Highmark's Weekly Capitol Hill Report

Issues for the week ending August 16, 2024

Federal Issues

Regulatory

CMS Announces Negotiated Prices for Ten Part D Drugs Selected for First Cycle of Medicare Drug Price Negotiations

CMS released the negotiated prices for the ten Part D drugs selected for negotiation under the Medicare Drug Price Negotiation Program.

Why this matters: In its fact sheet, CMS lists the negotiated price for a 30-day supply of each drug selected for negotiation for calendar year 2026. In addition, the fact sheet outlines details of the negotiation process with the drug companies for the drugs selected for negotiation; the estimated Medicare net savings in 2023 had the negotiated prices been in effect; and projected savings for people with Medicare Part D coverage in 2026. CMS also provides a timeline of key milestones for the first cycle of negotiations and several questions and answers about the program. The agency also released a related infographic.

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The Office of the Assistant Secretary for Planning and Evaluation (ASPE) also released new data "detailing historic pricing trends of the 10 drugs selected for the first cycle of the negotiation program. The report finds that from 2018 to 2023, list prices increased as much as 55 percent." HHS has also issued a related press release.

Reminder: The selected drugs are Eliquis, Jardiance, Xarelto, Januvia, Farxiga, Entresto, Enbrel, Imbruvica, Stelara, and insulin aspart (including formulations Fiasp; Fiasp FlexTouch; Fiasp PenFill; NovoLog; NovoLog FlexPen; NovoLog PenFill).

Next Steps: The second cycle of negotiations will include up to 15 additional drugs covered under Part D for potential negotiation, to be published by CMS by February 1, 2025. This second round of negotiations will occur during 2025, and any negotiated prices will be effective starting January 1, 2027. The pharmaceutical industry continues to seek to overturn the IRA drug price negotiation program through a number of lawsuits filed by manufacturers and allied organizations.

- **AFHC Spotlights Hospital Billing Practices**
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CMS Releases Final Notice on Medicare Transitional Coverage for Emerging Technologies

The Centers for Medicare & Medicaid Services (CMS) issued a final procedural notice for the Transitional Coverage for Emerging Technologies (TCET) pathway, which establishes a new Medicare coverage pathway for breakthrough medical devices. The TCET pathway is voluntary for manufacturers and uses the current national coverage determination (NCD) and coverage with evidence development (CED) processes to expedite Medicare coverage of certain breakthrough devices.

Why this matters: The notice finalizes many of the pathway details from the proposed rule, on which AHIP submitted supportive comments. Key components of the pathway to facilitate evidence development include an evidence preview and an evidence development plan (EDP). Based on comments received, CMS made several changes to

the pathway, including a more frequent quarterly timeframe for reviewing TCET nominations and additional details for EDPs to ensure adequate progress and timely completion. CMS also indicated its intent to soon release the proposed factors it will use to prioritize TCET nominations.

A fact sheet on the final procedural notice with a description of the TCET pathway can be found here.

CMS Issues New Medicaid Guidance on Family Planning Services

The CMS Center for Medicaid and CHIP Services (CMCS) issued a CMCS Informational Bulletin (CIB) to outlining state obligations related to Medicaid coverage of family planning services and supplies. It also describes state options for helping to ensure timely access to these services.

Why this matters: Best practices highlighted in the CIB for meeting coverage requirements in fee-for-service and managed care include:

- Allowing for the prescription or provision of 6- to 12-months of contraception supplies.
- Providing timely, patient-centered, comprehensive coverage of contraceptive services.
- Improving access to over-the-counter (OTC) contraception by issuing statewide protocols or allowing standing prescription orders for an OTC drug, so that pharmacists can issue prescriptions for an OTC drug to Medicaid enrollees directly at the point of sale.
- Paying directly for immediate postpartum long-acting removable contraceptives (LARC) insertion and unbundle payment for this service from labor and delivery services.
- Removing administrative and logistical barriers for supply management of LARC devices.
- Paying for replacement or reinsertion of expelled IUDs, including those placed immediately postpartum, as well as removal upon request.

The CIB also refences specific provisions for managed care contracts:

- Reinforcing the requirement to cover the full range of covered family planning services and supplies without cost sharing and with freedom of choice of providers.
- Requiring plan networks to include essential community providers for family planning services.

The guidance also covers information on postpartum coverage best practices, OTC drug best practices, confidentiality requirements, and quality of care recommendations, including highlighting the Adult Core Set/Child Core Set quality measures for contraceptive care.

