



Issues for the week ending January 10, 2025

Federal Issues

Regulatory

CMS Releases 2026 Medicare Advantage/Part D Advance Notice & Draft Part D Redesign Program Instructions for Comment

CMS [released](#) two proposed payment updates for comment:

1. [Contract Year \(CY\) 2026 Advance Notice for Medicare Advantage \(MA\) & Part D](#)
2. [Draft CY 2026 Part D Redesign Program Instructions](#)

MA Payment Policies: According to CMS, county benchmarks will increase by 5.93 percent, but CMS estimates the **net payment impact for plans on average will be 2.23 percent** before accounting for potential changes in risk scores. In the [Fact Sheet](#) released in conjunction with the Advance Notice, CMS suggests the expected change in revenue for 2026 is 4.33 percent if an expected MA risk score trend of 2.1 percent is included.

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Guidance in the Draft CY 2026 Program Instructions updates or modifies policies stated in the Final CY 2025 Program Instructions on topics that include: **Enhanced Benefit Plan; Meaningful Difference; Creditable Coverage.**

Topics that are newly addressed in the Draft CY 2026 Program Instructions include: **Selected Drug Subsidy; Successor Regulation Exception to the Formulary Inclusion Requirement for Selected Drugs.**

Go Deeper:

- AHIP's [summary](#) of the two proposals
- CMS's [Advance Notice Fact Sheet](#)
- CMS's [Part D Redesign Program Instructions Fact Sheet](#)

Context: The Advance Notice must be released annually at least 60 days before issuance of final MA rates and Part D payment-related information for the upcoming contract year.

Next Steps: Comments are due to CMS by **February 10, 2025, at 11:59 p.m. ET.**

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- CMS Publishes Updated Marketplace 2025 Open Enrollment Period Report: National Snapshot
- CMS Releases Data on the Experiences & Health of Women in the Medicare Program

OCR Releases Proposed HIPAA Security Rule Modifications

On December 27, the HHS Office for Civil Rights (OCR) released a [proposed rule](#) to modify the HIPAA Security Rule to require health plans, clearinghouses, most providers and their business associates to strengthen cybersecurity protections for individuals' protected health information (PHI). The proposed rule is intended to address more frequent cyberattacks targeting the health care system.

Key Updates:

- Removing the distinction between “required” and “addressable” implementation specifications and making all implementation specifications required (with exceptions).
- Adding specific compliance time periods for many existing requirements.
- Requiring the development and revision of a technology asset inventory and network map that illustrates the movement of ePHI throughout the regulated entity's information system(s) on an ongoing basis, but at least once every 12 months.

Next Steps: Comments are due by March 7, 2025.

Go Deeper: See the HHS [press release](#) and [fact sheet](#).

Biden Administration Issues Final Rule Banning Medical Debt from Credit Scores

On January 7, 2025, the Consumer Financial Protection Bureau (CFPB) issued a [final rule](#) amending Regulation V, which implements the Fair Credit Reporting Act (FCRA), concerning medical information.

Why this matters: The final rule bars lenders from considering medical information in making decisions, eliminates a current carve-out that allows lenders to use certain medical information, and bans consumer reporting agencies from including medical-debt information on credit reports and credit scores. The final rule is estimated to remove \$49 billion in medical bills from credit reports for 15 million Americans.

HHS Releases First Report to Congress on the Prescription Drug Data Collection (RxDC) Data for 2020-2021

Last month the Department of Health and Human Services Office of the Assistant Secretary for Planning and Evaluation (ASPE) [released](#) the first [Report to Congress](#) analyzing the data submitted under the RxDC program. In addition to the Report, ASPE

also released [background report](#) from RAND that included a literature review and analysis of the RxDC data.

Key Findings

Prescription Drug Pricing Trends

- Estimates of recent trends consistently suggest gross drug prices have been growing more rapidly than prices net of rebates paid by manufacturers to PBMs.
- Rebates accounted for 20-22 percent of gross drug spending in employer-sponsored and individual market plans in the RxDC data, a smaller share than the 31 percent in Medicare Part D or the 53 percent in Medicaid.

Improving RxDC

The RAND report details the limitations of the RxDC data collected for calendar years 2020-2021, including the suspension of the aggregation restriction (which has since been reinstated), and the resulting limitations placed on any analyses. The report makes recommendations for improving the data and the collection process, including earlier updates to submission templates and instructions and ongoing engagement with plans and issuers to improve the quality of the data submitted.

FDA Seeks Comment on Draft Guidance for Development of Weight Reduction Drugs

The U.S. Food and Drug Administration (FDA) [announced](#) the release of draft guidance for industry entitled, “[Obesity and Overweight: Developing Drugs and Biological Products for Weight Reduction](#).” The draft guidance provides recommendations to drug manufacturers regarding the development of drugs and biological products regulated within the Center for Drug Evaluation and Research intended for reduction and long-term maintenance of body weight in patients with obesity or overweight.

