

## Federal Issues

### Regulatory

#### Tri-Departments Propose New Rules on Transparency in Coverage

The Centers of Medicare and Medicaid Services (CMS), Department of Labor, and Treasury Department ("the Departments") jointly issued a pre-publication [proposed rules](#) on Transparency in Coverage.

**Why this matters:** The proposed rules build on the 2020 Transparency in Coverage (TIC) final rules, which established existing requirements for public disclosure of in-network negotiated rates and out-of-network allowed amounts via machine readable files and updates requirements for issuer cost estimator tools.

- The proposed rules do not address requirements for implementation of prescription drug MRFs.
- The Departments are considering responses to the June 2025 RFI on prescription drug reporting and are evaluating how to implement prescription drug reporting requirements in technical implementation guidance or future rulemaking.

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- Note some of the reporting changes in this proposed rule would also apply to prescription drug files.

The proposed rules are scheduled to be published in the [Federal Register](#) for a 60-day comment period, **with comments due on February 21**. CMS also issued a [press release](#) and [fact sheet](#).

- Rural Health Transformation Program Awardee Decisions Announced

## Overview of Proposed Rule

### **In-Network and Out-of-Network Machine Readable Files**

Earlier this year, the Administration issued [Executive Order 14221](#), “Making America Healthy Again by Empowering Patients with Clear, Accurate, and Actionable Healthcare Pricing Information.” In response to that Executive Order, the proposed rules update requirements for disclosure of in-network negotiated rates and out-of-network allowed amounts through MRFs under the 2020 Transparency in Coverage final rules.

The Departments identify three concerns raised by stakeholders as barriers to achieving the goals of the 2020 TIC rules: (1) large file size making rates inaccessible, (2) lack of context alongside raw data, and (3) misalignment across hospital and health plan transparency requirements that make comparing public rates challenging. The Departments propose the following changes to improve the standardization, accuracy, and accessibility of rates disclosed in the in-network and out-of-network MRFs:

- **Exclude rates for services a provider is unlikely to perform.** To reduce file size for in-network files, health plans would be required to 1) exclude from in-network MRFs rates for services for which the provider contract may assign a rate but that provider would be unlikely to perform (e.g., a psychiatrist with a rate for a heart transplant) using internal provider taxonomy mapping used in claims adjudication processes; 2) post the internal provider taxonomy mapping they used to prepare the in-network rate file; and 3) post a new “Utilization File” for each in-network MRF that includes all providers who have submitted and received reimbursement for at least one claim for a covered service over the 12-month period ending 6 months before the posting of the file.
- **Report in-network rates by network, rather than by plan.** To reduce duplication, the Departments propose to shift the level of reporting for in-network rates. Specifically, health plans would be required to report in-network rates at the network level, rather than for each plan or policy, as required under current rules. This would also align with hospital price transparency reporting.
- **Increase reporting of out-of-network allowed amounts.** The Departments raise concerns that the current 20-claim threshold for reporting out-of-network allowed amounts leads to little or no data in out-of-network allowed amount files. To increase the reporting of information on out-of-network allowed amounts, the Departments propose to: 2) require plans to aggregate out-of-network MRFs by market type (large group, small group, and self-insured); 2) lower the claims threshold from 20 to

11 claims; and 3) increase the period of reporting from 90 days to 6 months and the lookback period from 180 days to 9 months.

