



Issues for the week ending September 11, 2026

Federal Issues

Regulatory

CMS Releases Guidance on Community Engagement (Work Requirements) Medical Frailty Exclusion

On September 8, CMS released [guidance](#) on implementing the medical frailty exclusion from the new Medicaid community engagement requirements.

Why this matters: The guidance follows CMS's June 2026 interim final rule with comment period, "[Medicaid Program; Community Engagement Requirement for Certain Individuals](#)." The guidance gives states a model for implementing the medical frailty exclusion ahead of the January 1, 2027, effective date. However, questions remain about when a diagnosis alone is sufficient and when states will need supplemental data or an individualized review to demonstrate that a condition significantly impairs an individual's ability to meet the community engagement requirement.

The details: CMS outlines a three-tier model states may use to verify medical frailty:

- **Tier 1:** Diagnoses which may independently establish both the presence of a condition and

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if the condition impairs an individual's ability to work.

- **Tier 2:** Diagnoses which may establish medical frailty when paired with supplemental information, such as utilization, pharmacy, durable medical equipment, or other clinical data.
- **Tier 3:** Cases that cannot be resolved through available data would proceed to individualized review and potentially documentation.

CMS describes the framework as a model rather than a mandate, leaving states responsible for selecting their own methodologies and code sets. CMS also highlighted Louisiana's tiered approach, which allows certain supplemental codes, such as hospitalization or durable medical equipment use, to support a medical frailty determination without being specifically linked to the underlying diagnosis.

CMS intends to begin collecting information on state methodologies this fall. Although this is not currently a formal approval process, states must be prepared to provide CMS with their medical frailty code lists and related processes and track changes over time.

Department of Labor Releases Targeted MHPAEA Enforcement Priorities and Guidance

What's happening: The Department of Labor's Employee Benefits Security Administration (EBSA) released a [field assistance bulletin](#) outlining a narrowed set of focus areas for MHPAEA enforcement. EBSA also released updated [enforcement guidance](#) designed to provide plans with a clearer understanding of MHPAEA compliance expectations.

Why this matters: EBSA's narrowed enforcement focus is likely to ease administrative burden for Plans and provide a more operationally feasible MHPAEA compliance framework.

The details: EBSA will prioritize and focus MHPAEA NQTL comparative analysis enforcement in three categories based on the highest potential for significant harm to participants and beneficiaries:

- Separate treatment limitations, including exclusions.

- Medical necessity standards and review process, including prior authorization, concurrent review, and retrospective review.
- Standards for determining network adequacy with a focus on network admission standards and provider reimbursement methodologies.

While EBSA will focus enforcement in these areas, EBSA may investigate other categories of NQTLs as issues arise, particularly when responding to participant complaints. EBSA confirmed that it will not pursue enforcement actions of the portions of the 2024 Final Rule that are new in relation to the 2013 Final Rule.

The enforcement guidance provides plans with concrete examples of practices that may be “red flags” signaling potential MHPAEA compliance problems. The guidance also provides tips for reviewing several common NQTLs to ensure they satisfy parity requirements.

White House Announces \$500 Refunds for Select ACA Enrollees

On Sept. 10, 2026, the White House released a [fact sheet](#) announcing the federal government would issue refunds of \$500 per person to nearly one million Americans in 30 states.

Why this matters: Enrollees who do not receive premium tax credits under the Affordable Care Act (ACA) in the 30 states using Healthcare.gov will receive a refund check beginning in October.

CMS Updates

- **CMS Delays 2024 HHS-RADV Settlement Pending Appeal Review:** CMS announced it will delay collection and distribution of 2024 Benefit Year HHS-RADV-adjusted risk adjustment transfers while it reviews several issuer requests for reconsideration.

Why this matters: This appears to be the first significant operational use of the HHS-RADV appeal materiality framework finalized in the 2026 Payment Notice. Under 45 CFR 156.1220(a)(2)(i), CMS will only revise HHS-RADV-adjusted state transfer amounts when a successful appeal changes the filing issuer's transfer adjustment by at least \$10,000. CMS indicated the outstanding appeals could potentially be both actionable and material and therefore may require revisions to the transfer adjustments released on July 15, 2026. As a result, CMS is postponing collection of HHS-RADV charges and corresponding payments until the appeal review is complete. Issuers that incorporated the July 2026 HHS-RADV amounts into their 2025 MLR filings may reflect any subsequent revisions in the 2026 MLR reporting cycle.

