementia and unpaid caregivers.
  - Began Jul. 1, 2024 – will run for eight years; 320 participants
  - Beneficiary Model Tier / payment is determined based on a combination of their disease stage, whether they have a caregiver, and if applicable, their caregiver's needs.

Snapshot of Current Value-Based Programs

- ACCESS Model
  - Tests “Outcome-Aligned Payments” under which participating organizations will receive predictable recurring payments for managing patients’ qualifying conditions, with full payment tied to achieving measurable health outcomes.
  - Voluntary model, aimed at expanding access to technology-supported care for managing chronic conditions like high blood pressure, diabetes, musculoskeletal pain and depression
  - Launched in July 2026; almost 200 organizations participating
- Advancing All-Payer Health Equity Approaches and Development Model (AHEAD)
  - Voluntary total cost of care model designed to improve the total health of a state population and reduce costs.
  - Provides participating states with funding and other tools to address rising health care costs and support health equity.
  - Three primary components: Cooperative Agreement, Hospital Global Budgets and Primary Care AHEAD

Snapshot of Current Value-Based Programs

- Ambulatory Specialty Model
  - Tests whether adjusting payment for specialists based on their performance on targeted measures of quality, cost, care coordination, and meaningful use of CEHRT results in enhanced quality of care and reduced costs through more effective upstream chronic condition management.
  - Mandatory alternative payment model with 5 performance years beginning 1/1/2027 and ending 12/31/2031.
  - Chronic conditions to be addressed: heart failure and low back pain.
- Long-term Enhanced ACO Design (LEAD) Model
  - Voluntary model. Will run from Jan. 1, 2027—Dec. 31, 2036
  - Includes two voluntary risk-sharing options in which providers may elect to receive : (1) 100% of savings and be liable for 100% of total losses based on performance benchmarks; or (2) 50% of savings and be liable for 50% of total losses based on performance benchmarks
  - CMS released the RFA on March 31, 2026. Initial applications were due May 17, 2026
  - Participant selection, announcement and onboarding to occur in Summer 2026

Snapshot of Current Value-Based Programs

- IOTA Model
  - Mandatory model aiming to increase access to kidney transplants and improve efficiency and capabilities of participating transplant hospitals (89 Fed. Reg. 96280). Began Jul. 1, 2025.
  - Depending on performance scores, participating hospitals are eligible for up to $15,000 per Medicare fee-for-service transplant in the first performance year, or responsible for a down-side risk payment of $2,000 in the second year
  - CMS finalized PY2 model changes effective July 1, 2026 (91 Fed. Reg. 32788), including:
    - Medicare Advantage beneficiaries will now be included in calculating upside and downside risk payments
    - Low-volume participation threshold was increased from 11 to 15 kidney transplants annually.
    - Retained the maximum upside risk payment of $15,000 per transplant.

- ASC Prior Authorization
  - Providers initially directed to submit prior authorization requests beginning on Dec. 1, 2025 for dates of service on or after Dec. 15, 2025. Start dates delayed as follows:
  - Providers in CA, FL, TN, PA, MD, GA and NY can submit prior authorization requests beginning on Jan. 5, 2026, for dates of service on or after Jan. 19, 2026.
  - Providers in TX, AZ, and OH can submit prior authorization requests beginning on Feb. 2, 2026, for dates of service on or after Feb. 16, 2026.

Snapshot of Current Value-Based Programs

- MAHA Elevate
  - CMS will fund ($100 million) up to 30 cooperative agreements over 3-year performance period that have goal of collecting quality and cost data on whole-person functional or lifestyle medicine interventions
  - Applicants can include wide range of organizations (e.g., private medical practices, academic organizations, health systems, governments, senior living communities, functional / integrative / lifestyle clinics, etc.) that provide whole-person functional / lifestyle medicine
  - Voluntary model; first cohort will launch in Oct. 2026. Selected applicants will receive Notices of Award in Fall 2026.

- GENEROUS (GENErating Reductions fOr U.S Medicaid Model)
  - Manufacturers will enter negotiated agreements with CMS to provide set pricing on their portfolio of covered outpatient drugs. Pricing to participating state Medicaid programs will be calculated based upon select international pricing data.
  - Application deadline had been Mar. 31, 2026; extended to Apr. 30, 2026 and then further extended it to June 11, 2026. Manufacturer participation agreements were extended to July 17, 2026
  - CMS extended the deadline for state Medicaid programs to apply from July 31, 2026 to Sep.10, 2026, with participation agreements due by Sep.30, 2026.

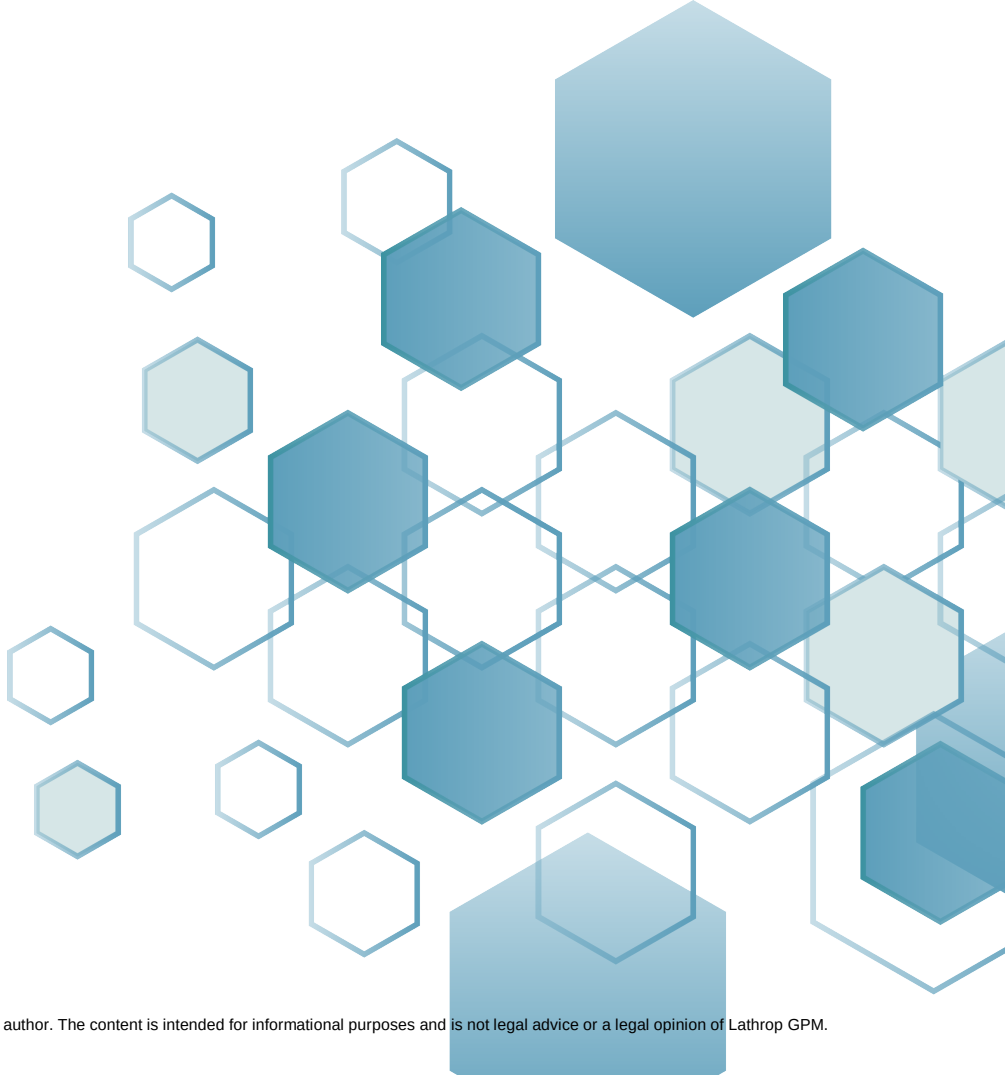
Snapshot of Current Value-Based Programs

- Comment period for GLOBE and GUARD closed on Feb. 23, 2026
  - Rebates paid by manufacturers would continue to be sent directly to the Part B Trust Fund.
- Guarding U.S. Medicare Against Rising Drug Costs (GUARD) Model (90 Fed. Reg. 60338)
  - Mandatory model: applies to manufacturers of drugs covered by Part D
  - Five-year model, starting Jan. 1, 2027 and encompassing 25% of Part D enrollees. Geographic areas randomly selected
  - Test an alternative calculation for manufacturer rebates under the Medicare Part D Inflation Rebate Program that uses a benchmark derived from international pricing information instead of the current domestic benchmark
- Global Benchmark for Efficient Drug Pricing (GLOBE) Model (90 Fed. Reg. 60244)
  - Mandatory model, applies to manufacturers of drugs covered by Part B that are not otherwise excluded from GLOBE model
  - Five-year model, running from Oct. 1, 2026—Sep. 30, 2031 and applying to 25% of Medicare beneficiaries within defined geographic area
  - Test an alternative calculation for manufacturer rebates under Part B Inflation Rebate Program that uses a benchmark derived from international pricing information instead of the current domestic benchmark. The benchmark would be based on either manufacturer-reported international pricing information or available information to CMS for economically similar countries.

GLP-1 Bridge Demonstration

- CMS launched the Medicare GLP-1 Bridge Demonstration on July 1, 2026, expanding access to certain GLP-1 weight-loss medications for eligible Medicare beneficiaries outside the Part D benefit
  - Eligible participants will pay a standardized cost of $50 per month for covered GLP-1 medications
- The demonstration will run through December 2027
- Serves as a temporary bridge to CMS's proposed BALANCE (Better Approaches to Lifestyle and Nutrition for Comprehensive hEalth) Model, which is intended to negotiate lower GLP-1 prices and standardized coverage terms

Home Health & DMEPOS



Highlights from 2027 HHA PPS Proposed Rule

- CMS-1844-P (July 1, 2026)
- Medicare Provider Enrollment
  - Changes affect providers / suppliers more broadly than HHA & DMEPOS
  - CMS proposes making all Medicare enrollment revocations retroactive to the date noncompliance began.
  - Proposes new and expanded revocation and denial authorities, including requirements related to changes in majority ownership and actions involving owners or managing employees
  - Builds off of series of provider enrollment changes made in 2026 Final Rule
- Aggregate payment update for CY 2027 is 2.4% increase ($420 million) determined as follows:
  - 2.1% home health payment update (+$370 million)
  - Impact of the proposed update to the fixed-dollar loss (FDL) ratio, estimated at 0.3% decrease. CMS proposes an FDL ratio of 0.29 for CY 2027.
  - Includes a proposed temporary -3.0% adjustment to continue budget-neutral implementation and recoupment related to the Patient-Driven Groupings Model (PDGM)

Highlights from HHA PPS Proposed Rule

- Home Health Payment System Updates
  - Proposed recalibration of PDGM case-mix weights, functional impairment levels, comorbidity subgroups, and LUPA thresholds for CY 2027.
  - Discussion of home health palliative care services under the Medicare home health benefit and includes a Request for Information (RFI) regarding the construction of a home health specific wage index.
- Home Health Quality Reporting Program
  - Proposed updates to reporting timelines and requirements to better align HH QRP with the Home Health Value-Based Purchasing (HHVBP) Model
  - Additionally, CMS is soliciting public comments on an RFI on future measure concepts for the HH QRP, specifically on a potential Advanced Care Planning measure
  - 2026 Final Rule made services of changes to QRP
- Home Health Value-Based Purchasing
  - No HHVBP-specific policy changes proposed for CY 2027.
  - 2026 HHS PPS Final Rule made series of changes to HHA value-based reporting

DMEPOS Competitive Bidding Program (CBP)

- 2026 HHA Final Rule (90 Fed. Reg. 55342 (Dec. 2, 2025)) created Remote Item Delivery Competitive Bidding Program
  - Established for seven high volume product categories because items at issue are generally furnished from suppliers who are remote from where beneficiaries reside
  - Timing:
    - Late spring / early summer 2026: announcement of lead items for CBP and number of contracts to be awarded; start of bidder education program
    - Late summer / early fall 2026: bidding registration begins; bidding window opens
    - Late summer / early fall 2027: contracts awarded and payment amounts announced
    - Beneficiaries will have 6-month period in 2028 to switch to contract suppliers
- In 2027 Proposed Rule, CMS proposes revising the DMEPOS CBP reporting form, known as Form C, to include a new “country of origin” field for lead items furnished by contract suppliers.

DMEPOS CBP (cont.)