- **Additional data reporting.** The Departments propose to require additional data elements including: the plan's or policy's product type (HMO, PPO, etc.) for each policy represented in an in-network or out-of-network file; a numerical enrollment count for each plan or policy in the in-network or out-of-network file; and the common network name associated with the provider network represented in the in-network file.
- **Public disclosure of a change log.** The rules would require plans to publicly disclose a new change log MRF which would reflect changes in data from one in-network MRF to the next published in-network MRF. This requirement would apply to in-network, out-of-network, and prescription drug files.
- **Facilitate automation of locating and downloading MRFs.** Plans would be required to publish a plain text (.txt file) in the root folder of a payer's website with information on the specific location of the MRFs. The file would also be required to include a point of contact, including name and email, for those responsible for the MRFs. Plans and issuers would also be required to include a footer on the home page of the plan's titled "Price Transparency" or "Transparency in Coverage" that redirects to the publicly available page where MRFs are posted.
- **Reduce cadence for posting in-network and out-of-network files to quarterly.** The Departments propose to decrease the frequency of MRF posting from monthly to quarterly. The Departments do not propose to change the monthly reporting cadence for prescription drug files.
- **Comment solicitation on a single file format.** The 2020 TIC rules allow plans to publish MRFs in any non-proprietary, open format, such as JSON, XML, or CSV. The Departments are considering updating technical guidance to restrict MRFs to one format—JSON or CSV.

**Effective Date:** The Departments propose the revised in-network and out-of-network MRF requirements would be applicable 12 months after publication of a final rule.

### **Issuer Cost Estimator Tools**

The proposed rules address the related requirements in the Transparency in Coverage final rules and No Surprises Act related that issuers provide a pre-service estimate of out-of-pocket cost-sharing for a specific service with a specific provider.

- **First**, the proposed rules would require that issuers make cost-sharing information available over the phone, upon request, to satisfy the No Surprises Act.
- **Second**, the Departments propose changes to notice requirements related to potential balance billing not captured in the cost-sharing information.

**Effective Date:** These changes would be applicable for plan years beginning on or after January 1, 2027.

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### **Judge Orders Temporary Pause to Contentious 340B Rebate Pilot**

A U.S. District Judge last week ordered a preliminary injunction against the federal government's proposed 340B Rebate Model Pilot Program.

The American Hospital Association, the Maine Hospital Association, and a group of safety-net health systems filed a complaint to block the federal government from implementing the rebate program, which was set to begin this month.

"The Agency's roll out has involved a rather threadbare administrative record that likely fails to consider and reasonably explain the impact of a rebate model on 340B hospitals, who rely on upfront price concessions to stretch few resources as far as possible to serve rural and poor communities," the judge wrote. As a result, the judge ordered a preliminary injunction against the "hastily assembled" pilot on the basis of "likely" violation of the Administrative Procedure Act's (APA's) arbitrary and capricious standard. "The APA likely requires more from Defendants."

As such, the Health Resources and Services Administration (HRSA) is, at least temporarily, enjoined from permitting the program's nine participating drugmakers from acting on their plans to swap longstanding upfront drug discounts for after-the-fact rebates.

**Why this matters:** Hospitals have argued since the pilot's proposal during the summer that the program is unnecessary and would place a substantial burden on covered entities, both due to new administrative burdens and the direct hit on some hospitals' limited liquidity.

The court's decision halts a rule that would have caused a devastating sea change in a 30-year-old program relied upon by hospitals that serve America's most vulnerable patients and communities.

The pilot program would require covered entities to submit a data report to a drugmaker within 45 calendar days of the drug being dispensed, with allowances for extenuating circumstances. The covered entities would then receive a rebate payment within 10 days of submitting their report.

Drug companies approved to participate in the pilot would oversee the IT framework for submitting these reports and the release of the rebates, giving drugmakers the ability to deny a rebate payment if they detect a duplicate or otherwise improper claim. Alongside their other cost and burden concerns, hospitals have pushed back against that structure over worries that the drug companies could abuse their position to improperly hold up payments.

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## **DEA Extends COVID-19 Telehealth Flexibilities**

The federal government has issued its fourth temporary extension of pandemic-era COVID-19 telehealth flexibilities through 2026.

The Drug Enforcement Administration's (DEA) extension allows registered practitioners to remotely prescribe Schedule II-V controlled medications via audio-video telehealth. This also includes Schedule III-V narcotic controlled medications for maintenance and withdrawal management treatment of opioid use disorder via audio-only visits, without having ever conducted an in-person medical evaluation.