Additionally, CMCS reminds states that the Medicaid federal matching rate for state expenditures attributable to the offering, arranging, and furnishing of family planning services and supplies is 90%.

HHS and DOL Send Industry Trade Groups Letter on Improving Customer Experiences

The Department of Health and Human Services (HHS) Secretary Becerra and Department of Labor (DOL) Acting Secretary Su sent a letter to AHIP and other industry trade organizations requesting they take action to save people time and money when interacting with their health insurance providers. The letter addressed issues including submitting claims online, call center wait times, provider directories, and using jargon-free communications.

Go Deeper: Read the letter from HHS and DOL here.

CMS Begins Generating Notices to Consumers with Dual Enrollment in Medicaid/CHIP and QHP Coverage

CMS began generating ad hoc notices to consumers with dual enrollment in Medicaid or the Children's Health Insurance Program (CHIP) and qualified health plan (QHP) coverage. Utilizing the Medicaid/CHIP periodic data matching (PDM) process, the Marketplace can periodically check if enrollees are enrolled in other coverage that qualifies as minimum essential coverage (MEC). CMS has additionally released a document with answers to frequently asked questions.

Why this matters: For the 2024 coverage year, Medicaid/CHIP PDM will send just one warning notice to consumers notifying them of their dual coverage and requesting that they take corrective action. The Exchange will not terminate advance payments of the premium tax credit (APTC) and cost-sharing reduction (CSR) eligibility for consumers. Multiple/final notices and eligibility terminations will resume in 2025.

TEFCA Update: New SOPs and Updated Resources Released

The Assistant Secretary for Technology Policy/Office of the National Coordinator for Health Information Technology (ASTP/ONC) and the Sequoia Project released a bundle of new Standard Operating Procedures (SOPs) for the Trusted Exchange Framework and Common Agreement (TEFCA). The bundle consists of five parts:

1. Public Health Exchange Purpose (XP) Implementation SOP
2. Health Care Operations XP Implementation SOP
3. Individual Access Services XP Implementation SOP (updated)
4. Exchange Purposes (XP) SOP (updated)
5. QHIN Security for the Protection of TEFCA Information (updated)

Why this matters: These new SOPs are immediately available for adoption and implementation. Of note, the Health Care Operations SOP will allow health plans to use

TEFCA for data collection to support calculation of NCQA's Healthcare Effectiveness Data and Information Set (HEDIS) measures as well as quality measurement broadly. The SOP states that TEFCA participants should respond to queries for data for these purposes. After 18 months, participants will be required to respond with this information.

CMS Posts Preliminary Proposed Rate Changes for Plan Year 2025
On August 1, 2024, CMS posted preliminary proposed rate changes for plan year 2025 single risk pool coverage. This includes both qualified health plans (QHPs) and non-QHPs in the individual, small group, and combined markets across all states and territories. The posting of rate review results meets an ACA mandate that the reviews be publicly accessible. Consumers can search for rate review information for QHPs and non-QHPs filtered by state, market, and year.

Industry Trends

Policy / Market Trends

Federal Appeals Court Vacates Certain *No Surprises Act* Regulations in TMA II Decision

The U.S. Court of Appeals for the Fifth Circuit issued a decision vacating certain regulations related to the independent dispute resolution (IDR) process under the *No Surprises Act (the Act)*. The lawsuits (Texas Medical Association v. HHS and LifeNet v. HHS) ("TMA II") challenge certain provisions of an August 2022 final rule detailing how arbitrators are to approach various factors laid out under the Act when considering payment disputes. Last week's decision affirms an earlier lower court ruling previously striking down the same regulations.

In its decision, the court of appeals agreed with the lower court's finding that certain provisions of the final rule improperly "place a thumb on the scale for the QPA." This includes a provision under the final rule that instructs arbitrators to consider the QPA before examining the other factors the Act specifies. It also includes vacating provisions that instruct arbitrators to only consider information they deem credible, that relates to the parties' disputed offer, does not duplicate information already contained in the QPA, and to issue written reports explaining why a ruling may depart from the QPA. In each case, the court of appeals held that such provisions either exceed the agencies' authority or go beyond the clear language of the Act.

AFHC Spotlights Hospital Billing Practices
The Alliance to Fight for Health Care (AFHC) issued a press release highlighting key moments from a recent Senate HELP Committee hearing on hospital billing practice and site-neutral payment reform proposals.

