Highmark's Weekly Capitol Hill Report



Issues for the week ending November 6, 2026

Federal Issues

Regulatory

CMS Publishes Proposed and Final Rules of Importance to Hospitals

Proposed Rule:

- **Changes to the Medicare Conditions of Participation to Reduce Administrative Burden for Hospitals and Other Providers** -- The Centers for Medicare & Medicaid Services Nov. 5 proposed changes to Medicare's Conditions of Participation (CoP) and other administrative requirements that are intended to remove or revise obsolete, outdated and excessively burdensome regulations for hospitals and other healthcare providers.

  Some of CMS' proposed changes reflect ideas the American Hospital Association (AHA) and individual hospitals shared with the administration in its list of 100 ideas for regulatory relief. Among the changes, CMS would revise its obstetrical services CoPs by eliminating certain staff training, quality assessment and performance improvement requirements. CMS also proposes new patient rights requirements related to birth tissue

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collection, including standards for obtaining informed consent and supporting families requesting birth tissue for cultural, religious or personal reasons.

For critical access hospitals (CAH), CMS proposes to clarify that CAH distance eligibility determinations are based on proximity to hospitals that provide acute care inpatient services or another CAH, rather than to hospitals that provide only specialty services such as a psychiatric or long-term acute care hospital. CMS also would implement new statutory requirements that allow CAHs that meet certain qualifying criteria to be exempt from the distance eligibility requirements.

CMS also proposes to remove COVID-19 and influenza data reporting requirements for rural emergency hospitals and long-term care facilities. The agency would also eliminate the requirement to offer COVID-19 vaccinations to long-term care facility residents.

Lastly, CMS proposes changes to its physical environment standards for all healthcare facility types by adopting the 2024 editions of the National Fire Protection Association Life Safety Code and Health Care Facilities Code. CMS also proposes to adopt the 2022 edition of the Emergency and Standby Power Systems Code, and to update its requirements to permit hospitals to use additional sources of emergency power.

CMS is accepting comments on the proposed rule through Jan. 11, 2027.

Final Rules:

- **CY 2027 Home Health Payment Rule** -- CMS Nov. 4 released the calendar year 2027 home health prospective payment system final rule, which also includes significant provisions affecting provider enrollment for all Medicare provider types.

Specifically, CMS finalized Medicare provider enrollment changes that it says are aimed at reducing improper payments and addressing fraud, waste and abuse, with most provisions applying to all enrolled provider types. The changes make all enrollment revocations retroactive to the date noncompliance began. They also expand grounds for denying or revoking enrollment.

In addition, CMS finalized its authority to deny or revoke enrollment for hospices, home health agencies and durable medical equipment suppliers that fail to meet reenrollment and survey/accreditation requirements following certain majority ownership changes. Additional provisions extend existing authorities for license and healthcare program suspensions or revocations to providers' owners and managing employees or organizations.

The home health PPS final rule increases payments by 2.4% in 2027 compared to 2026. This update includes a 3.1% market basket update, reduced by a 1.0% productivity adjustment and a 0.3% increase related to outlier payments. CMS will keep in place a 3.0% temporary reduction to the base payment rate to maintain budget neutrality due to implementation of the Patient Driven Grouping Model.

- **CY 2027 Physician Fee Schedule Final Rule** -- CMS Nov. 4 released its calendar year 2027 final rule for the physician fee schedule. As required by law, CMS will implement two separate conversion factors: one for qualifying alternative payment model participants, or QPs, and one for physicians and practitioners who are not QPs. The rule will decrease payments to physicians by reducing the QP conversion factor by 1.83% and the non-QP conversion factor by 2.31% in CY 2027 as compared to CY 2026.

  CMS finalized modifications to its proposal to reduce payment when a separately identifiable

office/outpatient evaluation and management visit is furnished on the same day as a global procedure. The agency also finalized its proposal to replace the office/outpatient E/M visit complexity add-on code with a modifier, which it states will increase payment for all levels of the base E/M code by 16%, and for practitioners participating in accountable care organizations by 32%.

CMS finalized its proposed changes to remote physiologic monitoring and remote therapeutic monitoring services, including one that RTM services must be furnished only to established patients, and another saying that practitioners billing for RPM or RTM services must furnish a separately reportable initiating visit at the onset of the services. However, the agency is delaying until Jan. 1, 2029, the requirement to allow payment for RPM and RTM services only when they are performed by clinical staff employed by the billing practitioner and not by a contractor.