- Following product categories in national RID CBP:
  - Class II continuous glucose monitors and insulin pumps
  - Urological supplies
  - Ostomy supplies
  - Hydrophilic urinary catheters
  - Off the shelf back braces
  - Off the shelf knee braces
  - Off the shelf upper extremity braces
- CMS has authority to update product categories so the above could change
- Specific bid limits apply, depending on the product at issue. Limits apply both for items included in CBP for the first time and for items that have previously been included in the CBP (see 42 C.F.R. § 414.412(b) for details):
  - E.g., bid limit for OTS back brace or OTS knee brace identified as the lead item in the product category for 2025 cannot exceed the average of the 2026 nonrural fee schedule amounts for the item. 42 C.F.R. § 414.412(b)(11)

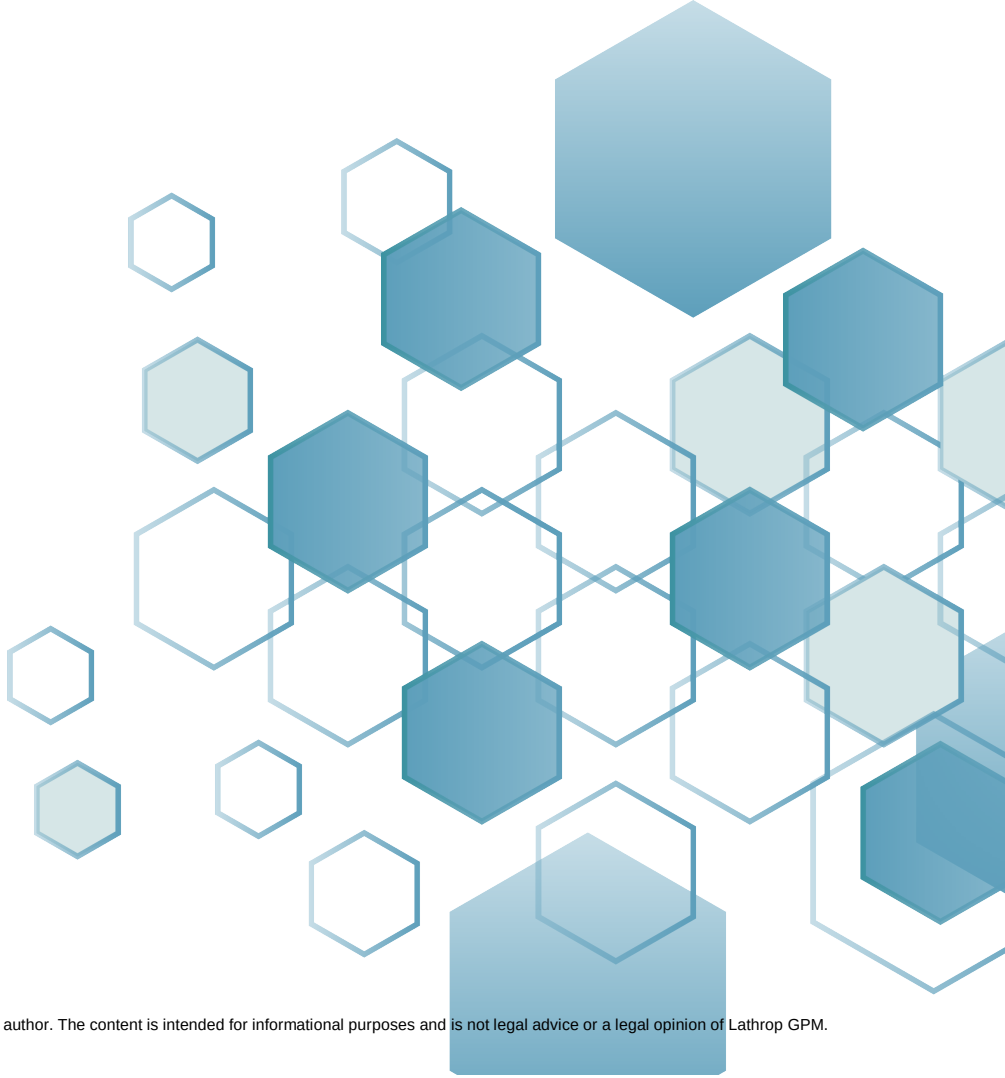
Additional Changes of Note for DMEPOS Suppliers (2026 Final Rule)

- DMEPOS prior authorization exemption process
  - DMEPOS suppliers achieving a target approval rate of 90% offered an exemption from required prior authorization
  - To determine eligibility for continued exemption, DME MACs will complete post payment medical review sample. From claim sample, suppliers must again meet 90% claim approval rate to continue exemption
  - DME MACs will provide notice of exemption or withdrawal of exemption at least 60 days prior to effective date
- Updates to DMEPOS accreditation
  - DMEPOS suppliers now required to be resurveyed / reaccredited annually (as opposed to every 3 years)
  - Removes 90-day “temporary accreditation” provision in DMEPOS certification standards (42 C.F.R. § 424.57(c)(23))
- More stringent requirements for becoming DMEPOS accreditation organization (AO), such as:
  - Increases in amount, specificity and frequency of data AOs must submit to CMS
  - CMS has expanded ability to monitor / review AO operations and respond to poorly performing AOs

DMEPOS (2027 Proposed Rule)

- Clarifies that a new DMEPOS face-to-face examination is not required for identical replacement items, provided documentation from the original encounter supports coverage and medical necessity.
- Durable Medical Equipment Benefit Expansion for Infusion Pumps and Drugs
  - Proposal to amend the definition of durable medical equipment (DME) at 42 CFR 414.202 to implement Section 6222(a) of the Consolidated Appropriations Act, 2026 (CAA, 2026) to expand coverage for certain external infusion pumps and associated home infusion drugs
    - Effective April 1, 2027
  - Applies when FDA-approved prescribing information requires administration by or under the supervision of a healthcare professional and a qualified home infusion therapy supplier oversees administration in the home.
  - Coverage would apply to drugs infused at least 12 times annually (at least monthly), either intravenously, subcutaneously, or at infusion rates requiring an external infusion pump.
  - CMS proposes that qualifying healthcare professionals include physicians, physician assistants, nurse practitioners, clinical nurse specialists, and registered nurses.

Other Updates

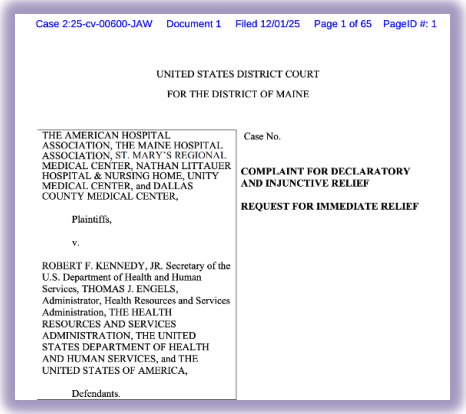


340B Program

- Section 340B of the Public Health Service Act was created under Section 602 of the Veterans Health Care Act of 1992 “to enable covered entities 'to stretch scarce Federal resources as far as possible, reaching more eligible patients and providing more comprehensive services.’”
- The way it works:
  - Pharmaceutical manufacturers enter into agreements, called “pharmaceutical pricing agreements (PPA),” with the HHS Secretary in exchange for having their drugs covered by Medicaid and Medicare Part B.
  - Under the PPAs, the manufacturers agree to provide covered outpatient drugs to specified safety-net providers called “covered entities” at significantly reduced prices – by way of front-end discounts.
  - The providers can then use the savings to expand access to care to vulnerable populations

Developments in 340B

- Aug 1, 2025: 340B Rebate Model Pilot Program
- Dec 1: *American Hospital Association et al. v. Kennedy et al.* filed by the AHA, Maine and 4 safety net hospitals
- Dec 29/Jan 8, 2026: Preliminary injunction obtained and upheld by appellate court obtained to prevent Program from going into effect
- Feb: U.S. District Court for the District of Maine vacated the Program and remanded to HHS
- Feb 17: HRSA releases RFI in Federal Register



Case 2:25-cv-00600-JAW Document 1 Filed 12/01/25 Page 1 of 65 PageID #: 1

UNITED STATES DISTRICT COURT

FOR THE DISTRICT OF MAINE

THE AMERICAN HOSPITAL ASSOCIATION, THE MAINE HOSPITAL ASSOCIATION, ST. MARY'S REGIONAL MEDICAL CENTER, NATHAN LITTAUER HOSPITAL & NURSING HOME, UNITY MEDICAL CENTER, and DALLAS COUNTY MEDICAL CENTER,

Plaintiffs,

v.

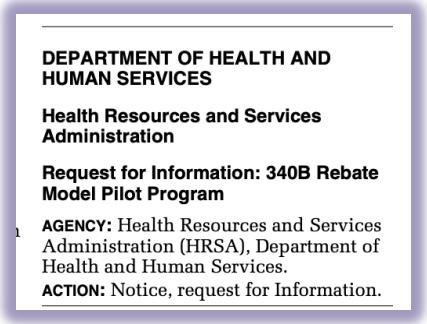
ROBERT F. KENNEDY, JR. Secretary of the U.S. Department of Health and Human Services, THOMAS J. ENGELS, Administrator, Health Resources and Services Administration, THE HEALTH RESOURCES AND SERVICES ADMINISTRATION, THE UNITED STATES DEPARTMENT OF HEALTH AND HUMAN SERVICES, and THE UNITED STATES OF AMERICA,

Defendants.

Case No.

COMPLAINT FOR DECLARATORY AND INJUNCTIVE RELIEF

REQUEST FOR IMMEDIATE RELIEF



DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Request for Information: 340B Rebate Model Pilot Program

AGENCY: Health Resources and Services Administration (HRSA), Department of Health and Human Services.

ACTION: Notice, request for Information.

Developments in 340B

- March: The U.S. District Court for the District of Columbia vacated HRSA's 2013 policy interpreting the 340B GPO prohibition to bar disproportionate share hospitals (DSHs) from using a replenishment (virtual inventory) model.
- Jun. 1: Eli Lilly announced it will withhold 340B discounts from hospitals that do not submit claims-level data for all dispensing of Lilly products, regardless of setting
- Jun. 25: Senate HELP Committee Chair Bill Cassidy released draft legislation aimed at increasing 340B program transparency, accountability, and oversight.
  - The proposal contemplates allowing manufacturers to provide discounts through a rebate mechanism and increasing program transparency and reporting requirements.
- Jul. 14: Beginning January 1, 2027 340B covered entities and contract pharmacies will be required to submit claim-level information for covered Part D drugs to CMS's Medicare Part D Claims Data 340B Repository
- CY 2027 OPPS Proposed Rule would reimburse many 340B drugs at ASP – 33.4%

Medicare Drug Price Negotiation: IRA

- Inflation Reduction Act of 2022 (IRA) authorized CMS to negotiate with drug manufacturers on single-source brand name drugs. First round of negotiations concluded Aug. 1 2024, pricing effective Jan. 1, 2026. 10 drugs included.
- In Nov. 2025, CMS announced negotiated prices for 15 drugs included in second round. Those prices will become effective Jan. 1, 2027.
- In Sep. 2025, CMS released final guidance on third round of program
  - Broadens exclusion from negotiation for orphan drugs to include those designated by FDA as treating one or more rare diseases or conditions. Exclusion was previously limited to orphan drugs designated as treating only one rare disease or condition.
  - Calls for including both Medicare Advantage encounter data and traditional fee-for-service claims data in calculating total expenditures for drugs and biological products payable under Part B.

Medicare Drug Price Negotiation: IRA, cont.

- On Feb. 1, 2026 CMS announced 15 additional drugs covered under Part D or payable under Part B for third cycle of negotiations.
  - First time in IRA where Part B drugs have been included
- Drug companies required to decide by Feb. 28 whether to participate in negotiations. Prices negotiated during third round become effective Jan. 1, 2028
- Not without controversy—
  - Various pharma companies have filed lawsuits alleging drug negotiation program is unconstitutional and will undermine development of new medications. Suits have been unsuccessful.
    - Third Circuit ruled against Novo Nordisk on Oct. 6; court recently rejected similar suits brought by Novartis, Johnson & Johnson and Bristol Myers Squibb
  - On Feb. 11, AbbVie sued HHS over inclusion of Botox in IRA drug price negotiation program
- June 12, 2026 – CMS Proposed Rule
  - CMS proposed a permanent regulatory framework for the Medicare Drug Price Negotiation Program.
  - Would transition the program from guidance-based administration to codified regulations.
  - CMS would continue selecting up to 20 negotiation-eligible drugs in future cycles

Medicare Drug Price Negotiation: Tariffs

- Administration pursuing use of most favored nation policy with specific drug manufacturers. On Sep. 29, issued statement pushing certain pharma companies to implement MFN pricing within 60 days or face new tariffs
- On Sep. 29, Pfizer announced agreement that would permit purchases of certain drugs at discounted rates through government website. No tariffs for 3 years as long as company agreed to certain domestic manufacturing commitments.
- In Nov. and Dec. 2025, Administration announced agreements with number of pharma companies
  - Eli Lilly and Company and Novo Nordisk to lower prices on certain weight loss medications in exchange for three-year reprieve on tariffs (along with broader coverage under Medicare) for GLP-1s)
  - Amgen, Bristol Myers Squibb, Boehringer Ingelheim, Genentech, Gilead Sciences, GSK, Merck, Novartis, and Sanofi.
  - Conditions treated include: type two diabetes, rheumatoid arthritis, multiple sclerosis, asthma, chronic obstructive pulmonary disease (COPD), hepatitis B and C, human immunodeficiency virus (HIV)

No Surprises Act: IDR Operations Final Rule

- Improving Communications Between Payers and Providers
  - Payers must use standardized Claim Adjustment Reason Codes (CARCs) and Remittance Advice Remark Codes (RARCs) to identify whether claims are subject to the No Surprises Act and eligible for Federal IDR.
  - Additional disclosures required, including payer/plan identification information and instructions for initiating open negotiation.
- Open Negotiation
  - Open negotiation requests must be submitted through the Federal IDR Portal.
  - Formal Open Negotiation Response Notice required by the 15th business day of the 30-business-day negotiation period.