The draft guidance emphasizes the need for diverse clinical trials, across participant body mass index (BMI), age, sex, gender, race, and ethnicity. The guidance also encourages manufacturers to report concrete data when delay of type II diabetes is reported as an outcome, including duration of delay and evaluation measurements to support the determination. The guidance indicates the need to evaluate neuropsychiatric functions among participants when evaluating new products, and provides additional criteria for which certain outcomes data should be reported, among other issues raised.

Feedback on the draft guidance is due by April 8, 2025. The draft guidance updates and replaces existing guidance from February 2007.

CMS Announces State Recipients for the Transforming Maternal Health Model

The Centers for Medicare & Medicaid Services (CMS) announced 15 states selected to participate in the Transforming Maternal Health (TMaH) Model: California, Washington, DC, Illinois, Kansas, Louisiana, Maine, Minnesota, Mississippi, New Jersey, Oklahoma, South Carolina, West Virginia, and Wisconsin.

Why this matters: TMaH aims to improve health outcomes for mothers and infants enrolled in Medicaid and CHIP by providing access to care and resources to address individual physical health, mental health, and social needs during pregnancy and postpartum. The Medicaid agencies for each selected state will receive targeted technical support in three key areas: 1.) access to care, infrastructure, and workforce capacity, 2.) quality improvement and safety, and 3.) whole-person care delivery. TMaH launched on Jan. 1, 2025 and will run for a period of ten years. [Read More](#)

CMS Releases Updated Complaints Tracking Module (CTM) Standard Operating Procedures

On Jan. 6, CMS issued an HMPS memo providing an updated CTM SOP that will be effective for the 2025 contract year.

Why this matters: This replaces the current SOP that was released in May 2019. Of note, CMS has renamed the subcategory “beneficiary has a cost-sharing/co-insurance issue” to incorporate Medicare Prescription Payment Plan (MPPP) costs. BCBSA previously recommended that CMS not include MPPP-related complaints within CTM or establish new subcategories for MPPP-related complaints that distinguish between complaints related to issues within the plan’s control and those not within the plan’s control.

State Issues

New York

Legislative

2025 Session Opens

Lawmakers returned to Albany last week for the start of the 2025 Legislative Session. “Affordability” was the catchphrase of the Democratic leaders of the Senate and Assembly in their opening remarks to both houses. Assembly Speaker Carl Heastie floated the idea of reducing the amount of money small businesses owe for unemployment insurance and possibly completely eliminating income taxes for low-income families. Senate Majority Leader Andrea Stewart-Cousins said the theme of this year is “Putting Affordability at the Heart of Progress,” identifying working toward universal childcare and continuing to fight for meaningful prescription drug reforms to reduce prices for consumers as priorities.

The Senate Majority Leader and Assembly Speaker also announced committee assignments for the new session. Senator Jamaal Bailey was named the Senate Insurance Committee Chair, succeeding the recently retired Neil Breslin, while Senate Health Committee Chair Gustavo Rivera, Assembly Health Committee Chair Amy Paulin,

and Assembly Insurance Committee Chair David Weprin are returning as chairs of their respective committees.

Pennsylvania

Legislative

Return to Session

202 members of the General Assembly were sworn in on Tuesday, January 7 to start the 2025-2026 Legislative Session. Representative Matt Gergley (D-Allegheny County), still recovering from a medical event in late December, was not in attendance to be sworn in. The House of Representatives is currently at a tie of 101 Democrat members -101 Republican members. In leadership elections, Senator Kim Ward was reelected as President Pro Tempore of the Senate and Representative Joanna McClinton was reelected House Speaker.

Following swearing in, the House began the process of forming committees and assigning them to members. For our three House Oversight Committees, the members are:

House Insurance

Majority Chairman Perry Warren (Bucks)
Representative Aerion Abney (Allegheny)
Representative Tim Brennan (Bucks)
Representative Morgan Cephas (Philadelphia)
Representative Jim Haddock (Luzerne)
Representative Bridget Kosierowski (Lackawanna)
Representative Steven Malagari (Montgomery)
Representative Robert Merski (Erie)
Representative Brian Munroe (Bucks)
Representative Darisha Parker (Philadelphia)
Representative Christina Sappey (Chester)
Representative Mike Schlossberg (Lehigh)
Representative Greg Scott (Montgomery)
Representative Arvind Venkat (Allegheny)
Minority Chairperson Tina Pickett (Bedford)
Representative Aaron Bernstine (Lawrence)
Representative Ann Flood (Northampton)
Representative Jonathan Fritz (Susquehanna)
Representative Keith Greiner (Lancaster)
Representative Thomas Kutz (Cumberland)
Representative Robert Leadbeter (Colombia)
Representative Eric Nelson (Westmoreland)
Representative Jeff Olsommer (Wayne)
Representative Lou Schmitt (Blair)
Representative Dane Watro (Bucks)
Representative David Zimmerman (Lancaster)