What They're Saying:

- "*One of the many factors driving health care costs and medical debt is unfair fees for routine care, even for Americans who have health insurance*." **– Maggie Hassan (D-NH)**
- "*We have a number of policies on the books that encourage lots of consolidation on the provider side. And what that allows people to do is both take advantage of rules in Medicare to charge higher prices and in the commercial market, charge higher prices to anybody who walks through the door. So the combination of those two things clearly contributes to high health costs, and it surely contributes to medical debt.*" **– Benedic Ippolito, Senior Fellow, American Enterprise Institute**

Policy Spotlight: AFHC spotlighted site-neutral payment reforms and transparency policies that aim to eliminate payment discrepancies based on the site-of-care. They urged the Committee to close the loophole that exists in Medicare payment law that unintentionally incentives such hospital billing practices.

Go Deeper: See recent AFHC materials on the benefits of site-neutral reform in lowering costs for cancer patients.

CBO Pushes Back on Criticism of Site-Neutral

The "CBO is throwing cold water on a common criticism" of proposed site-neutral reforms to protect patients from excessive, hidden, and unjustified hospital fees, *Axios* reports.

The bottom line: Expanding site-neutral payments in Medicare "would not increase the prices paid by commercial insurers," the non-partisan budget watchdog explained in a response to lawmakers' questions.

Why this matters: Common-sense site-neutral reforms would protect Americans from being charged more by providers for the same care based on where the services take place.

Go Deeper: Read more from *Axios*.

AHIP Responds to KFF Analysis of Prior Authorization in Medicare Advantage

A new Kaiser Family Foundation (KFF) analysis of Medicare Advantage (MA) data found that the share of overall claims fully or partially denied via prior authorization rose to 7.4% in 2022 after being between 5.6% and 5.8% in each of the 3 previous years.

The bigger picture: The data comes as lawmakers increasingly scrutinize MA insurers for claim denials, including for those involving artificial intelligence. More than half of Medicare beneficiaries are now enrolled in a private alternative.

In response to the analysis, AHIP, said that prior authorization is a "vital process to ensure patients receive safe, evidence-based care, and to reduce low-value and inappropriate services so that coverage is as affordable as possible."

CDC Reports Trends and Disparities in Childhood Vaccinations

The Centers for Disease Control and Prevention (CDC) released the findings of a report that examined vaccination coverage among children eligible for the CDC's Vaccines for Children (VFC) program.

Background: The VFC program, established in 1994, provides vaccines to children whose parents or guardians may not be able to afford them. According to the CDC, the VFC Program is a primary driver of health equity in public health and supports improved immunization coverage levels among eligible children by:

- Protecting children's health
- Providing free vaccines
- Minimizing barriers to vaccination
- Improving public-private collaboration

Report findings: Among the VFC-eligible children, coverage with measles, mumps, and rubella (MMR) vaccine was high and stable during 2012 through 2022, but the report details there is room for improvement to increase coverage with other routinely recommended vaccines. For example, while more than one half of children (52.6%) born in 2020 were eligible for the VFC program, vaccination coverage was 4–14 percentage points lower among children who were eligible versus non-eligible for the VFC program. Immunizations for VFC-eligible children were 3.8% lower for the MMR vaccine, 11.5% lower for rotavirus vaccine, and nearly 14% lower for the combined 7-vaccine series of routine vaccinations.

Go deeper: Read AHIP's one-pager on how health insurance providers are stepping up to ensure children are up to date on routine care and vaccines.

WHO Declares Mpox a Global Health Emergency

The World Health Organization declared mpox a global public health emergency following a deadly outbreak of a new strain in Africa.

Background: The WHO first declared mpox – formerly known as monkeypox – a global health emergency in July 2022 but revoked its emergency declaration in May 2023 following a decline in cases.

U.S. Preparedness: In a press release, the Department of Health and Human Services (HHS) stated that "the risk to the general public in the United States…is very low, and there are no known cases in the United States at this time." The Centers for Disease Control and Prevention (CDC) also issued an alert to American health care providers with additional information on the outbreak.

AHIP Supporting Public Health: Earlier this year, AHIP co-founded the Common Health Coalition to better equip health care organizations to collaborate with public health

systems in preparation for the next public health emergency. As the new mpox outbreak develops, read more about the Coalition's commitments to advance preparedness in the U.S.

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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