No Suprises Act: IDR Operations Final Rule

- Batching
  - Expanded flexibility for batching claims involving same patient encounter, same or comparable service codes, and certain anesthesia, radiology, pathology, and laboratory services
  - New cap of 50 line items per batched dispute.
- IDR Eligibility
  - Certified IDR entities must determine dispute eligibility within 5 business days of selection
  - Parties must provide additional requested information within 5 business days or risk dispute closure.
- Administrative and Certified IDR Entity Fees
  - Finalized $15 administrative fee per party per dispute.
  - Clarifies consequences for failure to timely pay administrative or IDR entity fees.
- New Federal IDR Registry
  - Payers must register with the Departments and receive a unique IDR Registration Number.
  - Intended to improve payer identification, dispute processing, eligibility reviews, and enforcement.

Highlights from 2026 Hospice Final Rule

- 90 Fed. Reg. 37404 (Aug. 1, 2025)
- Hospice payment rate increased by 2.6% ($750 million / annual cap = $35,361.44) determined as follows:
  - 3.3% inpatient market basket increase, reduced by 0.7% productivity adjustment
  - Hospices that do not submit required quality data would see adjustment of -1.4% over previous year's payment rate (2.6% increase minus 4%)
- Physician member of hospice interdisciplinary group may recommend hospice admission (aligns hospice payment regulations with CoPs)
- Signature and date requirements for face-to-face attestation restored (inadvertently omitted)
- Elimination of requirement that hospice attestation must be separate and distinct document. Attestation can be completed as part of signed / dated clinical note within medical record or a clearly titled section of / addendum to recertification form

2027 Hospice Proposed Rule

- (CMS-1851-P)
- CMS proposes a 2.4% hospice payment rate increase for FY 2027, representing an estimated $785 million increase in hospice payments.
- Proposed FY 2027 hospice aggregate cap: $36,210.11 (up from $35,361.44 in FY 2026).
- Hospices that fail to meet quality reporting requirements would face a 4 percentage-point annual payment update penalty
- CMS introduced a new Hospice Service & Spending Variation Index (SSVI) based on nine claims-based measures evaluating hospice utilization and non-hospice spending.

2027 Hospice Proposed Rule

- New Hospice Election Requirements
  - CMS proposes making the Hospice Election Statement Addendum mandatory for all hospice elections, rather than only upon beneficiary request
- Hospice Quality Reporting Program (HQRP)
  - CMS proposes adding a public icon on Medicare Care Compare identifying hospices that fail to submit required HOPE quality data.
- Operational & Regulatory Changes
  - Expands flexibility by allowing a physician designee or interdisciplinary group physician member, in addition to the hospice medical director, to discharge hospice patients.
  - Updates hospice telehealth face-to-face requirements consistent with the Consolidated Appropriations Act, 2026.

Hospice Enforcement

- In January 2026, CMS expanded its Provisional Period of Enhanced Oversight (PPEO) and Expanded Prepayment Review (EPR) programs to hospices in Georgia and Ohio, joining Arizona, California, Nevada, and Texas
- Claims may be subject to prepayment review, requiring submission of extensive supporting documentation before payment is released.
- Failure to timely respond to documentation requests (ADRs), insufficient eligibility documentation, high error rates, or operational deficiencies can result in:
  - Claim denials
  - Extended review periods
  - Medicare enrollment revocation
  - Loss of billing privileges

Adoption of Standards for Health Care Claims Final Rule

- Administrative Simplification; Adoption of Standards for Health Care Claims Attachments Transactions and Electronic Signatures Final Rule
  - CMS-0053-F.
- CMS finalized the first-ever HIPAA standards for electronic health care claims attachments, enabling secure electronic exchange of supporting documentation such as medical records, clinical notes, imaging, laboratory results, and telehealth documentation.
- Establishes federal electronic signature requirements to ensure secure, authenticated, and compliant transactions.
- Expected Benefits
  - Eliminate manual fax and mail-based attachment processes.
  - Estimated $781 million in annual healthcare industry savings.
  - Faster claims processing and adjudication.
  - Reduced provider and payer administrative burden.
  - Improved security and workflow efficiency

Adoption of Standards for Health Care Claims Final Rule

- X12 Version 6020 Standards
  - X12N 275 (Additional Information to Support a Health Care Claim)
  - X12N 277 (Request for Additional Information)
- HL7® Standards
  - Consolidated Clinical Document Architecture (C-CDA) Implementation Guides
  - HL7 Attachments Implementation Guide (March 2022 version)
- Standardized electronic signature requirements for claims attachment transactions.
- Final rule effective: May 26, 2026.
- Compliance deadline: 24 months after the effective date (May 2028).

Organ Procurement Organizations Conditions for Coverage

- Proposed rule, issued on Jan. 30 (91 Fed. Reg. 4190). Comments deadline Mar. 31, 2026.
  - The proposal remains pending. CMS has not yet issued a final rule.
- Changes focused on quality, safety and oversight:
  - Series of definitional changes that can trigger decertification (e.g., “unsound medical practices” as failures by OPO that create imminent threat to health / safety)
  - Add definition of “medically complex donor” as part of revision geared towards assisting OPOs in facilitating appropriate placement and utilization of organs to increase organ pool available for transplantation
  - Removing regulatory limits that prevented certification of new OPOs
  - New record-keeping requirements for research organs, including pancreata used for islet cell research, including requiring approval documentation from IRB or other formal authorizing body
  - More stringent requirements for OPO oversight of Donation Service Areas (DSAs)
    - During re-certification, CMS evaluates each OPO’s DSA’s separately on the outcome measures and remove the OPO’s designation to underperforming DSAs
    - OPO with tier 3 performance on all DSAs will be decertified

Organ Procurement: OIG Focus

- OIG targeting potential manipulation of allocation systems, performance reporting inaccuracies and procurement or contracting irregularities within OPOs

HHS FINDS SYSTEMIC DISREGARD FOR SANCTITY OF LIFE IN ORGAN TRANSPLANT SYSTEM

Secretary Kennedy Threatens Closure of Deficient Organ Procurement Organization

WASHINGTON—July 21, 2025— The U.S. Department of Health and Human Services (HHS) under the leadership of Secretary Robert F. Kennedy, Jr. today announced a major initiative to begin reforming the organ transplant system following an investigation by its Health Resources and Services Administration (HRSA) that revealed disturbing practices by a major organ procurement organization.

"Our findings show that hospitals allowed the organ procurement process to begin when patients showed signs of life, and this is horrifying," **Secretary Kennedy said**. "The organ procurement organizations that coordinate access to transplants will be held accountable. The entire system must be fixed to ensure that every potential donor's life is treated with the sanctity it deserves."

HRSA directed the Organ Procurement and Transplantation Network (OPTN) to reopen a disturbing case involving potentially preventable harm to a neurologically injured patient by the federally-funded organ procurement organization (OPO) serving Kentucky, southwest Ohio, and part of West Virginia. Under the Biden administration, the OPTN's Membership and Professional Standards Committee closed the same case without action.

Under Secretary Kennedy's leadership, HRSA demanded a thorough, independent review of the OPO's conduct and the treatment of vulnerable patients under its care. HRSA's independent investigation revealed clear negligence after the previous OPTN Board of Directors claimed to find no major concerns in their internal review.

HRSA examined 351 cases where organ donation was authorized, but ultimately not completed. It found:

- 103 cases (29.3%) showed concerning features, including 73 patients with neurological signs incompatible with organ donation.
- At least 28 patients may not have been deceased at the time organ procurement was initiated—raising serious ethical and legal questions.
- Evidence pointed to poor neurologic assessments, lack of coordination with medical teams, questionable consent practices, and misclassification of causes of death, particularly in overdose cases.

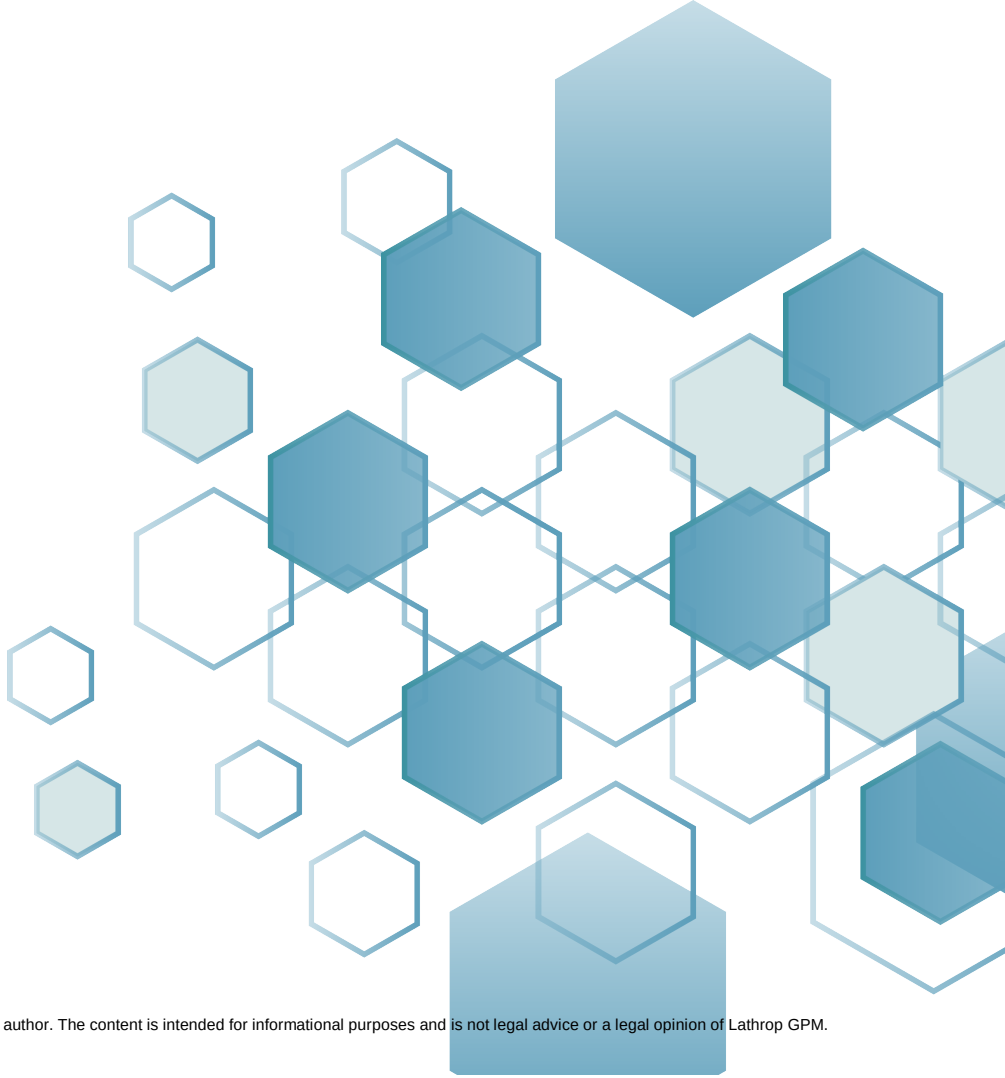
Vulnerabilities were highest in smaller and rural hospitals, indicating systemic gaps in oversight and accountability. In response to these findings, HRSA has mandated strict corrective actions for the OPO, and system-level changes to safeguard potential organ donors nationally. The OPO must conduct a full root cause analysis of its failure to follow internal protocols—

Rural Health Transformation Program

Laura Sutter, *Minnesota Department of Health*

Zora Radosevich, *Minnesota Department of Health*

Randy Schultz, *Lathrop GPM*



MINNESOTA
RURAL HEALTH TRANSFORMATION

Rural Health Transformation Program

Office of Rural Health and Primary Care RHTP Team

This project is supported by the Centers for Medicare & Medicaid Services (CMS) of the U.S. Department of Health and Human Services (HHS) as part of a financial assistance award totaling $193,090,618.14 with 100 percent funded by CMS/HHS. The contents are those of the author(s) and do not necessarily represent the official views of, nor an endorsement, by CMS/HHS, or the U.S. Government.