**Why this matters:** The extension ensures continuity of care, prevents a backlog of patients needing in-person appointments, and allows time to finalize and implement new regulations that maintain access to care while preventing drug diversion.

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## CMS Announces Rural Health Transformation Program Awards

On December 29, 2025, the Centers for Medicare & Medicaid Services (CMS) [announced](#) the awards that states will receive in 2026 as part of the Rural Health Transformation Program (RHTP) established in [Public Law 119-21](#).

RHTP allocates \$50 billion in funds to approved states over five years, with \$10 billion available each year from 2026 through 2030. Fifty percent of the funding is to be distributed equally among all approved states while 50 percent is allocated based on a variety of factors as described in the [Notice of Funding Opportunity](#) released in September 2025.

The CMS announcement indicates FY2026 funding awards range between \$147 million to \$281 million and were granted to all 50 states. In addition, CMS released [RHT Program State Project Abstracts](#) which contain one page summaries that each state submitted to CMS as part of the proposed project package.

CMS also [announced](#) the establishment of the Office of Rural Health Transformation within the Center for Medicaid and CHIP Services (CMCS), and said it will convene program meetings in 2026 to provide ongoing guidance and technical assistance to states during implementation. States are also required to submit regular updates to CMS to track progress and assist in identifying best practices across states.

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## CDC Updates Childhood Immunization Recommendations

The Department of Health and Human Services (HHS) [announced](#) updates to the children's immunization schedule following a Presidential Memorandum directing the HHS and Centers of Disease Control and Prevention (CDC) to review vaccine policies in peer countries.

The CDC accepted the recommendations. An HHS [fact sheet](#) is included.

**The updated recommendations reorganize the childhood immunization schedule into three categories:**

1. Immunizations recommended for all children,
  2. Immunizations recommended for certain high-risk groups or populations, and
  3. Immunizations based on shared clinical decision-making between families and clinicians.
- **Recommendations for all children:** CDC's updated recommendations include that all children be immunized against measles, mumps, rubella, polio, diphtheria, tetanus, pertussis, Haemophilus influenzae type b (Hib), pneumococcal disease, human papillomavirus (HPV), and varicella (chickenpox).
  - **Recommendations for high-risk groups:** Vaccines for respiratory syncytial virus (RSV), hepatitis A, hepatitis B, dengue, meningococcal ACWY, and meningococcal B are recommended for certain high-risk groups or populations based on factors such as underlying medical conditions, exposure risk, or risk of transmission.

- **Recommendations for shared decision making:** The CDC recommends shared clinical decision-making for influenza, COVID-19, rotavirus, meningococcal disease, hepatitis A, and hepatitis B, allowing families and clinicians to determine vaccination based on individual circumstances.

HHS and CDC stated that these updated recommendations reflect international comparisons, scientific evidence, and trends in vaccine uptake and public trust. CDC plans to work with states, clinicians, and other partners to support implementation and education.

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### **CMS Provides Enforcement Discretion for States to Convene Medicaid Interested Parties Advisory Groups**

The Centers for Medicare & Medicaid Services (CMS) released an [informational bulletin](#) (CIB) announcing that CMS does not anticipate taking enforcement action against states with respect to the deadlines to convene the new “interested parties advisory group” to advise and consult on rates for specified Medicaid home and community-based services, and for states to publish the groups’ recommendations, as required at 42 CFR § 447.203(b)(6) and as promulgated in the Access Final Rule (89 FR 40542).

**Why this matters:** CMS is pushing out the deadline for convening the group to January 1, 2029, and for publishing its recommendations to February 1, 2029, but provides states flexibility to convene and publish earlier.

CMS states in the CIB that the revised Medicaid Advisory Committee (MAC) and new Beneficiary Advisory Council (BAC) requirements from the Access Final Rule remain, and CMS will consider proposing changes to the interested parties advisory group requirements in future notice-and-comment rulemaking. CMS states another reason for extending the deadlines for the interested parties advisory group is to allow states to focus critical resources on implementing recent federal legislation.