House Health Committee

Majority Chairman Dan Frankel (Allegheny)
Representative Tim Brennan (Bucks)
Representative Lisa Borowski (Delaware)
Representative Heather Boyd (Delaware)
Representative Liz Hanbidge (Montgomery)
Representative Kristine Howard (Chester)
Representative Tarik Khan (Philadelphia)
Representative Bridget Kosierowski (Lackawanna)
Representative Krajewski (Philadelphia)
Representative La'Tasha Mayes (Allegheny)
Representative Danielle Friel-Otten (Chester)
Representative Ben Sanchez (Montgomery)
Representative Melissa Shusterman (Chester)
Representative Arvind Venkat (Allegheny)

Minority Chairperson Kathy Rapp (Warren)
Representative Tim Bonner (Mercer)
Representative Stephanie Borowicz (Clinton)
Representative Marla Brown (Lawrence)
Representative Gary Day (Lehigh)
Representative Mike Jones (York)
Representative Charity Grimm-Krupa (Fayette)
Representative Leslie Rossi (Westmoreland)
Representative Joanne Stehr (Schuylkill)
Representative Tim Twardzik (Schuylkill)
Representative Jamie Walsh (Luzerne)
Representative David Zimmerman (Lancaster)

House Human Services:

Majority Chairman Dan Williams (Chester)
Representative Anthony Bellmon (Philadelphia)
Representative Jess Benham (Allegheny)
Representative Melissa Cerrato (Montgomery)
Representative Jose Giral (Philadelphia)
Representative Roni Green (Philadelphia)
Representative Keith Harris (Philadelphia)
Representative Tarik Khan (Philadelphia)
Representative Emily Kinkead (Allegheny)
Representative La'Tasha Mayes (Allegheny)
Representative Danielle Friel Otten (Chester)
Representative Jim Prokopiak (Bucks)
Representative Nikki Rivera (Lancaster)
Representative Arvind Venkat (Allegheny)

Minority Chairman Doyle Heffley (Carbon)
Representative Marc Anderson (York)
Representative Josh Bashline (Clarion)
Representative Jamie Flick (Lycoming)
Representative Ann Flood (Northampton)
Representative Joe Hogan (Bucks)
Representative Shelby Labs (Bucks)
Representative Milou Mackenzie (Lehigh)
Representative Brenda Pugh (Luzerne)
Representative Chad Reichard (Franklin)
Representative John Schlegel (Lebanon)
Representative Eric Weaknecht (Berks)

The Senate is still in the process of forming their committees and will be announced at a later date.

Following the swearing in and formation of the Chambers, members began to introduce legislation and adjourned until January 27.

Industry Trends

Policy / Market Trends

CSRxP: 2025 Drug Price Hikes Outpace Inflation

The Campaign for Sustainable Rx Pricing (CSRxP) [highlighted](#) drugmakers' first prescription drug price hikes of 2025, which are outpacing the rate of inflation.

By the Numbers: Of the first [250](#) prescription drug price increases to start the year, the median increase was 4.5%, significantly exceeding the [2.7% rate of inflation](#).

Why It Matters: Price hikes have little relationship to any improved clinical value for patients. According to a December [analysis](#) from the Institute of Clinical and Economical Review (ICER), the top five drugs with substantial net price increases in 2023 lacked adequate evidence to support any price increase, which resulted in a total of \$815 million added costs to U.S. payers.

Go Deeper: Read more from CSRxP on the first round of 2025 price increases [here](#).

CMS Publishes Updated Marketplace 2025 Open Enrollment Period Report: National Snapshot

On January 8, 2025, CMS published an updated [fact sheet](#) highlighting Marketplace open enrollment data so far for plan year (PY) 2025. They report that 23.6 million consumers have selected a plan representing 11.6 million more enrollees compared to the 2021 Open Enrollment Period. Nearly 3.2 million consumers without current health care

coverage and more than 20.4 million existing consumers have signed up for coverage in 2025. The fact sheet provides further breakdowns by state and platform.

2025 plan selections since November 1:

- Total: All Marketplaces – 23,608,657
- New Consumers – 3,178,138
- Returning Consumers – 20,430,519

Additionally: Enhanced tax credits have lowered health care costs for consumers, making Marketplace coverage more accessible and affordable for Americans. Unless Congress takes action to extend these enhanced tax credits, they will expire at the end of the year. Learn more about the benefits of enhanced tax credits [here](#).

CMS Releases Data on the Experiences & Health of Women in the Medicare Program

In collaboration with the White House Gender Policy Council, CMS released its first-ever [Women's Health Data Book](#) on the experiences of women in the Medicare program and an accompanying [public use file](#).

Why this matters: This data book reports the percentages of people with Medicare living in the community — broken out by sex — who report certain physical and mental conditions, living conditions, and conditions that impact access to care and health outcomes (e.g., affordability, transportation).

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 the Thomas website –
<http://thomas.loc.gov/>.

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