As part of efforts to reform the indirect practice expense methodology, CMS finalized its proposals to phase out the indirect practice cost index over two years, implement a practice expense stabilization adjustment and allocate indirect practice expense using both the work relative value unit and clinical labor practice expense relative value unit.

CMS also finalized several changes to the Medicare Shared Savings Program's financial methodology, quality performance standard and beneficiary policies. Under the Quality Payment Program, it will delay the sunsetting of the Merit-based Incentive Payment System until 2031 (rather than 2029, as proposed) and finalized the adoption of three new MIPS Value Pathways. The agency also finalized proposed updates to the mandatory Ambulatory Specialty Model.

In addition, CMS finalized its proposal to require 340B covered entities to submit certain

claims data elements for Medicare Part D drugs purchased under the 340B program to the agency's 340B claims data repository starting Jan. 1, 2027.

- **CY Hospital Outpatient PPS Rule** -- CMS Nov. 4 issued a final rule that increases Medicare hospital outpatient prospective payment system rates by a net 2.3% in calendar year 2027 compared to 2026. This includes a 3.2% market basket update, offset by a 0.9 percentage point cut for productivity. In addition, CMS finalized its proposal to expand its site-neutral payment policy to imaging without contrast services furnished in grandfathered off-campus hospital outpatient departments, setting the site-neutral rate at 40% of the outpatient PPS rate. As with the other site-neutral policies, CMS exempts rural sole community hospitals from this policy. The agency estimates this policy will cut outpatient PPS spending by $260 million in CY 2027.

  Beginning Jan. 1, 2027, CMS finalized payment for separately payable 340B drugs at average sales price of the drug minus 28%, rather than the proposed ASP minus 33.4%. The new payment rate is based on 340B ceiling price data it received from the Health Resources and Services Administration rather than the results of the drug acquisition cost survey the agency conducted earlier this year. The payment reduction will be implemented in a budget-neutral manner, meaning CMS will increase payments for non-drug items and services by 7.5%. CMS will exempt rural sole community hospitals as well as PPS-exempt cancer hospitals and children's hospitals. Non-340B hospitals will continue to be paid for separately payable drugs at ASP plus 6%.

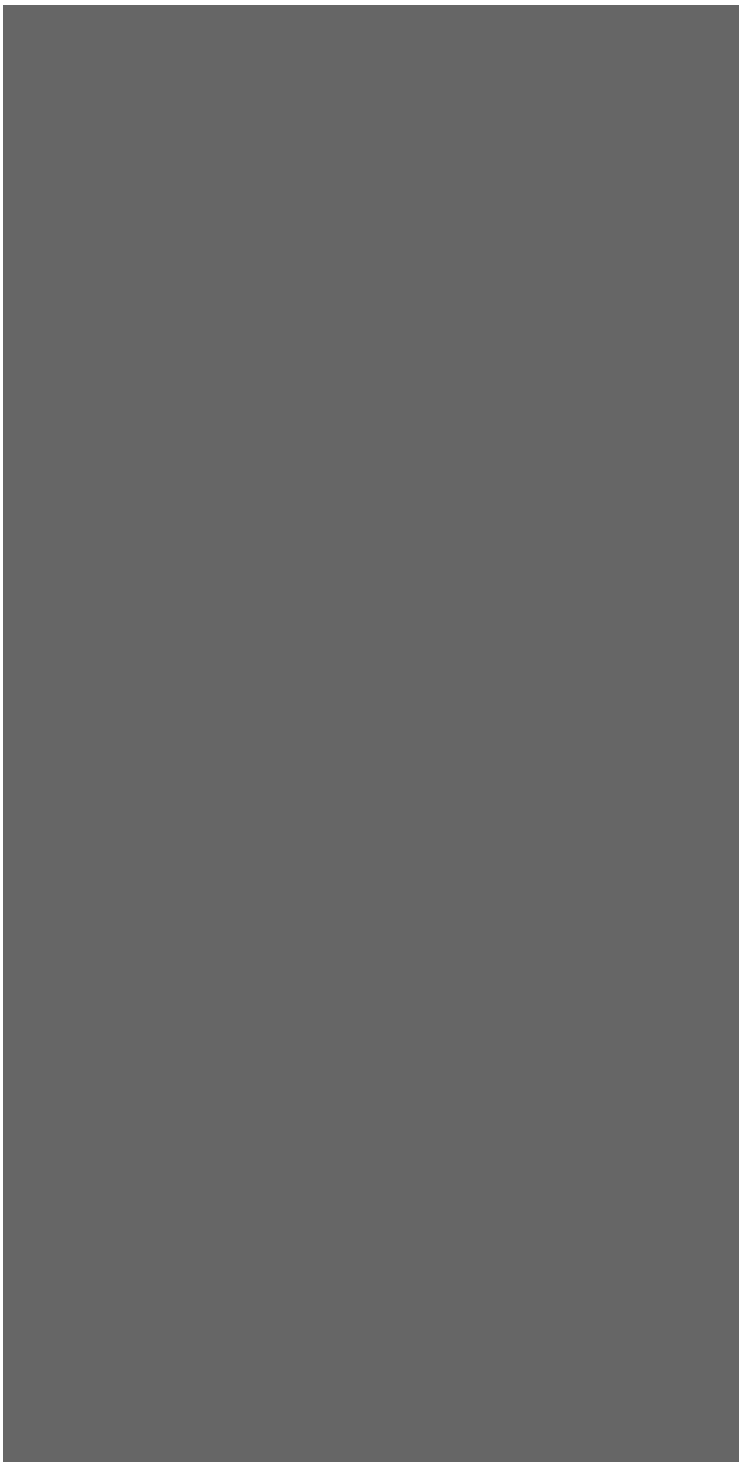
  Separately, CMS finalized a policy to accelerate recoupment of the prior 340B payment remedy by increasing the annual outpatient PPS conversion-factor reduction from 0.5% to 2% beginning in CY 2027, with