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### **CMS Expands Access to GLP-1s Through New BALANCE Model**

On Dec. 23, CMS [announced](#) a new voluntary model to expand access to GLP-1 drugs for weight loss to Medicare and Medicaid beneficiaries.

**Why this matters:** When taken properly, GLP-1 medications have shown promise in promoting weight management, but with an average monthly [list price](#) of \$1,000, these drugs present an enormous financial burden for patients.

The details: Under the [Better Approaches to Lifestyle and Nutrition for Comprehensive hEalth \(BALANCE\) Model](#), CMS will negotiate directly with GLP-1 manufacturers for lower net prices and standardized coverage terms.

**Who can participate:** Plans that offer standalone prescription drug plans, MA coordinated care plans or MA prescription drug plans, including Special Needs Plans, and employer/union group waiver plans that offer Part D.

- Plans will have the option to participate in Medicare and/or provide coverage under Medicaid contracts if a state elects to participate.

**What's next:** CMS will leverage insights from the Part D sponsor-submitted [notice of intent](#) (NOI) to better facilitate a smooth application process and inform negotiations with participating manufacturers. Of note, an NOI submission does not bind a Plan to participate, and the NOI is not required for participation at a later date.

- State Medicaid agencies can join the model starting in May 2026.
- Part D plans can join in January 2027.

**Yes, and:** CMS also intends to launch a short-term demonstration in July 2026 as a bridge to the BALANCE Model, expanding access to GLP-1s to Part D beneficiaries.

**Take action:** The deadline to submit an NOI is Jan. 8, 2026.

**Dig deeper:** Get more details about the [model](#) and [NOI submission](#)

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## **HHS Releases NPRMs Impacting Gender-Affirming Care for Youth in Medicaid, CHIP, and Hospitals Participating in Medicare**

The Department of Health and Human Services' Centers for Medicare & Medicaid Services (CMS) and Office for Civil Rights (OCR) released three Notices of Proposed Rulemaking (NPRM) impacting Medicaid and CHIP, hospitals participating in Medicare, and the definition of disability under Section 504 of the Rehabilitation Act.

- The first NPRM, [Prohibition on Federal Medicaid and Children's Health Insurance Program Funding for Sex-Rejecting Procedures Furnished to Children](#), prohibits doctors and hospitals from receiving federal Medicaid or CHIP reimbursement for gender-affirming care provided to patients under the age of 18 (under the age of 19 for CHIP recipients). The rule prohibits federal Medicaid and CHIP funding for procedures classified as "sex-rejecting" which includes surgical and medical interventions intended to alter biological sex characteristics.
- The second NPRM, [Hospital Condition of Participation: Prohibiting Sex Rejecting Procedures for Children](#) blocks all Medicaid and Medicare funding for any services at hospitals that provide pediatric gender-affirming care. The proposed rule creates a new Hospital Condition of Participation (CoP) that prohibits Medicare- and Medicaid-certified hospitals from performing "sex-rejecting procedures" on youth. Hospitals that perform these services on youth would not meet the CoP and could lose eligibility to participate in Medicare and Medicaid.
- The third NPRM, [Nondiscrimination on the Basis of Disability in Programs or Activities Receiving Federal Financial Assistance](#), proposes revisions to Section 504 of the Rehabilitation Act of 1973's definitions of "disability" and "individual with a disability" to exclude gender dysphoria not resulting from physical impairments. The rule would also clarify that recipients of HHS funding that enact policies preventing or limiting gender-affirming care procedures do not violate Section 504's disability nondiscrimination requirements.

The CMS proposed rules have a 60-day comment period, due to CMS by 5:00 p.m. ET on February 17, while the OCR rule has a 30-day comment period with comments due on or before January 20.

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## **HRSA Finalizes Women's Preventive Services Initiative Guidelines on Cervical Cancer Screening**

On January 2, the Health Resources and Services Administration (HRSA) posted [a Federal Register notice](#) finalizing updates to the HRSA-supported Women's Preventive Services Guidelines related to cervical cancer screening. The updates were developed by the Women's Preventive Services Initiative (WPSI) and followed by a public comment period.