- **SBA, HHS, CMS Announce Rebrand of ICHRAs as CHOICE Arrangements:** On Sept. 3, 2026, the U.S. Small Business Administration (SBA), the U.S. Department of Health and Human Services (HHS), and the Centers for Medicare and Medicaid Services (CMS) [announced](#) the rebrand of Individual Coverage Health Reimbursement Arrangements (ICHRAs) as [CHOICE Arrangements](#).

Why this matters: This rebrand does not alter the structure of these arrangements which are a type of health reimbursement arrangement (HRA) that allows employers to give their employees tax-free money to purchase their own individual health insurance coverage instead of offering a traditional group plan.

- **CMS LEAD Model Introduces New Risk Adjustment Policies:** The Centers for Medicare & Medicaid Services (CMS) recently [released](#) frequently asked questions ([FAQs](#)) detailing the risk adjustment approach for the Long-term Enhanced ACO Design (LEAD) Model. LEAD will establish a separate High Needs beneficiary category with its own historical benchmark, trend factor, concurrent risk adjustment methodology, and risk score growth cap. CMS anticipates the High Needs cap will fall between 3% and 8%, although the final amount will depend on model recalibration and has not yet been established. CMS also plans to shadow test an AI-inferred risk adjustment model in 2028 and phase it into payment for the Aged & Disabled population beginning in 2029, subject to testing and validation.

Why this matters: While LEAD is a fee-for-service (FFS) Center for Medicare and Medicaid Innovation (CMMI) model rather than a Medicare Advantage (MA) policy, it may offer an early view into CMS' evolving approach to population-specific and inferred risk adjustment.

- **CMS Cracks Down on \$3.4 Billion Medical Equipment Fraud Scheme :** On Sept. 8, CMS [announced](#) it placed 11 durable medical equipment, prosthetics, orthotics, and supplies (DMEPOS) suppliers on its Preclusion List after identifying more than \$3.4 billion in suspected fraudulent billing across 2025 and 2026.

Why this matters: CMS stated the suppliers billed Medicare for equipment allegedly provided to deceased beneficiaries and individuals who never requested or received the products, and several had previously been revoked from FFS Medicare before billing MA plans. CMS indicated it is coordinating with the Department of Health and Human Services Office of Inspector General and using data analytics, payment suspensions, and other program integrity tools to prevent future MA and Part D payments to the entities.

- **CMS Releases Detailed Information on Medicare GLP-1 Bridge Monthly Utilization Reports:** On August 5, CMS issued a memorandum, "Medicare GLP-1 Bridge Monthly Utilization Reports," announcing the use of the Additional Beneficiary Information Initiative (ABII) portal to share data with Part D plan sponsors about their enrollees' Medicare GLP-1 Bridge utilization. The memorandum also shared CMS' expectations to issue GLP-1 Utilization Reports on a monthly basis beginning this fall.

Subsequently, on September 9, CMS issued a memorandum that provides additional information regarding the GLP-1 Utilization Report, including instructions for plan sponsors to request access to the report and responses to technical questions posed by plan sponsors.

In preparation for the release of the GLP-1 Utilization Report, CMS encourages Part D plan sponsors to request access to the ABII web portal, which provides a secure mechanism for sponsors to retrieve information about their enrollees for the purpose of improving administration of the Part D benefit. Once sponsors gain access to the ABII web portal, they may request the GLP-1 Utilization Report by submitting a data request form. Instructions for submitting data request forms are provided in Section C of the attached memo.

CMS states that GLP-1 Utilization Reports will be updated monthly and will become available for download approximately every 15th of the month. Notifications will be sent out when files are available.

Why this matters: To ensure timely access to the first GLP-1 Utilization Report to be released on September 30, 2026, Part D plan sponsors must complete all steps of the data request form submission process by September 23, 2026. For requests made after September 23, 2026, access will be granted to the next release of the GLP-1 Utilization Report on a rolling basis, corresponding to the applicable data request form submission deadline.

State Issues

Pennsylvania

Legislative

Pennsylvania Lawmakers Propose ‘Universal Health Care Act’

Democratic state lawmakers have introduced legislation to establish a state-administered, single-payer health insurance system covering all Pennsylvania residents.

[House Bill 2763](#), introduced by Rep. Greg Scott (D-Montgomery) alongside companion efforts led by Senator Nikil Saval (D-Philadelphia) in the state Senate, would create a “Medicare-for-All” style framework administered within the state government.

- **Coverage scope:** Guarantees comprehensive medical coverage for all Pennsylvania residents, as well as nonresidents working at least 20 hours per week in the state.
- **Cost structure:** Eliminates out-of-pocket costs, including deductibles, copays, coinsurance, and lifetime coverage caps.
- **Funding source:** Establishes a dedicated state trust fund financed through employer and employee payroll taxes.