recoupment of the estimated $7.8 billion expected to be completed by 2031.

In addition, CMS finalized its proposal to remove 637 additional services from the inpatient-only list. It also authorizes CMS-approved accrediting organizations to assess compliance with certain Emergency Medical Treatment and Labor Act administrative requirements; adds botulinum toxin injection codes to the services subject to prior authorization (as of July 1, 2027); and requires that by Jan. 1, 2028, hospitals must, for each of their off-campus outpatient departments, obtain a separate national provider identifier and attest to compliance with the provider-based rules in order to bill under the outpatient PPS as an off-campus provider-based department.

- **Oversight of Organ Procurement Organizations** -- CMS Oct. 30 released a final rule updating conditions for coverage for organ procurement organizations. The final rule eliminates a regulatory requirement that limited the Secretary of Health and Human Services in certifying new OPOs; clarifies the OPO designation process, including requirements for OPOs operating in multiple donation service areas; modifies the appeals process for OPOs; and updates and adds certain key definitions, among other changes specific to OPOs.

  While the final rule eliminated the requirement restricting new OPO certifications, it did not establish a process for certifying or designating new OPOs. CMS intends to address those processes in future rulemaking. **The final rule will take effect on Jan. 2, 2027.**



Court Rules for Jefferson Health in Denying Closed-door Arbitration of Aetna's 'Level of Severity' Policy

The U.S. District Court for the Eastern District of Pennsylvania Nov. 4 ruled in favor of Jefferson Health in granting a public resolution to determine the legality of Aetna's "level of severity" reimbursement policy. The Hospital & Healthsystem Association of Pennsylvania (HAP) and the American Hospital Association (AHA) submitted an **amicus brief** in support of Jefferson Health in the case. HAP also has previously written to **CMS** and **Aetna** outlining concerns about the policy change, which effectively violates CMS' "two-midnight rule."

Aetna previously moved to have the case decided in arbitration rather than federal court litigation.

Aetna's policy, effective since January, is a reimbursement for "low severity" inpatient stays that the company said will be "comparable" to observation rates.

In his opinion, Judge John M. Gallagher ruled that Jefferson Health is seeking equitable relief by asking Aetna to revert to its previous reimbursement policy, thus not requiring arbitration. "This will undoubtedly have monetary consequences," Gallagher wrote. "But that is not the same as seeking monetary damages. In other words, rather than seeking damages related to a specific set of reimbursements paid pursuant to a policy, Plaintiffs are seeking a substantive change to the policy itself."

Why this matters: The implications of this ruling are that the court's decision enables a public resolution rather than a private arbitration process. The ruling may have significant monetary consequences for Aetna, as it could affect how the company reimburses hospitals for inpatient stays classified as "low severity."

This ruling marks a significant step in the ongoing legal discussions surrounding healthcare reimbursement practices and the accountability of commercial insurers.

