Highmark's Weekly Capitol Hill Report

Issues for the week ending March 17, 2023

Federal Issues

Regulatory

HHS Releases Initial Guidance for Medicare Drug Price Negotiation Program

CMS released their initial guidance and supplementary fact sheet detailing the requirements and procedures for implementing the new Medicare Drug Price Negotiation Program as established by the Inflation Reduction Act. The first round of negotiations will occur during 2023 and 2024, resulting in prices effective in 2026.

Why this matters: The program, authorized under the Inflation Reduction Act, allows Medicare to negotiate drug prices for the first time in history.

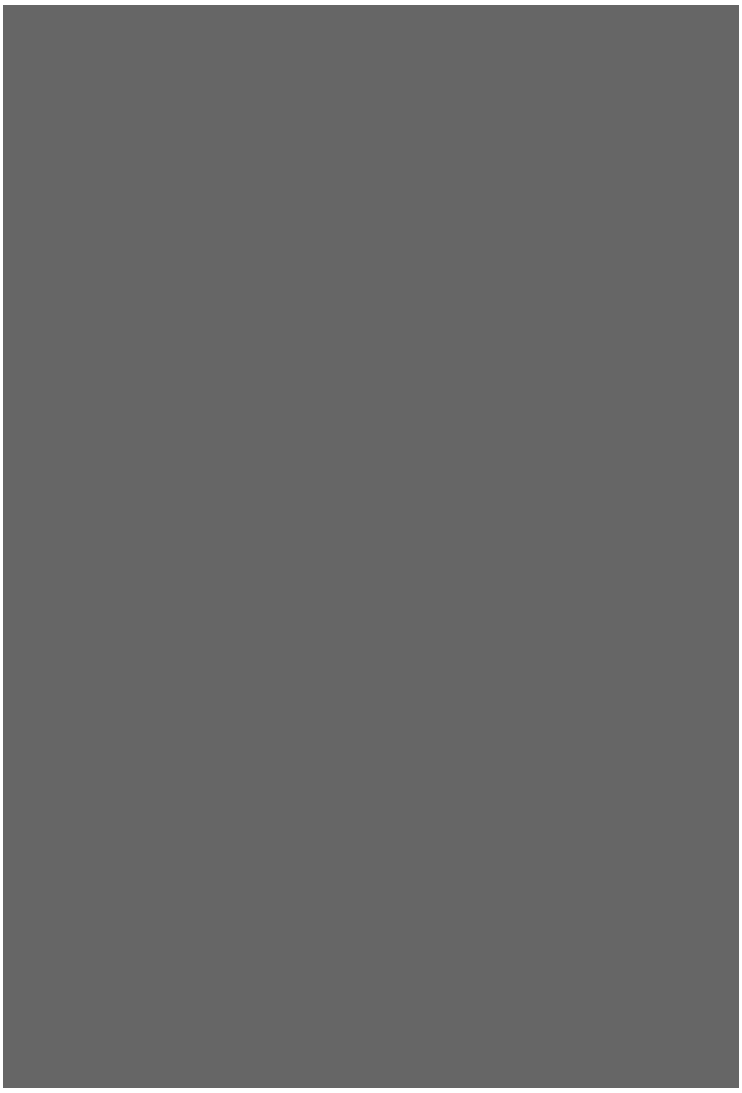
- The guidance outlines how Medicare intends to use its new authority to effectively negotiate with drug companies for lower prices on selected high-cost drugs.
- The negotiation process will focus on key questions, including but not limited to the selected drug's clinical benefit, the extent to which it fulfills an unmet medical need, and its impact on people who rely on Medicare**.**

In this Issue:

CMS is seeking public comment – due by April 14, 2023 – on key elements in the initial guidance, including:

- Terms and conditions contained in the manufacturer agreement (i.e. this is the document that manufacturers will sign to start the negotiation), including the manufacturer's and CMS' responsibilities.
- Approach for collecting the manufacturer-reported data elements and evidence about alternative treatments.
- Process for the offer and counteroffer exchange between CMS and manufacturers.
- An explanation for the maximum fair price.
- Method for applying the maximum fair price across different dosage forms and strengths of a selected drug.
- Dispute resolution process for specific issues that are not exempt from administrative and judicial review under section 1198.
- Processes for compliance monitoring and imposition of civil monetary penalties for violations.