Overview of Minnesota's RHTP

MINNESOTA
RURAL HEALTH TRANSFORMATION

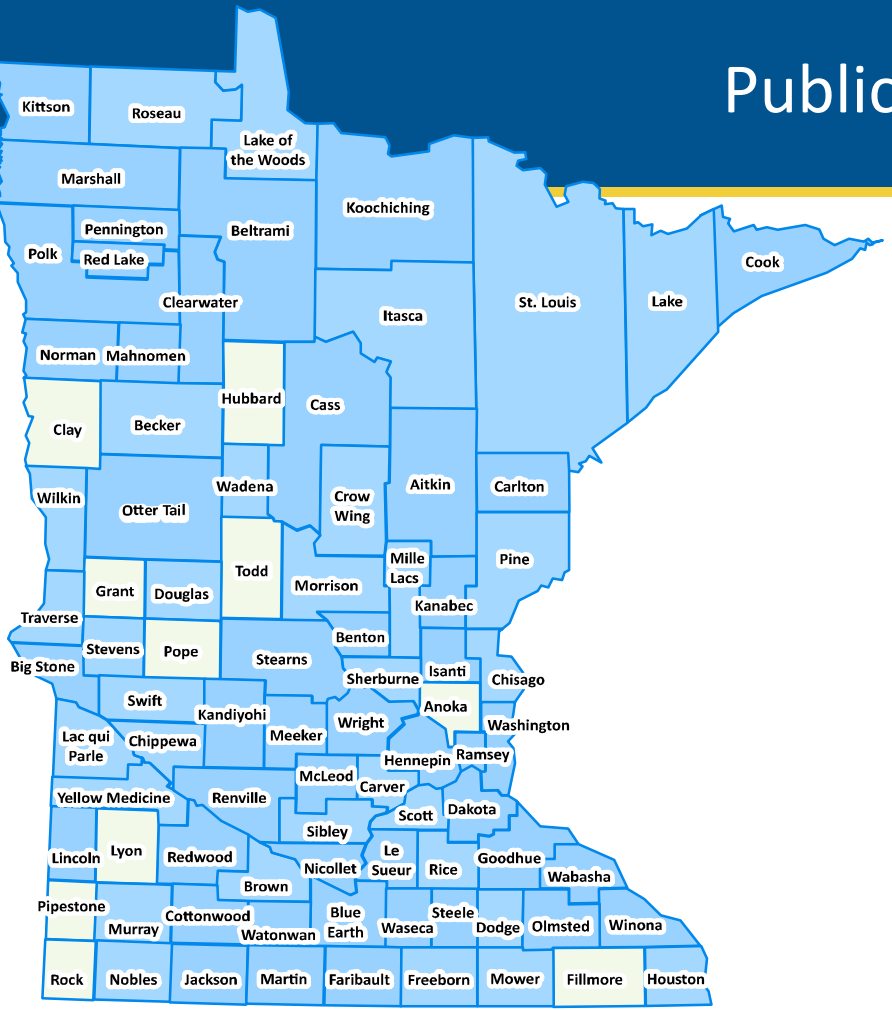
Funding history

- HR1 signed into law July 4, 2025 → Rural Health Transformation Program
- $50 billion over 5 FFYs (2026-2030) = $10 billion annually to be distributed to all 50 states
- MDH submitted an application to CMS on November 4, 2025.
  - Each state was asked to submit their application for $200 million annually.
  - One application was submitted for all five years of funding.
- Awards were made on December 29, 2025. MN will receive $193 million for FFY2026.

Guiding principles

- Create a bridge to a vibrant, responsive, sustainable rural health care system
- Ensure access to health care services for all rural residents
- Rural-centric/Rural in all policies
- Promote efficiency-driven payment models, innovation
- Engage communities & stakeholders to understand needs/priorities

Public Input into RHTP Application



350+ public comments

All counties in Minnesota represented except: Clay, Hubbard, Grant, Pope, Todd, Anoka, Lyon, Pipestone, Rock, and Filmore.

Engagement in the application process

50 meetings with external partners

Engagement with Legislative leads and the Congressional Delegation

Collaboration with the Minnesota Hospital Association, Minnesota Association of Community Health Centers, and Minnesota Association of Community Mental Health Programs

Letters of Support from both MNleg caucuses, GOP Congressional Delegation, Senators Smith & Klobuchar, MHA, MNACHC, Essentia, Sanford, MACMHP, MMA, AMC, OEMS

Minnesota's Rural Health Transformation Program

MINNESOTA
RURAL HEALTH TRANSFORMATION

health.mn.gov

DEPARTMENT OF HEALTH

Strategic Initiatives

Community-based preventive care and chronic disease management

Recruit and retain talent in rural communities

Sustain access to services to keep care closer to home

Create regional care models to improve whole person health

Invest in technology, infrastructure, and collaboration for financial viability

Technology

Initiative #1: Community-Based Preventive Care and Chronic Disease Management

- Chronic disease screening, education, referral, and follow-up
- Chronic disease self-management in clinic and community
- Physical activity, nutrition, and upstream drivers of health referrals
- Post-acute chronic disease care programs and support

Additional detail available on page 16 of Project Narrative

Initiative #2: Recruit and Retain Talent in Rural Communities

- Introduce more high school students to health care careers
- Develop allied health pathways through “Earn and Train” programs
- Expand rural clinical rotations
- Develop rural clinical training opportunities
- Develop a Technical Assistance Center for Excellence in Rural Clinical Training
- Pilot the Healthy Workplace strategy with a subset of rural health systems

Additional detail available on page 20 of Project Narrative

Initiative #3: Sustain Access to Services to Keep Care Closer to Home

- Implement or expand models that integrate frontline staffing into care settings
- Provide technical assistance to organizations interested in frontline workforce investment
- Support Community Mental Health Postvention with Regional Coordinators Programs
- Develop community telehealth access points
- Provide local care delivery with mobile units for physical or oral health

Additional detail available on page 25 of Project Narrative

Initiative #4: Create Regional Care Models to Improve Whole Person Health

- Establish and strengthen telehealth connections to expand access to specialty expertise
- Pilot a system to compensate ambulance services for 911 responses that result in patient contact but do not require transport to an emergency department
- Support the building of a Children's Mental Health Initiative
- Develop new mental health urgent care centers
- Implement a Project ECHO network to connect rural primary care providers with mental health specialists
- Develop a Rural Telehealth Services center
- Expand access to Medications for Opioid Use Disorder
- Provide bridge grants to eligible hospitals or birthing centers for balancing service line sustainability with regional population needs
- Build rural obstetrics skills through high-fidelity simulation led by physician faculty
- Implement an ECHO network that encompasses maternal health from prenatal through delivery to post-partum care

Additional detail available on page 29 of Project Narrative

Initiative #5: Invest in Technology, Infrastructure, and Collaboration Needed for Financial Viability

- Supporting the acquisition of data management software, licenses, or technical assistance and skill-building for health care providers to boost capabilities for internal data management and utilization needs
- Providing funding to rural health care providers to leverage a range of AI applications to improve the efficiency of their clinical operations and increase the capacity for clinical staff to work at the top of their license
- Investing in a secure statewide integrated rural health data network
- Investing in cybersecurity as a necessary tool to secure safe and secure operations of advanced technologies
- Investing in revenue cycle management tools

Additional detail available on page 36 of Project Narrative

Implementation Plans

MINNESOTA

Terms and Conditions

- MDH received a total award of $193,090,618 for FFY2026 pending a fully approved budget.
- There are restrictions on how funds may be spent, some typical of federal funding and some RHTP-specific.
- Funds must be used by the end of the FFY following the FFY in which the funds were allotted. Unused funds will be redistributed across states.
- Administrative costs, including direct and indirect costs, are limited to 10% of overall spending by the State and sub-recipients.
- Outgoing grants and contracts will be implemented, pending a fully approved budget.

Disseminating RHTP Funds

- Year 1 focuses on efficiently getting funds into community through direct allocations to eligible rural hospitals, Tribal Nations, Federally Qualified Health Centers (FQHCs), and Community Behavioral Health Clinics/Community Mental Health Centers (CBHCs/CMHCs)
- Some competitive grants in year 1, and a greater emphasis on competitive grants in years 2-5
- Eligible rural hospitals, Tribal Nations, FQHCs, and CCBHCs/CMHCs may apply for those opportunities, along with other eligible organizations

Allocation Applicant summary

- 125 eligible applicants
- 121 applications submitted
  - 94/94 Hospitals
  - 14/16 Certified Community Behavioral Health Clinic and/or Community Mental Health Centers
    - Human Development Center declined funds for budget Period 1
    - MDH awaits answer from Freeborn County Mental Health
  - 5/5 Federally Qualified Health Centers
  - 8/10 Tribal Nations have submitted
    - Mille Lacs Band of Ojibwe declined funds for Budget Period 1
    - MDH awaits answer from Prairie Island Indian Community

Direct Grants

- MDH has received approval to make direct grants to recipients that were named in the application
- Examples of these grants:
  - University of Minnesota Rural Clinical Training Technical Assistance Center, FM OB Fellowship and Obstetric Simulation Training
  - K-12 Healthcare Exposure Grants to Healthforce Minnesota and the MN Community Health Worker Alliance
- Some competitive funding opportunities will also be available in year 1, on a slightly later timeline than the direct allocation grants

These grants are still pending a fully approved budget.

Continued Funding

- For CMS to issue continuation funding for subsequent budget periods, Minnesota must demonstrate “satisfactory progress,” meaning:
  - Progress in implementing initiatives approved by CMS in the application
  - Adherence to the implementation plan and timeline
  - Progress on self-imposed metrics, including milestones and targets

Staying engaged

Website: Rural Health Transformation Plan - MN Dept. of Health

Email: rural.transformation.mdh@state.mn.us

Updates: *Subscribe for news on the RHTP*

Watch for regional conversations, updates/input through existing bodies

Questions?

MINNESOTA RURAL HEALTH TRANSFORMATION

DEPARTMENT OF HEALTH

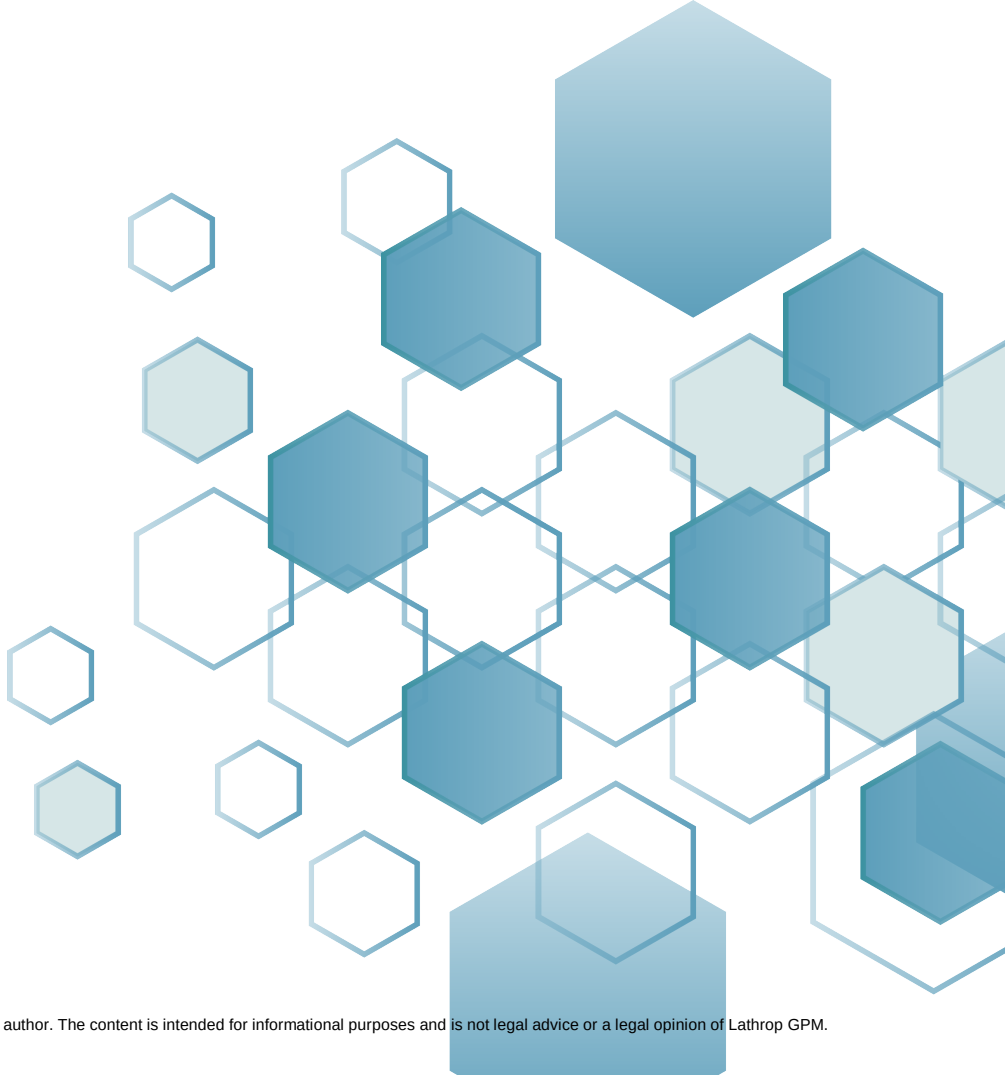
Thank You!