Agencies to Assess U.S. Pharmaceutical Materials in Effort to Improve Supply Chain and Domestic Manufacturing

The Administration for Strategic Preparedness and Response announced Nov. 3 that it will partner with the Bureau of Industry and Security and the Assistant Secretary of Defense for Health Affairs on an assessment of U.S. pharmaceutical key starting materials (KSMs) in an effort to identify supply chain vulnerabilities and strategies to improve domestic manufacturing capabilities. KSMs are the chemical precursors and intermediates used to manufacture active pharmaceutical ingredients (APIs), the components that give medicines their therapeutic effects.

The assessment would examine supply chain elements of U.S. pharmaceutical manufacturing efforts, including domestic production capacity and the country's reliance on foreign or single sources of critical materials.

The KSM assessment builds on BIS's API industrial base survey, conducted in partnership with ASPR and completed earlier in 2026. That survey examined pharmaceutical manufacturers' production capabilities,

sourcing practices, and supply chain disruptions. The new assessment extends that work further upstream to examine the materials and suppliers on which U.S. API manufacturers depend.

Why this matters: The findings will be compiled into a comprehensive report on the state of the U.S. KSM industrial base, including production capacity, supply chain vulnerabilities, and emergency response capabilities. The report will include recommendations to improve supply chain resilience and public health emergency preparedness.

CMS Releases Final Rule on the Medicare Drug Price Negotiation Program

On November 5, CMS released the pre-publication version of the Medicare Drug Price Negotiation Program Final Rule. The rule is scheduled for publication in the Federal Register on November 9. Unless otherwise specified, the rule applies to initial price applicability year 2029 and all subsequent years. CMS also released a press release, fact sheet, and timeline of key milestones for initial price applicability year 2029.

The final rule largely codifies prior guidance, while also finalizing several new policies. Key provisions in the final rule include the following:

- **Identification of Negotiation-Eligible Drugs.** The rule generally codifies the process to identify, rank and select negotiation-eligible Part B and Part D drugs as outlined in the guidance for initial price applicability year 2028, including the methodology for calculating total expenditures for Part B drugs covered by Medicare Advantage plans and FFS Medicare.
- **Fixed Combination Drugs.** The rule finalizes the proposal under which a product with a single active ingredient, and a variation of that product with an additional active ingredient that allows it to be administered in a different form, are treated as the same single source drug for negotiation.

- **Formulary Inclusion of Selected Drugs**

    - The final rule codifies the requirement that Part D plan sponsors include each Part D drug that is a selected drug with a maximum fair price (MFP) in effect on their formularies. The final rule also codifies the exception that permits Part D plan sponsors to remove such a selected drug under certain circumstances involving immediate substitution of newly available generic drugs or interchangeable biologics that were not available on the market when the formulary was submitted for approval.
    - CMS will continue to use its formulary review process to assess and require reasonable clinical justification for instances where Part D plan sponsors (1) place selected drugs on non-preferred tiers; (2) place selected drugs on a higher cost-sharing tier than non-selected brand drugs in the same class; (3) require step therapy for a selected drug; or (4) impose other more restrictive utilization management policies for a selected drug compared to a non-selected brand drug in the same class.

- **Definition of "Negotiated Price."** The final rule codifies the required elements of the negotiated price from prior program guidance. It also codifies CMS's longstanding interpretation that negotiated price includes sales tax and vaccine administration fees.

Other new policies include clarification on how CMS will determine negotiation eligibility for drugs that formerly qualified for the orphan drug exclusion; revisions regarding the process and schedule of CMS review of information in making the determination whether a generic drug or biosimilar is subject to Bona Fide Marketing; implementation of the Temporary Floor for Small Biotech Drugs for initial price applicability years 2029 and 2030; and clarification of when off-label use would be considered for renegotiation eligibility and selection.

CMS states that the program guidance for initial price applicability years 2026, 2027, and 2028 remains applicable for those years. Any revisions would be addressed by CMS through publication of revised guidance. CMS states that it intends to codify requirements related to MFP effectuation for 2029 and subsequent years in future rulemaking.

Maternity Billing Changes Finalized, Plans Get Added Transition Time

HHS recently announced that health plans, doctors and hospitals can delay using a new billing approach for pregnancy, delivery and postpartum care through Dec. 31, 2027, for pregnancies that began in 2026.

Why this matters: The temporary flexibility gives Plans more time to effectively implement the new coding structure for members whose maternity care begins in 2026 and ends in 2027. It also helps limit disruptions and ensures providers are paid correctly.