In October 2025, HRSA requested public comment on [proposed updates](#) to the cervical cancer screening recommendations included in the Women's Preventive Services Guidelines. Under the Affordable Care Act, non-grandfathered group health plans and health insurance issuers must cover, without cost sharing, preventive services recommended by WPSI and supported by HRSA.

### **Updated Guidelines**

After reviewing public comments, HRSA accepted the WPSI recommendations and updated the Women's Preventive Services Guidelines. The final cervical cancer screening recommendation included minor revisions and is consistent with the proposed update:

- Recommends screening for average-risk women ages 21 to 65.
- Maintains cervical cytology (Pap test) every three years for women ages 21 to 29.
- Recommends primary high-risk human papillomavirus (hrHPV) testing every five years as the preferred screening method for women ages 30 to 65, with co-testing every five years as an alternative and cytology alone every three years when hrHPV testing is not available.
- Recognizes patient-collected hrHPV testing as an appropriate screening option for average-risk women ages 30 to 65.
- Clarifies that additional testing and pathologic evaluation, when clinically indicated, are part of completing the screening process.

**Why this matters:** Health plans subject to the Affordable Care Act's preventive services requirements will be required to cover the updated cervical cancer screening services without cost sharing for plan years, or policy years in the individual market, beginning one year after the date of the update. For most plans, this coverage requirement will take effect in 2027.

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## **State Issues**

### **Pennsylvania**

Regulatory

## **Rural Health Transformation Program Awardee Decisions Announced**

The Centers for Medicare & Medicaid Services (CMS) announced the awardees of the Rural Health Transformation Program (RHTP) in late December.

Pennsylvania will receive \$193.3 million in 2026 to execute Pennsylvania's plan aimed at strengthening the state's rural communities "where people of all ages can access timely, high-quality care close to home, accomplished by leveraging and strengthening local infrastructure through technology, innovation, and collaboration."

All 50 states were awarded funding through the RHTP and Pennsylvania ranked 34 among all the states in total funding.

Additional information regarding the timing and application process for the Rapid Response Grants as well as the Regional Care Collaboratives (RCC) will be forthcoming.

The Department of Human Services (DHS) will oversee the distribution of funds, but specific funding decisions will be made by the RCCs. RCCs will include rural health care providers directly delivering care in that region alongside other key local stakeholders such as local officials, business leaders, patients, educational institutions, foundations, and community-based organizations. According to the application, local hospital leadership will participate in the RCC, even if that hospital is part of a larger system, to maximize local impact.

### **RCCs will work regionally to:**

- Develop leadership, funding infrastructure, and boards comprised of key stakeholders.
- Build on existing board resources.
- Balance local input to facilitate decision-making and promote long-term sustainability.
- Review and prioritize CMS-approved initiatives and invest in initiatives based on regional needs, and available funds.
- Monitor initiatives, collect data, report to project team, and hold public meetings.
- Participate in RCC steering committee for cross region communication/shared resources.

**Why this matters:** President Trump's Working Families Tax Cuts legislation (Public Law 119-21 (Section 71401) authorized \$50 billion to be allocated to approved states over five fiscal years (FY), with \$10 billion of funding available each FY, beginning in FY 2026 and ending in FY 2030.

- 50 percent to be distributed equally amongst all approved states.

- 50 percent will be allocated by CMS based on a variety of factors including rural population, the proportion of rural health facilities in the state, the situation of certain hospitals in the state, and other factors to be specified by CMS in the Notice of Funding Opportunity.

The goal of the funding is to strengthen and modernize health care in rural communities across the country. This federal investment will help states expand access to care in rural communities, strengthen the rural health workforce, modernize rural facilities and technology, and support innovative models that bring high-quality, dependable care closer to home.

**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](http://www.legis.state.pa.us).

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

For copies of congressional bills, access the Thomas website – <http://thomas.loc.gov/>.

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