The guidance can be found here and the fact sheet here.



Updated Surprise Billing IDR Guidance and Resumption of Payment Determinations

The Departments of Health & Human Services, Labor, and the Treasury ("Departments") instructed Certified IDR Entities to resume making payment determinations as part of the Federal IDR process established by the *No Surprises Act* for all items and services, including those furnished on or after October 25, 2022. The standards governing a certified IDR entity's consideration of information when making payment determinations in these disputes are provided in the Requirements Related to Surprise Billing, August 2022 final rules, as revised by the opinion and order of the U.S. District Court for the Eastern District of Texas in *TMA II*. As of March 17, 2023, the Departments have completed the necessary updates to the Federal IDR portal and Federal IDR process guidance documents to reflect these revised payment determination standards.

The Departments released new guidance for certified IDR entities' payment determinations for items and services furnished on or after October 25, 2022. The Departments also released new guidance for dispute parties, including health insurance plans and issuers for disputes involving items and services furnished on or after October 25, 2022.

In addition, disputing parties will begin receiving a majority of their payment determination notices from the IDR portal, specifically from a government email address.

Timing of QHP Data Submission and Certification for 2024 Plan Year

CMS posted the Bulletin: Timing of QHP Data Submission and Certification for the 2024 Plan Year for Issuers in the Federally-facilitated Exchanges. The Centers for Medicare & Medicaid Services (CMS) is releasing this bulletin establishing the submission deadlines under 45 CFR 155 subpart K for health insurance issuers applying to offer qualified health plans (QHPs) on the Federally-facilitated Exchanges (FFEs). You can find the updates here.

CMS Issues Reports on Inflation Reduction Act Impact

- On Wednesday, the U.S. Department of Health and Human Services (HHS) issued a new report showing that in 2021, 3.4 million people with Medicare paid $234 million in out-of-pocket costs for recommended vaccines covered under Medicare Part D. As of January 1, 2023, these vaccines – including for shingles, which can cost some seniors almost $200 dollars, and Tdap, are now free. The Inflation Reduction Act eliminated out-of-pocket costs for recommended vaccines covered under Medicare Part D. A recent report from ASPE showed that approximately 1.5 million seniors and other Medicare beneficiaries are likely to save $500 per year on insulin because of the new law. The report examines vaccine use, total vaccine spending, and out-of-pocket spending for vaccines that are covered under Medicare Part D: shingles; tetanus/diphtheria (Td); tetanus, diphtheria, and pertussis – also known as whopping cough (Tdap); hepatitis A; and hepatitis B. Medicare Part B already covers flu, pneumococcal, COVID-19, and certain other vaccines without cost-sharing for people with Medicare.

- On Wednesday, the Department of Health and Human Services, through the Centers for Medicare & Medicaid Services (CMS), announced 27 prescription drugs for which Part B beneficiary coinsurances may be lower from April 1 – June 30, 2023. Some people with Medicare who take these drugs may save between $2 and $390 per average dose starting April 1, depending on their individual coverage. The Medicare Prescription Drug Inflation Rebate Program was a provision of the Inflation Reduction Act, providing another tool for Medicare to address rising drug costs. By reducing coinsurance for some people with Part B coverage and discouraging drug companies from increasing prices faster than inflation, this policy may lower out-of-pocket costs for some people with Medicare and reduce Medicare program spending for costly drugs. Lower Part B coinsurance will go into effect on April 1, 2023. This coinsurance adjustment applies to certain drugs and biologicals covered under Medicare Part B. The Part B drugs impacted by this coinsurance adjustment may change quarterly.