The details: The CPT Maternity Care Services code changes, which CMS finalized as part of its 2027 physician fee schedule, are scheduled to go into effect Jan. 1, 2027, and will delete 17 older codes that bundled maternity care into a single bill.

- Instead, 12 new codes will let providers bill for care separately as it happens.
- Pregnancies that begin in 2027 will be billed under the new system.

Yes, and: The new billing approach was proposed by the American College of Obstetricians and Gynecologists and approved by the American Medical Association's CPT Editorial Panel.

- HHS expects the global codes to be phased out as soon as operationally feasible in 2027.

Dig deeper: Read BCBSA's letter to the AMA asking for a one-year delay to the payment changes.

HHS/CMS Updates

- **CMS proposes tougher verification for marketplace tax credits: CMS released a proposed rule to implement verification requirements** in the Working Families Tax Cut. It would withhold financial assistance that lowers premiums and out-of-pocket costs for marketplace enrollees if their information does not match government records.

Why this matters: The proposal, which aims to improve program integrity and premium tax credit accuracy, would directly affect many enrollees' tax credits. CMS projects 332,500 fewer people in the individual marketplace and $7.6 billion less in annual tax credit spending.

CMS expects those who leave will be younger and healthier than average, which would impact the risk pool, raising premiums by an estimated 0.4% beginning in 2028.

- **The details:** If finalized, starting in 2028:
  - People with a data mismatch would pay full price or go without coverage until the mismatch is corrected
  - Automatic annual renewal of tax credits and cost-sharing reductions would end
  - Enrollees who do not confirm their information each year would be re-enrolled without financial help
- **Yes, and:** This proposal is closely tied to a recent proposal from the Department of Treasury and IRS that focuses on new eligibility verification requirements and ties tax consequences for enrollees to whether exchanges and enrollees satisfy them.

- **Federal court strikes down part of Medicaid work requirements rule:** A federal court in Massachusetts recently struck down one piece of the Medicaid community engagement interim final rule, which requires some adults to work, volunteer or take part in similar activities to keep coverage.
  - **Of note, the ruling does not change the Jan. 1, 2027, implementation date for the broader Medicaid community engagement requirements.**
  - **The case:** In Commonwealth of Massachusetts v. Oz, a coalition of 25 states and the District of Columbia sued CMS over a provision requiring members who qualify for a medical-frailty exception to prove that their condition makes it difficult to meet the community engagement requirement.
  - **The decision:** The court's ruling has three main parts:
  - **Burden of proof.** Members who meet a medical-frailty exception are not subject to the ability-to-comply test.
  - **Verification limits.** The court upheld the 12-month lookback on claims and encounter data and the limit of one self-attestation per continuous period of enrollment.
  - **Implementation penalties.** The 25 plaintiff states and the District of Columbia that sued CMS are protected from federal penalties related to implementation errors or delays for six months following the decision.
  - **The big picture:** The ruling comes late in the implementation process as states are preparing to implement the underlying community engagement requirements beginning Jan. 1, 2027. States may need to change systems and processes already under development and will need CMS guidance on how to adjust implementation.
  - **What's next:** Either party has 60 days from the Oct. 29 judgment to file a notice of appeal. An appeal, stay request, subsequent court order or CMS guidance could change implementation.

- **DOL finalizes PBM fee disclosure rule:** The Department of Labor (DOL) released a final rule significantly expanding existing compensation disclosure requirements for pharmacy benefit managers (PBMs) to increase transparency.

- **Why this matters:** DOL narrowed the scope, delayed the start date and accepted recommendations to give service providers and plan fiduciaries temporary good-faith compliance relief as they work toward compliance with the new — and overlapping — Consolidated Appropriations Act (CAA) 2026 requirements.
- **The details:** The new requirements apply to plan years beginning on or after July 1, 2027, and require PBMs and affiliated brokers and consultants performing PBM-related services to disclose how they are paid to large, self-insured employer-sponsored plans.
    - While smaller self-insured and fully insured plans fall outside the requirements, broader disclosure requirements may still apply.
    - Employers also can request records, including claim- and transaction-level data, to verify what PBMs report, and PBMs generally must respond within 60 days.
- **Yes, and:** Plans should begin evaluating the rule's potential implications for PBM contracts, data access and fiduciary oversight.

- **2027 Exchange Public Use Files Available:** Exchange Public Use Files (PUFs) for plan year 2027 have been made publicly available with data most recently imported as of Oct. 20, 2026.