Office of Rural Health and Primary Care RHTP Team

rural.transformation.mdh@state.mn.us

Real Estate Transactions for Health Care Entities

Robin Swingley, Lathrop GPM



Intersection of Healthcare and Real Estate Law

- Healthcare entities often own, lease, or operate real estate assets.
- Real estate transactions can be subject to health-care specific regulatory requirements.
- Our real estate team collaborates closely with our healthcare team and other subject matter experts to address transactions wholistically.

Deal Structuring in Healthcare Real Estate Transactions

Determining Structure

- Collaboration with healthcare attorneys and client teams is essential to determine appropriate structure to meet objectives.

Letter of Intent (LOI) Stage

- Attorney involvement is most valuable at this stage, when the transaction's structure and key business terms are established.

Common real estate transactions include:

- **Leasing**
- **Purchase and sale**
- Mortgages, financing, and ground leases
- Sale-leasebacks
- Options, ROFOs, or ROFRs
- 1031 Exchanges
- M&A Transactions
- Subdividing property – plats, parcel splits, lot line adjustments, registered land survey

Leasing –– Stark Law and Anti-Kickback Statute

Stark Law:
prohibits physicians from referring Medicare patients for “designated health services” to entities in which the physician (or an immediate family member) has a financial relationship. Strict liability applies.

Anti-Kickback Statute:
prohibits knowingly and willingly offering, paying, soliciting, or receiving payment in exchange for referrals for services or goods reimbursable by a federal healthcare program.

False Claims Act:
prohibits knowingly submitting false claims for government payment or retaining government payment which the party knows it is not entitled to.

Enforcement of Stark Law and Anti-Kickback Statute

- Penalties for violating the Anti-Kickback Statute include:
  - Fines up to $100k per violation plus
  - Imprisonment (up to 10 years)
  - Assessment of up to 3x the amount of kickback
  - Exclusion from programs
- Penalties for violating Stark Law:
  - Denial of payment and refunds of amounts collected
  - Monetary penalties and exclusion from programs
- The False Claims Act imposes treble damages plus mandatory civil penalties

Leasing – Compliance with Stark Law and Anti-Kickback Statute

Rent payments under leases can violate Stark or Anti-Kickback

EXCEPTIONS:
Office Space Rental Exception under Stark

Space Rental Safe Harbor under Anti-Kickback

Key lease requirements include:

- Written, signed agreement
- Clearly defined leased premises that include only the space reasonably necessary for legitimate business purposes
- A lease term of at least one year
- Rent that reflects fair market value
  - Value of rental property for general commercial purposes, without considering its specific intended use
  - Set in advance (including escalations)
  - Consider documentation:
    - Appraisal
    - Comparable rental properties
    - Arms-length negotiations

Leasing – Health Insurance Portability and Accountability Act (HIPAA)

Leases should consider:

- Locked or restricted-access areas where PHI is located
- Supervised entry for inspections, repairs, or emergencies
- Access to PHI and rights to remove PHI upon termination, expiration, or eviction
- Confidentiality provisions for inadvertent disclosures of PHI

Leasing – Public Accommodation Laws Including the Americans With Disabilities Act (ADA)

Leases should address:

- Accessible parking and sufficient parking ratios
- Patient drop-off or loading areas near entrance
- Access to entrances, restrooms, elevators, and common areas
- Responsibility for ADA-related improvements
- Allocation of costs between landlord and tenant
- Whether this is the right space for the use – nontraditional options

Leasing – Regulatory Changes and Assignment and Subletting Provisions

Healthcare leases should allow flexibility if laws, regulations, reimbursement rules, or licensure requirements change during the lease term.

Tenant may need the ability to modify operations, access, signage, space configuration, or use of premises to maintain compliance. Landlord may want to limit these changes as much as possible.

Landlords generally retain the right to assign a lease in connection with a sale of the property.

Tenants may desire rights to sublease or assign the lease to a third party to maintain flexibility. These should be carefully considered to avoid unintended consequences.

Purchase and Sale – Purchase Agreements

- Purchase and sale agreements should clearly define:
  - Property descriptions
  - Purchase price
  - Earnest money
  - Due diligence period
  - Title and survey review period
  - Financing contingency
  - Closing contingencies
  - Representations and warranties
  - Deliverables at closing
  - Remedies for default
  - Approval timeframes for required licensures or consents

Common Representations & Warranties

- Marketable title
- Existence of leases
- Zoning, land use, and building codes
- Pending legal actions
  - Eminent Domain
  - Environmental
  - Property disputes
- Building and mechanical conditions
- MN Specific:
  - Wells
  - Septic systems
  - Material defects buyer cannot reasonably discover that interfere with Buyer's use

Purchase and Sale – Purchase Agreements

Purchase and sale agreements should clearly define

- Property descriptions
- Purchase price
- Earnest money
- Due diligence period
- Title and survey review period
- Financing contingency
- Closing contingencies
- Representations and warranties
- Deliverables at closing
- Remedies for default
- Approval timeframes for required licensures or consents

Common Representations & Warranties

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Purchase and Sale – Due Diligence

- Purchase Agreements often provide a window of time for a buyer to investigate before committing to purchase a property.
- During its due diligence, a buyer should consider obtaining and reviewing:
  - Title Insurance Commitment
  - ALTA/NSPS Survey
  - Property Condition Assessments
  - Phase I Environmental Site Assessment and, if necessary, Phase II testing
  - Estoppel certificates from tenants or others with rights to the property
  - Zoning reports or zoning confirmation letters
  - ADA compliance reports
  - Specialized systems inspections

Purchase and Sale – Closing

Recordable Documents
- Ensure proper form for execution, and recording
- Minnesota requires notarization and sometimes requires wet-ink signatures
- Permanent records!

Closing Documents
- Ensure proper form, execution, and recording

Finalize Title Insurance Policy
- Requires “proving up” many aspects of due diligence completed
- Once final, will insure marketable title in the buyer
- Always recommended and nearly universally required by lenders

Closing Payments
- Purchase price
- Loan payoffs
- 3rd parties – brokers, surveyors, attorneys, and others

Prorations & Adjustments
- Real estate taxes
- Utilities and operating expenses
- Rents and security deposits

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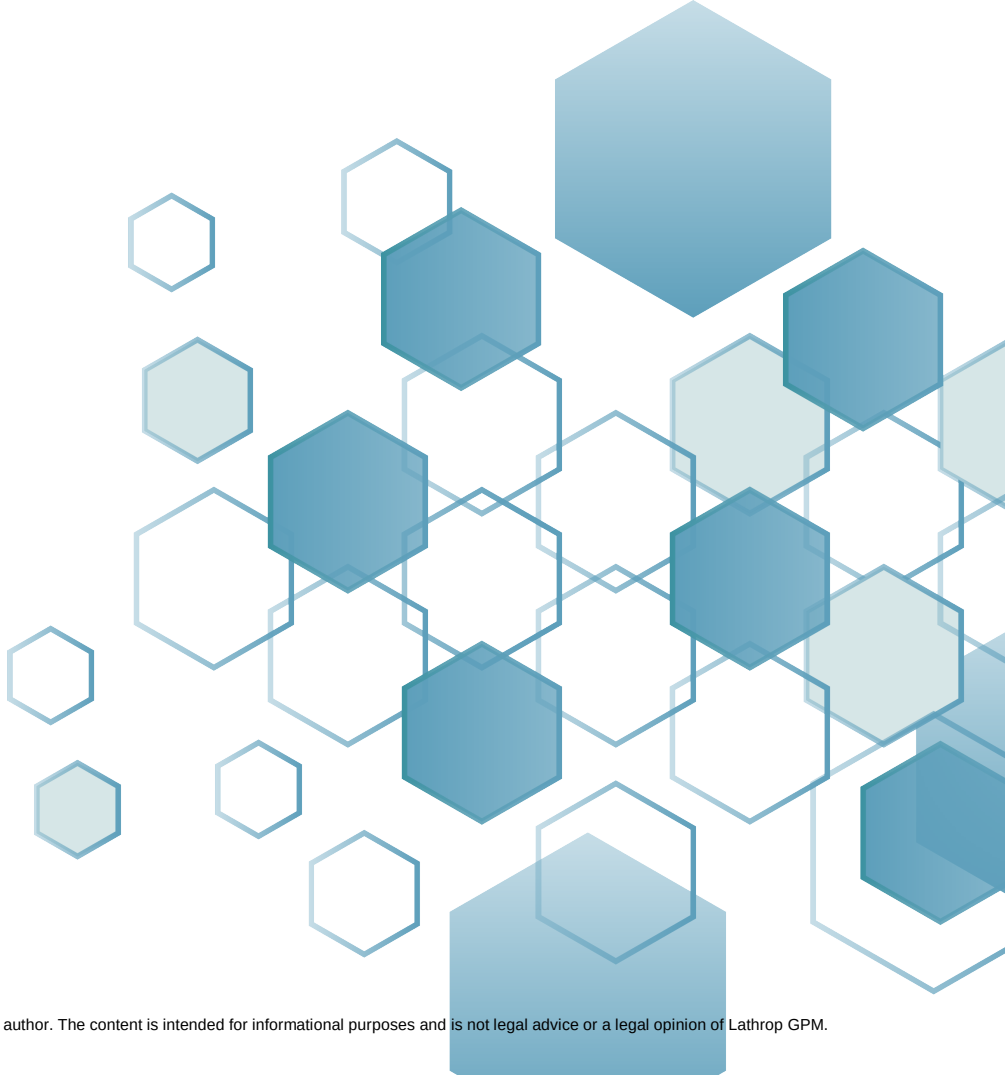
Culture of Compliance

Nancy Musick, Lathrop GPM



Agenda

- Importance of Compliance Programs
- 7 Elements of Effective Compliance Programs
- Top Tips for Effective Compliance Programs
- Additional Resources

Check-in Questions

Where does your compliance program live right now?

When was the last time your compliance program was updated?

If the government investigated your organization tomorrow, what would they say about your compliance program?

What’s the big deal about Compliance Programs?

Effective compliance programs prevent/reduce fines or litigation

There are strong incentives for reports to be made against your organizations

- Whistleblowers, qui tam lawsuits

Damages for claims rack up fast!

- Treble damages, plus penalties!

A program’s existence is one thing, but being effective is another.

- When federal prosecutors investigate healthcare fraud the “adequacy and effectiveness of a corporation’s compliance program at the time of the offense” is a factor that must be considered

The numbers don’t lie.

Kaiser Permanente	January 2026 settlement for $556 million Largest Medicare Advantage fraud settlement in history
2026 National Health Care Fraud Takedown	Charges against 455 defendants Centers for Medicare and Medicaid revoked billing privileges for over 1,400 providers
1,297 whistleblower filings in FY2025, a 32% increase over the previous record	Trump administration is encouraging whistleblower litigation (qui tam lawsuits)

Out of the $6.8 billion recovered under the False Claims Act in FY2025, $5.7 billion was related to the healthcare industry.

Effective Elements of Compliance Programs

- The Seven Elements:
  - Written Policies and Procedures
  - Compliance Leadership & Oversight
  - Training & Education
  - Effective Lines of Communication & Disclosure Programs
  - Enforcing Standards: Consequences & Incentives
  - Risk Assessment, Auditing, and Monitoring
  - Responding to Detected Offenses and Developing Corrective Action Initiatives
- New OIG Resources and Guidance
  - Updated 2023 and ongoing
  - https://oig.hhs.gov/compliance/compliance-guidance/

Elements of Effective Compliance Programs

Written Policies

- Code of Conduct
- Compliance Policies & Procedures
- Policy Maintenance (Updating Them/Living Documents)
  - GUIDANCE: Annual Review of Policy; or when leadership changes!

Compliance Leadership & Oversight

- Compliance Officer
  - GUIDANCE: What compliance officers should NOT do (report to Legal or Finance and should report to CEO or Board)
- Compliance Committee
  - GUIDANCE: Should conduct annual Risk Assessments
- Board Oversight

Elements of Effective Compliance Programs

Training and Education

- GUIDANCE: Annual training to all staff on compliance needs. Training program should also be reviewed annually.
- GUIDANCE: Having training opportunities throughout the year (compliance item on agendas for regular meetings, compliance messaging given in a variety of meetings/spaces)

Effective Lines of Communication

- Anonymous reporting
  - GUIDANCE: At least one anonymous reporting path through a channel independent of the business/operational functions (hotline, website, email)
  - GUIDANCE: Maintain disclosure log about all relevant information each disclosure makes.
- Multiple lines of reporting

Elements of Effective Compliance Programs

Enforcing Standards

- Consequences
- Incentives: Recognition; Performance reviews
- GUIDANCE: Consequences should be consistently applied/enforced, regardless of the position the responsible party holds. Can be remedial or punitive
- GUIDANCE: Consider if incentive plans can be achieved in an ethical/compliant manner. Do sales/admission goals encourage noncompliant behavior?