Outlook: Unlikely to advance in the Pennsylvania General Assembly this legislative session with limited legislative session days scheduled.

HB 2763 has been referred to the House Insurance Committee for initial consideration.

Dive Deeper: The [Partnership for America's Healthcare Future](#) is an advocacy group that highlights the potential negative impacts and high-costs of transitioning to a government-controlled and operated system – like a public option, single-payer/Medicare for All – while offering policy solutions to help expand access to affordable, high-quality coverage.

Pennsylvania

Regulatory

DOH Proposes Significant Update to Regulations for Communicable and Non-Communicable Diseases

The Pennsylvania Department of Health (DOH) is proposing an overhaul of Chapter 27 of the state's health and safety regulations, governing rules around reporting and responding to communicable and noncommunicable diseases. The [proposed regulatory language](#) would modernize the existing regulations, last updated in 2001, and better align requirements with federal guidelines.

There are a number of regulatory proposals in the package that would apply to health care practitioners and health care facilities. Some of the proposals with the most direct impact on hospitals would:

- Require hospital emergency departments (ED) to report visit data elements to DOH within 24 hours of a patient's presentation for syndromic surveillance. DOH indicates that hospitals already make these reports but that right now it's voluntary.
- Expand the list of diseases, infections, and conditions that health care practitioners and health care facilities are required to report from 52 to 125 to align with standards from the Centers for Disease Control and Prevention and American Academy of Pediatrics.
- Add 53 new diseases, infections, and conditions to the reporting requirements for clinical laboratories.
- Require health care practitioners, facilities, or other individuals to report administration of vaccines to DOH's designated immunization information system unless the patient declines (already in place in Philadelphia).
- Create an electronic birth defect registry and require health care practitioners or health care facilities to report certain types of birth defects and congenital anomalies. (Pennsylvania is the only state that doesn't currently have this.)

Additional changes would give DOH the following expanded authority:

- **Quarantine and Isolation:** The new regulations will broaden the PA DOH's authority to enforce quarantine and isolation measures.
- **Masking Requirements:** There will be an expansion of the authority to mandate masking in certain situations.

Comments on the proposed regulations are due September 21.

Why this matters: These proposed changes are part of a broader effort to improve public health responses, particularly in light of recent health challenges. The PA DOH aims to ensure that regulations are effective in managing outbreaks and protecting community health.

Industry Trends

Policy / Market Trends

Highmark Specialty Pharmacy Program Improves Access and Affordability

Highmark BCBS members are receiving their specialty medications faster and at a more affordable price thanks to the Plan's [specialty drug management program](#) powered by Free Market Health.

Why this matters: Specialty medications, while able to better manage certain chronic diseases, come with very high costs. Balancing access to and cost of specialty medications is one of the biggest challenges facing today's healthcare system and requires tangible solutions to address.

The details: The specialty drug management program matches medication referrals with pharmacies to support each member's individual needs while balancing overall costs and quality of care.

- The program also expands access to new, lower-cost generic medications offered through CivicaScript and supports Highmark BCBS' biosimilar-first initiatives — increasing access to and affordability of medications for individuals with complex conditions.

The impact:

- Specialty medication access rates for first-time users of a specialty drug have improved by more than 50% compared to members not managed in the program.
- Highmark BCBS' insured business saw an average 2% improvement in specialty medication discount value through the program.

Yes, and: Highmark BCBS has tailored the program to address other factors driving health. For example: Participating specialty pharmacies are incentivized to administer assessments to the most medically complex members, with identified members referred to a Highmark BCBS social worker to help address their social health needs.

"Our specialty drug management program enhances specialty prescription drug access and adherence and care pathways for members with complex health conditions," said Sarah Marche, SVP of pharmacy for Highmark Inc. "With fewer episodes of drug abandonments and lower claims costs for medications, members and group customers both benefit."

Zoom out: Highmark and other BCBS plans are also partnering through [Evio Pharmacy Solutions](#) to use direct purchasing and value-based agreements with pharmaceutical manufacturers to lower prices for high-cost and specialty medications.

Interested in reviewing a copy of a bill(s)? Access the following web sites:

Delaware State Legislation: <http://legis.delaware.gov/>.

New York Legislation: <https://nyassembly.gov/leg/>

Pennsylvania Legislation: www.legis.state.pa.us.

West Virginia Legislation: <http://www.legis.state.wv.us/>

For copies of congressional bills, access <https://www.congress.gov/>

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