    - **Why this matters:** The Exchange PUFs include plan and issuer level information on Qualified Health Plans and stand-alone dental plans offered to individuals and small businesses through the Exchanges. The PUFs include data from states participating in the Federally-facilitated Exchanges as well as State-based Exchanges that rely on the federal platform. They generally exclude data from State-based Exchanges. Each of the PUFs can be accessed here.

- **OIG Updates Fraud and Abuse FAQs:** On Nov. 5, the Department of Health and Human Services Office of Inspector General (OIG) added a new frequently asked question (FAQ) addressing whether a hospital may offer gift cards to Federal health care program beneficiaries or their family members as an incentive to transfer to another hospital within the same health system.

    - **Why this matters:** The FAQ provides additional guidance on how federal fraud and abuse authorities apply when hospitals provide remuneration to patients, including circumstances that may implicate the Federal Anti-Kickback Statute and the Beneficiary Inducements Civil Monetary Penalty. OIG maintains a series of FAQs addressing how these authorities apply to specific health care arrangements, including the provision of items or other remuneration to Medicare and other Federal health care program beneficiaries.

- **HHS Finalizes Section 504 Rule on Gender Dysphoria:** The Department of Health and Human Services (HHS) Office for Civil Rights published a final rule in the Federal Register to codify HHS's interpretation that "gender dysphoria not resulting from a physical impairment" is not a covered disability under Section 504 of the Rehabilitation Act of 1973.

    - Section 504 prohibits discrimination on the basis of disability in programs and activities that receive Federal financial assistance. The statutory language for section 504 excludes as a covered disability "gender identity disorders not resulting from physical impairments." The preamble to the 2024 section 504 rule (89 FR 40066) issued by the prior Administration indicated that gender dysphoria was not a "gender identity disorder" for purposes of this statutory interpretation. This suggested that gender dysphoria could be a disability covered

by section 504. However, that language was not included in the body of the section 504 regulatory text.
    - The current Administration issued a notice in April 2025 indicating that the preamble language was not legally enforceable. This final rule now specifies in the regulatory text that the statutory exemption in section 504 relating to gender identity does include gender dysphoria. At the same time, the preamble clarifies that the rule does not regulate treatment or standards of care, is consistent with section 1557 and ADA title II, and does not alter recipients' obligations under other nondiscrimination laws.
    - The effective date of the rule is January 4, 2027.

ONC Eases Health IT Rules, Signals Data-sharing Shift

The Office of the National Coordinator for Health IT (ONC) released a final rule that makes it easier for software companies to meet certification requirements while steering the industry toward a more modern, standardized way of sharing health information.

Why this matters: CMS and ONC are increasingly relying on FHIR-based APIs across federal data-sharing initiatives. The shift could lower compliance costs for technology developers and lay the groundwork for future systems that automate tasks, work faster, and cover a wider range of data.

The details: The final rule is narrower than proposed, leaving policies not addressed in this rule under consideration. Two outcomes align with BCBSA recommendations:

- **More time for older formats.** Several older certification requirements were removed or revised. One older document-sharing format will now be phased out by 2030 instead of 2027, giving the industry extra time to transition.
- **One standard replaces another.** The rule drops an older data definition in favor of a newer, broader standard.

Yes, but: ONC did not finalize proposed changes to rules related to information blocking. The changes included updating definitions to account for automated activity, including AI systems, which BCBSA supported.

Industry Trends

Policy / Market Trends

Departments Deny Recertification of Two IDR Entities

What's happening: The Departments of Health and Human Services, Labor and the Treasury (Departments) announced they are denying recertification of two Independent Dispute Resolution Entities (IDREs). Island Peer Review Organization, Inc. (IPRO) and Network Medical Review Company, LLC failed to meet minimum performance standards required of IDREs and are no longer eligible to accept new disputes under the IDR process.

Why this matters: BCBSA has long urged the Departments to exercise additional oversight and enforcement of IDREs, including through a more robust IDRE certification and recertification framework. We

previously submitted a formal letter to the Departments with detailed data on Plans' experiences with the IDR process, including concerning data from IPRO and several other IDREs. These denials of recertification are an indication that the Departments are more closely reviewing IDREs' performance and lack of compliance with program requirements and considering the data being shared by BCBSA and other partners.

What's Next: IPRO and Network Medical Review Company, LLC have the right to appeal their denials of recertification. There are multiple IDREs still under review for recertification following the closing of public petition periods, and the Departments will make future announcements regarding the status of **those** applications.

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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