Elements of Effective Compliance Programs

Risk Assessment, Auditing, & Monitoring

- GUIDANCE: Compliance committee should do risk assessment at least annually
- GUIDANCE: Routine monitoring and auditing of compliance risk should be included in plan. Ex: Monthly screening of State Medicaid exclusion lists; regular screening of state licensure/certification databases.

Responding to Offenses

- GUIDANCE: Compliance officer should maintain following documentation (alleged violation, description of investigative process; copies of interview notes; log of witnesses interviewed, results of investigation.
- GUIDANCE: Prompt reporting to appropriate agencies should happen within 60 days of credible violation. Some types of violation are serious enough to warrant immediate reporting.

Top Reminders

Document, document, document!

Everything should be documented in program. Committee meeting should have agendas & minutes. Engage counsel when conducting investigations.

Make compliance program review itself a recurring responsibility.

The compliance program itself should be updated and reviewed at frequent and regular intervals.

Make compliance accessible through training and reporting

Do employees know where to find information about compliance? Do they know where to report it?

Ensure compliance program is not an afterthought – “Culture of Compliance”

Systems should not just be in place but not used. Would your processes work in a real scenario? Does the compliance team leadership know how to navigate issues and challenges?

Additional Resources

HHS Compliance Program Guidance

HHS-OIG General Compliance Program Guidance | November 2023

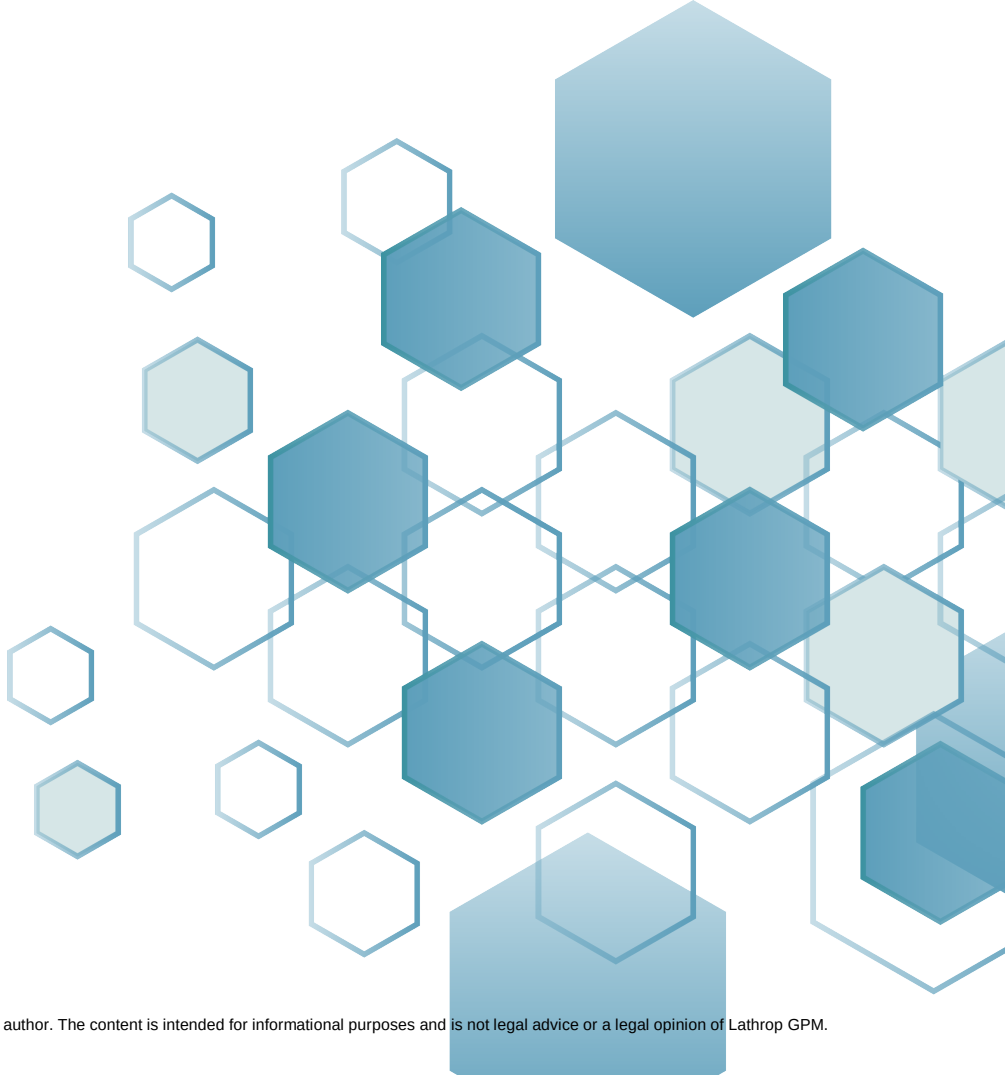
DOJ Compliance Program Evaluations

https://www.justice.gov/criminal/criminal-fraud/page/file/937501/dl?inline=

Employment Update

Megan Anderson, Lathrop GPM

Caitlin Gehlen, Lathrop GPM



MN Employment Law – Refreshers and Updates

Meal and Rest Breaks –January 1, 2026

MN FLSA – Meal and Rest Breaks for Non-Exempt Employees

- Rest break of at least 15 minutes, to use nearest convenient restroom or other reasons, within every four hours of consecutive work
  - Rest breaks of 20 minutes or less must be paid and counted as working time
- An employee working six or more consecutive hours must be allowed a non-working meal break of at least 30 minutes
  - This non-working meal break can be unpaid and is not counted as working time
- Exemptions for “exempt” employees and certain agricultural or seasonal day camp staff members or for employees covered by a CBA
- New remedies for violations - employer is liable for rest / meal time that was denied at employee’s regular rate of pay, plus an equal amount as liquidated damages

Meal and Rest Breaks – Effective January 1, 2026

- Breaks can be voluntarily waived by employee, but should get waiver in writing
- May need to consider creative staffing or scheduling options for operational areas
  - Shorter “working” shifts
  - Can combine breaks – such as into one hour break – so long as timing results in compliance with MN law
- MN Department of Labor and Industry Guidance and FAQs
  - https://www.dli.mn.gov/breaks

MN Earned Sick and Safe Time (ESST) Changes as of January 1, 2026

- For unexpected absences, notice can be required as “reasonably required by the employer” (versus “as soon as practicable”)
- Employers may require an employee to provide documentation for the absence after two (rather than three) consecutive days of sick and safe absences
- For employees starting mid-year, can estimate accrual and advance it so long as employer trues-up if needed to ensure employee receives what they should have actually accrued
  - Can switch them to a frontloading model (if use that for others) as of the employer’s next accrual year

2026 Dept of Labor and Industry Rules on ESST

- DLI adopted rules that became effective July 6, 2026
- Highlights – Accrual:
  - If the employer does not clearly communicate a different accrual year, then the accrual year is a calendar year (Jan 1 through Dec 31).
  - An employer can change its accrual year if:
    - (1) it provides written notice of the new start and end dates of the accrual year before the change takes effect and the notice is given as part of the written notice of changes to employment terms required earning statements; and
    - (2) the change does not negatively impact an employee's ability to accrue ESST
  - Employers can change from ESST accrual to frontloading (or vice versa) if they provide written notice.
    - Change would become effective first day of the next accrual year.
    - If an employer fails to provide timely notice of a change to the accrual method, the prior accrual method will remain in effect, unless the employee agrees to the change

2026 Dept of Labor and Industry Rules on ESST

- Highlights - Usage
  - If an employee requests not to use ESST for an absence, the employee's leave is not subject to the ESST law's protections.
  - Misuse of ESST (e.g. use of ESST for a non-qualifying reason) is not subject to the ESST law protections and the employee may be disciplined ***per an employer's policies***.
  - An employer may ask for reasonable documentation from an employee when there is a clear pattern of suspected ESST misuse, even if the employee has not been absent for two consecutive work days.
  - Pattern of misuse includes:
    - Repeatedly using ESST before or after a holiday or scheduled day off;
    - Repeatedly using ESST at the start or end of a shift;
    - Using ESST for a day previously requested off and denied.
  - Employers cannot deny an employee's request for ESST for a qualifying purpose as a result of past misuse or suspicion of misuse.

Minnesota Paid Leave – January 1, 2026

- State social insurance program for qualifying employee leaves – administered by Family and Medical Benefits Division of MN DEED
  - Or MN DEED-approved private insurance plan equivalent
- Under MPL, an eligible employee may take:
  - Up to 12 weeks of paid medical leave per year for own serious health condition; and
  - Up to 12 weeks of paid family leave per year for qualifying family leave reason
  - Except - total MPL time available per year is capped at 20 weeks
  - Leave may be taken in block or intermittently, subject to certain conditions
- Quarterly wage reporting requirements apply and, as of **April 30, 2026**, employers should be paying quarterly premiums to MN DEED

MPL in Practice

- Payroll Deductions for Premiums
  - MPL: Larger employers must fund at least 50% of the premium and may collect remaining 50% from employees through payroll deductions
  - MN payroll deduction law: employees may authorize payroll deductions through a written authorization
  - Employers do not need to obtain authorization prior to payroll deductions for MPL so long as they have met the state law's employee notice requirements and included premium data in the notice
- Employer Designation of Time Off as MPL Leave
  - An employer may notify DEED or a private insurer of an employee's previous leave so that MPL leave taken after 1/1/2026 may be deducted from the employee's available leave time
  - An employer may designate employee's leave as MPL time provided the employee has provided sufficient notice to determine that the absence qualifies for leave under the MPL law
    - An employee's decision to not apply for MPL wage-replacement benefits does not impact the employer's ability to designate the leave as MPL.

MPL in Practice

- Calculating Leave Entitlement
  - An individual on MPL can only use leave for the hours or days they are scheduled to work
    - Example: If employee works a 32-hour week prior to leave, the employee will be eligible for 284 hours of leave (32 hours x 12 weeks)
- Intermittent Leave
  - 480 hour cap under MPL law
  - MPL permits employer to require it in full work day increments, but, if FMLA applies, FMLA permits it in one hour increments

MPL in Practice

- Return to Work
  - Job protections are not available until after the employee's 90th day of employment
    - The employee's time on leave counts as days of employment (and can count towards the 90 days of employment)
  - Once job protection exists, the employee must be restored to same or equivalent position with same pay, benefits, seniority, and working conditions
    - If employee is no longer qualified for job due to inability to attend a necessary training, course, renew a license, etc., they must be given an opportunity to fulfill those conditions
    - Employee is entitled to any unconditional pay increases that would have occurred during the leave (such as COLA adjustment)

MPL in Practice

- Return to Work
  - Pay increases conditioned on seniority, length of service, or work performed must be granted in accordance with the employer's policy, practice, or contract with respect to other employees on an equivalent leave status
  - If a bonus or other payment is based on the achievement of a specified goal such as hours worked, products sold, or perfect attendance, and the employee has not met the goal due to MPL leave, the payment may be denied, unless otherwise paid to employees on an equivalent leave status for a reason that does not qualify for leave under this chapter

Federal Employment Law Updates

EEOC Update

- EEOC finally has a “quorum” as of October 2025
- EEOC is actively pursuing President Trump administration’s shifted discrimination law interpretations and focus on alleged “illegal DEI”
- EEOC issued a new National Enforcement Plan on June 4, 2026, for 2025-2029 years
  – https://www.eeoc.gov/sites/default/files/2026-06/NEP_-_signed.pdf

EEOC NEP 2025-2029 Priorities

- Focus on disparate treatment (e.g. intentional discrimination), not disparate impact discrimination

- Focus on intentional discrimination by employers via “illegal” DEI programs:
  - Race or sex-based quotas, preferences, exclusions or differential treatment
  - Diverse slate policies or hiring panel policies
  - Diversity statements from candidates
  - Compensation tied to diversity goals
  - Sharing of race or sex data with the public, managers, or non-HR personnel or legal representatives

EEOC NEP 2025-2029 Priorities

- Focus on antisemitism discrimination and harassment
- Focus on anti-American bias as a form of national origin discrimination
  - New technical assistance document issued in November 2025
    - https://www.eeoc.gov/discrimination-against-american-workers-against-law
  - Ads stating preference or requirement for applicants from particular country or with particular visa status (e.g. “H-1B preferred” or “H-1B only”)
  - Making it more difficult for applicants of one national origin to apply (e.g., subjecting U.S. workers to more laborious application methods than H-1B visa holders during the PERM labor certification process)

EEOC NEP 2025-2029 Priorities

- Focus on religious liberties, discrimination, and accommodations
  - Feb. 2026 - Creation of Presidential Task Force to Eradicate Anti-Christian Bias
    - April 2026 Task Force Report: https://www.eeoc.gov/newsroom/presidential-task-force-publishes-report-eradicating-anti-christian-bias-and-restoring
  - Filed multiple lawsuits alleging religious discrimination and accommodation claims related to vaccine mandates