State Issues

New York

Legislative

Legislative One-House Budgets Revealed

The Assembly and Senate last week released their one-house budget proposals. Both houses called for spending above the $227 billion proposed by the Governor. The Assembly's proposal would increase total spending by $5.9 billion, which includes $3 billion in added health care spending, while the Senate plan would increase overall spending by $10.8 billion, with $4.9 billion of that earmarked for added health and Medicaid spending. **The following is an overview of how each house approached the key health care items that impact the health insurance industry:**

Executive Proposal	Assembly	Senate
Pay & Pursue	Omitted	Omitted
Pharmacy Carve Out	Repealed	Repeals and Modified
Private Right of Action on Behavioral Health	Omitted	Included
Quality Pools Eliminated	Restored in Part	Restored in Part
Site of Service Review	Omitted	Included
Health Guaranty Fund	Modified/Prohibit plans from including the cost in premiums	Included

Negotiations are expected to kick into high gear in the coming weeks as the state faces an April 1 deadline to adopt an "on time" budget.

Industry Trends

Policy / Market Trends

AHIP Files Amicus Brief Supporting Government's Defense of *No Surprises Act* QPA Regulations

AHIP filed an amicus brief supporting the federal government's continuing effort to implement the *No Surprises Act*. It marks AHIP's 5th amicus brief in support those efforts and reflects AHIP's ongoing commitment to ensure patients are protected from surprise medical bills and to help stem excessive and inflationary healthcare costs.

Why this matters: The underlying lawsuits (*Texas Medical Association v. HHS* and *LifeNet v. HHS*) ("*TMA III*") challenge the regulation that sets forth the methodology used to calculate the Qualified Payment Amount (QPA), which is relied on to help resolve out-of-network payment disputes subject to independent dispute resolution (IDR) under the Act. The cases are currently pending in the U.S. District Court for the Eastern District of Texas and assigned to the same judge that ruled in favor of the same plaintiffs in several earlier lawsuits. Those earlier lawsuits challenged aspects of the agencies' interim final rule anchoring the IDR process around the QPA and a later final rule governing various IDR-related processes.

In addition to highlighting how the current IDR process is achieving widespread success in preventing patients from receiving surprise bills, AHIP's brief also explains why the agencies' QPA methodology best

implements Congress's goal of adequately compensating providers based on a QPA that reflects fair and reasonable market-based rates. This includes, among other things, explaining why the agencies properly exclude retrospective, provider-specific value-based payments as well as supracompetitive, single-instance air ambulance rates from the QPA. AHIP also emphasizes the significant disruption that would occur if the court were to grant the plaintiffs' request to vacate the current regulations. Other groups filing amicus briefs in support of the government include the American Benefits Council along with a group of employers and various patient advocacy groups led by the Leukemia & Lymphoma Society.

These lawsuits by TMA and LifeNet allege the agencies exceeded their authority and violated the Administrative Procedure Act by arbitrarily and capriciously excluding value-based payment adjustments from the QPA, allowing plan administrators to use aggregated rates across plan sponsors, not allowing use of one-off, single-case air ambulance rates, defining how geographic regions are used for air ambulance-related IDR claims, as well as other requirements related to IDR transparency and claim timing.

The summary judgment briefing is scheduled to conclude on April 14 with a hearing to follow on April 19. Read the full Amicus Brief here.

New Coalition Launches One-stop Shop for Medicaid Redeterminations

The national Connecting to Coverage Coalition (CCC) launched as a single source of trusted, evidence-based information about the Medicaid redetermination process.

Why it matters: More than 15 million Medicaid beneficiaries—including 6.7 million children—are projected to lose coverage as states begin the months-long redetermination process, which was paused during the COVID-19 public health emergency in an effort to keep people covered.

The details: Led by AHIP, the coalition consists of a diverse group of leading organizations, including BCBSA, which will support a smooth transition back to normal Medicaid eligibility by connecting consumers to resources and helping them gain coverage through other available health insurance.

Available resources include:

- **FAQs** for Medicaid enrollees
- **Links** to CMS and federal agency information on the redetermination process
- **Best practices**, key messages and toolkits for engaging Medicaid enrollees
- **Studies and surveys** on individuals' understanding of the redetermination process

Yes, and: AHIP also released a state-by-state analysis of coverage available to those transitioning from Medicaid, which was conducted by NORC at the University of Chicago.

What's next: States must resume Medicaid redeterminations on April 1.

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/.**