EEOC NEP 2025-2029 Priorities

- Litigation Priorities – broad impact litigation
  - Clarification of unresolved statutory interpretation
    - E.g. *Ames v. Ohio Department of Youth Services*
  - U.S. Supreme Court precedent
    - E.g*. Bostock v. Clayton County*
  - Resolving federal appellate court splits.
  - Voluntary affirmative action plan defense
  - Rights of pregnant workers
  - Religious liberties and accommodations
  - Single-sex access to women’s restrooms

Other EEOC Developments

- January 23, 2026 - rescinded the 2024 “Enforcement Guidance on Harassment in the Workplace”
  - Guidance had applied Supreme Court’s *Bostock* ruling under Title VII to harassment claims, including LGBTQ+ based harassment

- June 30, 2026 - withdrew 1979 guidance titled “Affirmative Action Appropriate Under Title VII of the Civil Rights Act of 1964 as Amended” and related “Compliance Manual Section 607 on Affirmative Action”
  - Materials had provided guidance on creating a voluntary affirmative action plan as a legal defense to a claim that race or sex-conscious action violates Title VII
  - EEOC maintains that past guidance is inconsistent with text of Title VII and obsolete based on recent case law and changes in historical and cultural factors

Other EEOC Developments

- July 6, 2026 - Published regulatory agenda within the “Unified Agenda of Federal Regulatory and Deregulatory Actions”
- Proposes, among other agenda items:
  - Rescission of EEO Reporting Requirements (proposal stage)
    – Employers should proceed with preparing EEO-1s for 2026 for now)
  - Rescission of Uniform Guidelines on Employee Selection Procedures and related recordkeeping (final action pending)
  - Rescission of 1980 “The Guidelines on Discrimination Because of National Origin”
  - Revisions to the Pregnant Workers Fairness Act (proposed rule anticipated)

Impact of EEOC Developments and Activity

- Demonstrates attempt to advance Trump administration policy and enforcement priorities
- Sets out EEOC position on interpretation of laws it enforces
- Does not change existing statutory language, regulations, or case law
- Does not change employer's obligation to comply with applicable state and local employment discrimination laws, such as the Minnesota Human Rights Act

Minnesota Human Rights Act (MHRA) Obligations

- Minnesota Human Rights Act
  - Expressly prohibits discrimination or harassment based on gender identity or sexual orientation
    - Restroom and locker room access cases vary, but MN Department of Human Rights' position is that gender-identity based access is required
  - May permit disparate impact discrimination claims
  - Religious exemption provisions may vary from federal law
  - Contains state contractor affirmative action plan and reporting requirements to the state

MHRA - Business and Public Accommodation

- Business Discrimination (Minn Stat. § 363A.17): It is discriminatory for a person engaged in a trade or business or in the provision of a service:
  - To intentionally refuse to do business with, contract with, or discriminate in the basic terms, conditions, or performance of the contract because of a person's race, national origin, color, sex, gender identity, sexual orientation, or disability, unless the alleged refusal or discrimination is because of a legitimate business purpose
- Public Accommodation Discrimination (Minn. Stat. § 363A.11): It is discriminatory for a place of public accommodation to:
  - deny any person the full and equal enjoyment of the goods, services, facilities, privileges, advantages, and accommodations of a place of public accommodation because of race, color, creed, religion, disability, national origin, marital status, sexual orientation, sex, or gender identity

MHRA - Business and Public Accommodation

- *Anderson v. Aitkin Pharmacy Services* (Minn. Ct. App. 2024): pharmacist refused to dispense prescribed emergency contraception medicine to customer because of his conscientious objection
  - Pharmacist's refusal was motivated by customer's potential pregnancy in violation of the MHRA's business discrimination provision
  - Aitkin Pharmacy did not violate MHRA's business discrimination or public accommodation provision because it intended to disperse the drug by a different pharmacist before the customer transferred the prescription to a different pharmacy

MN Department of Human Rights (MDHR) Update

- MDHR will enforce MHRA per its terms and is seeking to develop more state court case law interpretations
- No EEOC – MDHR workshare agreement as of October 1, 2025
  - MDHR not willing to sign workshare agreement amendment that required certification of non-discrimination obligations inconsistent with MN Human Rights Act
  - Claimants must separately file charges with EEOC and MDHR to preserve rights and meet federal administration exhaustion requirements
  - MDHR currently planning to investigate charges filed first with MDHR
  - Employers could face dual agency response processes and potential litigation in more than one forum

AI in Healthcare Compliance

Leveraging Automation Without Increasing Regulatory Risk

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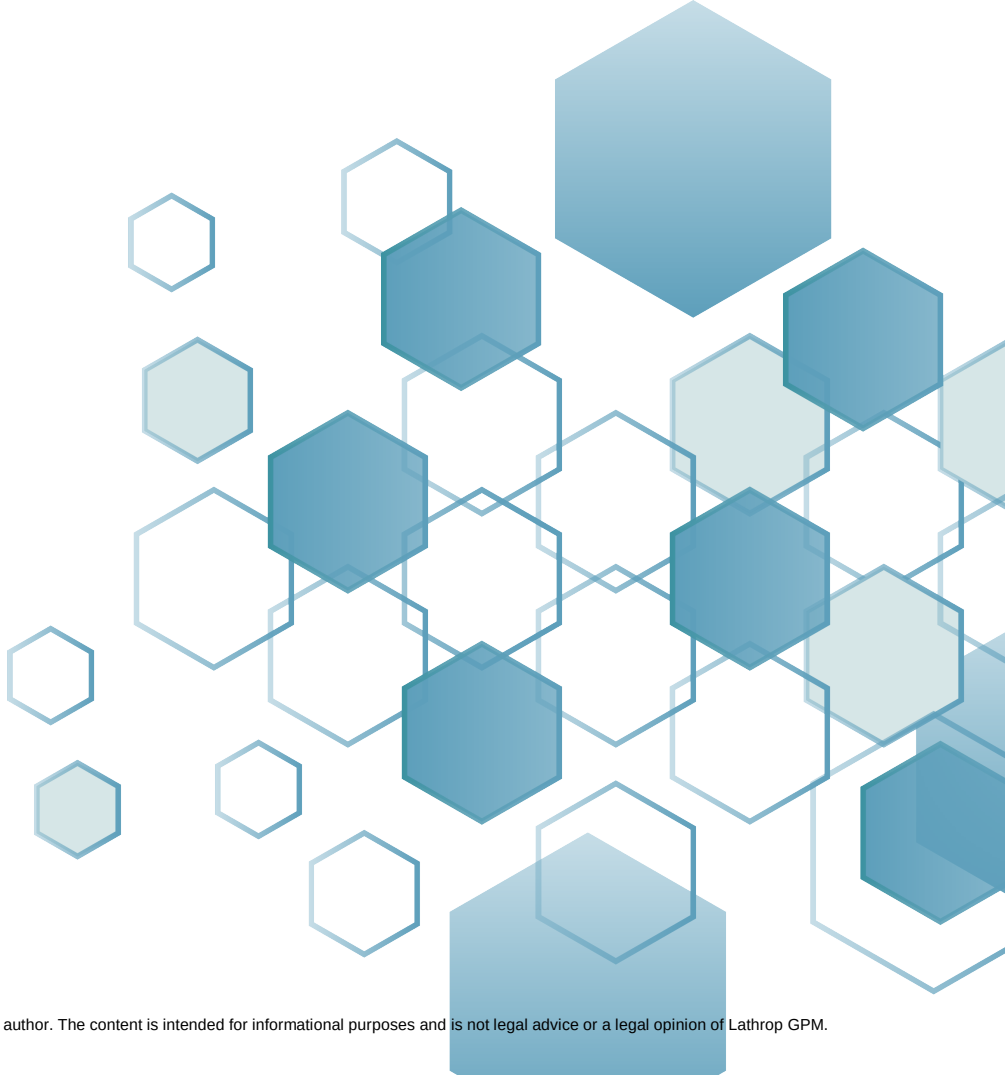


Agenda

- Overview: AI in Healthcare
- Why Compliance Matters: Core AI Risks
- Developing Regulatory Landscape
- Litigation and Enforcement Actions
- Mitigating Compliance Risk

Overview: AI in Healthcare

What It Is and Why It Matters

AI in Healthcare: What it is and Why it Matters

- Artificial Intelligence (AI) is already embedded throughout healthcare, often in ways patients and providers may not realize.
  - AI is increasingly moving from an experimental technology to a practical tool that helps address workforce, operational, and clinical challenges.
- AI is a tool—not a substitute—for professional judgment, clinical expertise, or organizational accountability.
  - Healthcare organizations remain responsible for overseeing AI use and ensuring it is deployed safely, ethically, and in compliance with regulatory requirements
- ***Takeaway: AI can augment human capabilities, but humans remain responsible for decisions, oversight, and compliance.***

Where AI is Being Used in Healthcare Today

Administrative & Operational Support

Clinical Productivity & Care Delivery

Revenue Cycle Management

Administrative and Operational Support

- Patient chart and visit summaries
- Automated documentation and note generation
- Patient communication (e.g., MyChart messages)
- Bed management and workflow optimization
- Billing support and administrative automation

Clinical Productivity and Care Delivery

- Medical imaging analysis (radiology, pathology, etc.)
- Early disease detection and risk screening
- Patient triage and care coordination
- Ambient AI tools that generate visit notes
- Personalized treatment recommendations

Revenue Cycle Management

- Charting and Coding
- Prior Authorization Support
- Billing and Claims Processing Workflows
- Support with Claim Approval and Denial Determinations

AI's Impact on Healthcare: Opportunity and Risk

OPPORTUNITIES

Improving Efficiency
- Reduces administrative burden
- Addresses workforce shortages
- Streamlines workflows
- Cost reduction

Enhancing Clinical Care
- Earlier disease detection
- Faster imaging review
- Identification of high-risk patients

Driving Innovation
- Assess business opportunities
- Develop models for improved performance
- Research
- Personalized treatment
- Population health insights

OPPORTUNITIES **RISKS**

KEY COMPLIANCE TAKEAWAYS

- AI can simultaneously increase efficiency and create new risks.
- Organizations benefit most when AI is treated as an assistive tool subject to meaningful human oversight, validation, and accountability.

CHALLENGES & UNINTENDED CONSEQUENCES

Accuracy, Bias & Reliability Risks
- Flawed or biased data
- Inaccurate or misleading outputs
- Risk of inappropriate use and overreliance by workforce

Operational Burdens
- Training obligations
- Technology implementation costs
- AI vendor contracting risk
- Increased monitoring and governance costs
- Costly errors

Reimbursement Issues
- AI-assisted denials or delays
- More appeals and documentation
- Increasing regulatory scrutiny

Why Compliance Matters
Core AI Risks

Organizational Risks

- AI tools are not substitutes for legal counsel
  - Numerous pitfalls of AI
- Discrimination
- Misinformation
- Treatment applications
- Diagnostic errors and incomplete care
- Security and confidentiality risks
  - HIPAA and other compliance
  - Patient consent
  - Data breach
- Biased data and inequity
- Billing, coding and revenue cycle
- Data degradation
- Scams
- Harassment
- Impersonation
- Blackmail
- Extortion
- Intellectual property
- AI “Black Box”
- Shadow AI – what is actually happening with your information?

Emerging Regulatory Concerns

- Human oversight
- Health ethics
- Transparency
- Accountability
- Billing and reimbursement
- Federal preemption

Regulatory Landscape - Federal

- Federal
  - Biden 2024 EO – comprehensive approach to AI regulations
  - Trump Administration – advocating for federal preemption of state regulations
    - December 2025 EO
    - January 2026 EO
    - June 2026 EO
  - AI LEAD Act (bipartisan)
  - Trump America AI Act
  - FDA
    - More than 1400 AI-enabled med devices (Spring 2026)
    - 2026 Clinical Decision Support Software Guidance
  - HTI-1 (ONC 2024)
  - HHS Demonstration Models (ACCESS, WiSER)
  - Proposed updates to HIPAA Security Rule
  - Additional laws and guidelines affecting AI

WISeR Model

- Wasteful and Inappropriate Service Reduction Model
  - “will help protect American taxpayers by leveraging enhanced technologies, such as Artificial Intelligence (AI) and Machine Learning (ML), along with human clinical review, to ensure timely and appropriate Medicare payment for select items and services.”
- First Innovation Center Model in which technology innovators are only participants
- Tests use of enhanced technology to decrease certain wasteful (low-value) services shown to have little to no clinical, evidence-based benefit. Technology companies participating in the model will help streamline the review of medical necessity for select items and services earlier in the claims process to: (1) reduce inappropriate utilization, (2) lower spending in Original Medicare, (3) expedite decision making and (4) ease provider administrative burden.
- Non-exclusive examples: skin and tissue substitutes, electrical nerve stimulator implants, and knee arthroscopy for knee osteoarthritis.
- WISeR will run from Jan. 1, 2026—Dec. 31, 2031
- Model participants receive percentage of expenditures associated with “wasteful, inappropriate” care identified in their reviews
- Senate democrats introduced measure to repeal WISeR; defeated 46-50 in party line vote (July 16)

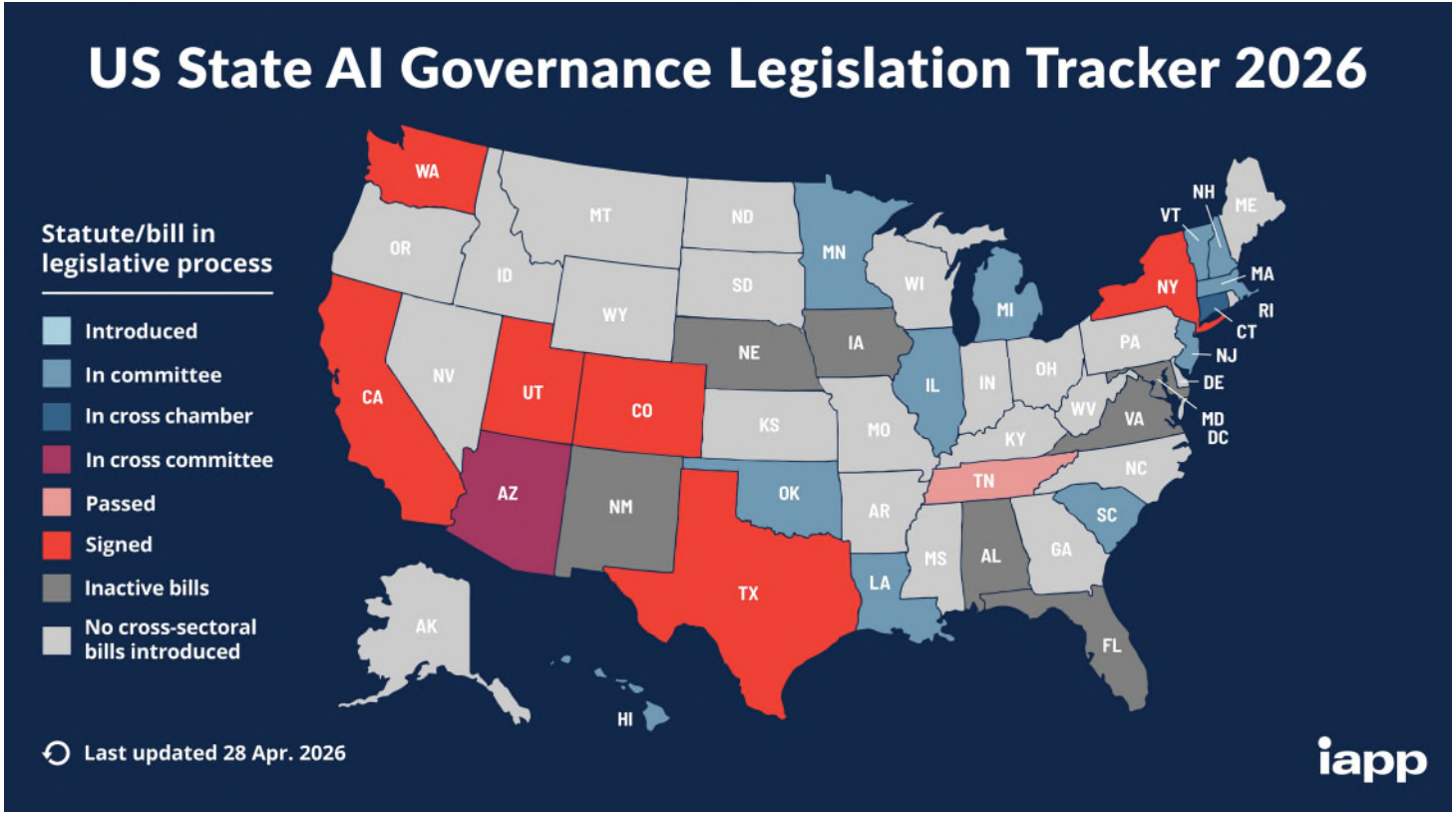
WISeR Model

- 6 participants in WISeR
  - Cohere Health, Inc, (Texas)
  - Genzeon Corp. (New Jersey)
  - Humata Health, Inc. (Oklahoma)
  - Innovaccer Inc. (Ohio)
  - Virtix Health LLC (Washington)
  - Zyer, Inc. (Arizona)
- Providers / suppliers have choice of submitting prior authorization request for selected services or going through post-service / pre-payment review
- While enhanced technology aims to expedite the prior authorization process, any recommendations that coverage should not be provisionally affirmed will be made by an appropriately licensed human clinician, not a machine.
- “Gold carding” exemption program slated to begin in 2026. Providers / suppliers that consistently meet coverage criteria will be exempt from pre authorization / pre-payment review. The first Gold Card exemption rollout is scheduled to begin July 6, 2026, starting in Washington, with phased expansion to the other WISeR states.
- To qualify, providers generally must:
  - Achieve a 90% affirmation rate
  - On a minimum of 10 prior authorization requests during the evaluation period

Regulatory Landscape - State

- Transparency requirements
  - Disclosure and consent
  - Reporting obligations
  - Chatbots
- Ambient listening and wiretap compliance
- Human Oversight requirements
  - Limits on utilization review
  - Limits on insurance decisions
- Governance requirements
  - Written policies and procedures
  - Risk management
- Payer / utilization management
- Use-Case Restrictions
  - Therapy/psychotherapy
  - Administrative support but not direct patient care
  - Ambient AI uses

2026 State Law Status



Minnesota Developments

- Focused on protecting nuanced, personalized medicine
  - HF 2500/H 4188 – prohibited from using AI when approving or denying prior authorization requests
    - *Moving through MN legislature right now*
  - SF 1856 – prohibited from using AI in any part of a utilization review, evaluation, determination, or appeals process
    - *Moving through MN legislature right now*
  - SF 1886 – would have required broad disclosure of AI use to consumers
    - *Died in Committee*
  - Minnesota Consumer Data Privacy Act – gives consumers certain rights to their data and imposes obligations on processors/controllers of data

Lawsuits & Enforcements Actions

- Patient lawsuits
  - Recent examples include: *Sutter Health, UHC, Cigna, Mayo*
  - Improper consent
  - Ambient AI
  - Privacy / data breach
  - Clinical liability and malpractice
  - Plaintiffs lawyers and class actions
- False Claims Act enforcement
  - Retaliation
- DOJ / OIG / CMS enforcement
- Government payor / commercial payor oversight

Using AI as Part of a Healthcare Compliance Program

Successful AI implementation requires governance through the entire AI lifecycle

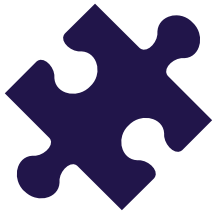
General Tips for AI Monitoring

1. The right people.
2. Solid policies and procedures.
3. Proper follow through and monitoring.

- AI Leadership teams
- Establish:
  - A shared vision/understanding of AI's usage, purpose, and goals
  - Strong internal policies regarding AI
  - Internal risk evaluation policies, metrics, and criteria for vetting AI tools and output
- Set processes for data inventory, risk assessment, and auditing that generates a paper trail
- Facilitate AI training for providers/employees

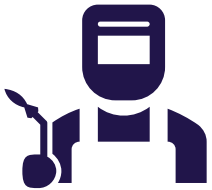
Best Practices in Action

Establish the “WHY”: Why is AI the solution?



What are we trying to solve?

What outcomes define success?



What are the risks?

Who should participate?

Select the AI Tool: Key Questions

What is the AI tool? What is it being used for? Who is the vendor?

What are the tool's training and practices?

What is the input and expected output?

Are there applicable laws and legal issues with using this tool?

Is the tool a regulated product?

Has this tool been used in a clinical setting before?

Other considerations?

Are we ready?

Negotiating Vendor Contracts: Key Terms & Conditions

- Data rights & data use restrictions
  - Make sure the contract shows clear ownership of data input, derived data, outputs, and insights.
  - Best practice is that there are explicit limits on what customer data the model can train on, aggregating customers data, and commercialization of the customer’s data
  - Clarify data disclosure, usage, and ownership.

Key Terms & Conditions

- Privacy, security, & HIPAA/MHRA compliance
  - Consider
    - HIPAA & healthcare compliance
    - Use, disclosure, and safeguards within the agreement
    - Confidentiality of the tool
    - Auditing and oversight process

Key Terms & Conditions

- Transparency, explainability, & audit rights
  - There are terms within contracts that you should look for related to transparency/audit rights:
    - Algorithmic transparency representations
    - Documentation requirements
    - Specific customer audit rights
    - Service levels
  - Transparency matters because of the AI black box effect

Key Terms & Conditions

- Model updates, changes, & regulatory changes
  - Silent updates can affect clinical outputs
  - Be aware of certain provisions:
    - Notice of model updates
    - Customer approval rights for material changes
    - Regulatory change clauses

Key Terms & Conditions

- Liability, indemnification, & insurance
  - Consider:
    - Malpractice exposure
    - Products liability
    - Allocation of fault
    - IP and data security risks
  - Balance Risks of:
    - Indemnification of IP
    - Violations of law
    - Data misuse

Key Terms & Conditions

- Termination, exit, & data portability
  - Consider if there are immediate termination rights, post-termination obligations, data portability restrictions, etc., and what that could mean for you.

Implementation, Ongoing Governance and Vendor Oversight

- Rely on AI leadership teams, policies, and procedures
- Integration into existing or new workflows
- Continued workforce trainings

Internal Monitoring

- Rely on the AI leadership teams, policies, and procedures
- Provide regular training for providers/facilities and update that training to reflect changes in technology and regulation
  - Best rule of thumb – Human in the loop – Providers need to be able to explain the clinical basis for following an AI recommendation for a patient
- Engage legal and risk management early and frequently
- Once implemented, conduct periodic audits (scheduled audits) to check performance of existing AI tools for compliance, bias and quality, as well as assessing security practices and policies for handling data, and ongoing integration of the tool into existing workflows.
  - These can be built into standard operating procedures
- Conduct periodic risk assessments to identify new challenges to the current AI tools/landscape and adapt the AI usage accordingly.

Output Monitoring

- Focus on the outputs:
  - Accuracy
  - Fairness
  - Quality
- Continue asking about:
  - Patient risk?
  - Regulatory risk?
  - Compliance risk?

Bias Monitoring

- Consider bias creep as the tool is implemented.
  - **Algorithmic Bias**: present in the tool itself; the algorithm can inadvertently amplify biases present in the data or create their own.
  - **Automation Bias**: People often perceive an automated decision as more accurate than a human one, which can lead to overlooking errors or disregarding their own reasoning.
  - **Data Bias**: The training date for a model may reflect historical, societal or systemic biases. AI will use past patterns and continue them.
  - **Environmental Bias**: Socio-environmental factors, like social determinants of health (income, education, and living conditions) and urban vs. rural environments can impact data collection and AI predictions.

Bias Monitoring

- Continued
  - **Empathy Bias**: It is difficult to integrate human experience and qualitative elements into AI systems. AI tools can overlook a patient's nuanced experience, preferences, or other circumstances.
  - **Human Bias**: This is the plain ol' bias that comes with any project created by a human. Humans that design systems can unintentionally embed their own biases in models.
  - **Interpretation Bias**: Misinterpretation or misapplication of AI outputs.
  - **Sampling or Exclusion Bias**: If data does not represent an entire population, it can lead to skewed results. E.g. rural vs. urban population data used for training.

Bias Monitoring

Figure 4. **Prompt Engineering to Address Potential Bias**

Example Generic Prompt	What is Potential Risk for Bias?
"Create a list of healthy meals for adults to reduce the risk of heart disease."	The prompt could produce biased outputs by favoring foods from specific cultures, ignoring diverse dietary needs, and suggesting expensive or inaccessible ingredients. The output may exclude individuals with dietary restrictions, cultural preferences or limited resources, potentially perpetuating health inequities.
Example of a Bias Reduction Approach	
"Provide a culturally diverse, cost-conscious and inclusive list of dietary options to reduce the risk of heart disease. These should reflect geographic availability, individual dietary restrictions (e.g., allergies, religious practices, lifestyle choices), and the broader social determinants of health (e.g., income, education, food accessibility). Include multiple perspectives to ensure cultural adaptability, and highlight indigenous or local foods where applicable."	This approach significantly reduces potential biases by promoting inclusivity and accessibility, though it may not completely eliminate biases. Individuals aiming to reduce bias in AI-generated content should provide nuanced community context for more relevant and culturally specific messaging.

Source: Kansas Health Institute.

Top 5 Compliance Takeaways

1. Human oversight and AI transparency is essential throughout entire AI lifecycle (adoption, implementation, and evaluation)
2. AI leadership teams and policies are necessary for ongoing compliance and monitoring
3. Ongoing awareness of legal developments and risks can help you be successful in implementing AI technologies
4. Vigilant vetting and evaluation of vendor contracts, tools, and output is critical for risk mitigation
5. AI is a useful assistant—not a substitute—for compliance teams