Issues for the week ending September 1, 2023

Federal Issues

Regulatory

CMS Releases List of 10 Drugs for Medicare Price Negotiation

The Centers for Medicare & Medicaid Services (CMS) announced the first group of 10 drugs subject to Medicare price negotiation under a new program established by the Inflation Reduction Act.

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).

- **Of note:** Insulin is already subject to a $35 monthly co-pay cap for Medicare prescription drug plan enrollees under a different provision of the Inflation Reduction Act.

Why this matters: The negotiations for these drugs will take place in 2023 and 2024 and any negotiated prices will become effective in 2026.

- CMS estimates the selected drugs accounted for approximately 20% of total Medicare Part D gross covered prescription drug costs, or $50.5

In this Issue:

billion in gross costs, between June 1, 2022, and May 31, 2023.

- Some of the highest-cost Medicare drugs were not eligible for this round of negotiations, either because they still have market exclusivity, they're the only option for a rare disease or another factor.

Next Steps: Absent a court ruling that postpones implementation, companies whose drugs are selected for negotiation under the program must choose whether to sign agreements to participate in negotiations by October 1, 2023. The negotiation period will end on August 1, 2024. If the drugmaker does not comply with the negotiation process, it could face an excise tax that starts at 65% of a product's domestic sales - or withdraw all their products from Medicare and Medicaid.

CMS stated they will publish the maximum fair prices negotiated for the selected drugs by September 1, 2024, which will go into effect starting January 1, 2026.

The Biden Administration also issued several fact sheets on the selection of the 10 drugs:

- CMS Fact Sheet
- Assistant Secretary for Planning and Evaluation (ASPE) Fact Sheet
- White House Fact Sheet

The fact sheets provide information on what conditions each drug is commonly used to treat, the number of Medicare enrollees who have taken the drug in the outlined time period, and gross and out-of-pocket spending for each drug.

CMS also announced opportunities for public engagement during the negotiation process for these 10 drugs. CMS stated that the agency will host patient-centered listening sessions for each selected drug this fall. They stated that "the public is also invited to submit data on selected drugs, therapeutic alternatives to the selected drugs, data related to unmet medical need, and data on impacts on specific populations by October 2, 2023."

CMS Issues Letter on Compliance with Medicaid Redetermination Rules

The Centers for Medicare & Medicaid Services (CMS) sent a letter to all state Medicaid directors requiring them to determine whether they have an eligibility systems issue that could cause otherwise eligible individuals, especially children, to be disenrolled from Medicaid or CHIP.

Why this matters: The focus of the letter is on whether states are conducting *ex parte* renewals at a family-level, which CMS states is improper, or at an individual-level, as individuals in a family may have different eligibility requirements to qualify for Medicaid and CHIP. If these individuals fail to return their renewal forms in a timely manner, they may lose Medicaid coverage for procedural reasons. Children, who typically qualify for Medicaid at a higher income level than adults, are particularly vulnerable to disenrollment due to this system error. Due to differing Medicaid and CHIP eligibility criteria for each individual in a household, states conducting automatic renewals in this manner may be requesting renewal forms from all members of a household, even if the state has sufficient information to renew eligibility for some on an ex parte basis. CMS says states must take steps to avoid CMS action: pause procedural disenrollments for those individuals impacted (in multi-member households); reinstate coverage for all affected individuals; implement CMS-approved mitigation strategies; and fix state systems.

To address this issue, CMS has requested that all states review their renewal processes and report any areas of non-compliance to CMS no later than Sept. 13, 2023; or, to contact CMS with details of areas of non-compliance as well as the state's plan and timeline for reinstatement and implementation of mitigation strategies. CMS reminds states that failure to identify and address issues of non-compliance will lead to CMS taking compliance action, including requesting a corrective action plan, civil monetary penalties, and additional penalties including but not limited to disqualification for the temporary enhanced FMAP.

Read the letter here and CMS press release here.

CMS Releases Medicaid & CHIP Quality Measures Final Rule

The Centers for Medicare & Medicaid Services (CMS) published the Mandatory Medicaid and Children's Health Insurance Program (CHIP) Core Set Reporting final rule.

Why this matters: The new rule finalizes requirements - initially outlined in an August 2022 proposed rule - for mandatory annual state reporting of three different quality measure sets starting in federal fiscal year 2024:

- Core Set of Children's Health Care Quality Measures for Medicaid and CHIP
- Behavioral health measures on the Core Set of Adult Health Care Quality Measures for Medicaid; and
- Core Sets of Health Home Quality Measures for Medicaid

CMS notes that states will be required to report stratified data for measures over time, using potential stratification factors such as geography and race/ethnicity.

- While the proposed rule noted CMS would issue subregulatory guidance identifying the populations for which states would be required to report, the final rule clarifies states will be required to report on these Child and Adult Core Set measures for all Medicaid beneficiaries across both fee-for-service and managed care delivery systems. States must begin reporting all new mandatory measures in Fiscal Year 2024.

The rule can be found here on the *Federal Register* website.

State Issues

New York

Regulatory

DFS Announces Final 2024 Individual and Small Group Rates

The Department of Financial Services (DFS) last week announced final rate decisions for the 2024 individual and small group markets. In the individual market, DFS reduced the rates from the 22.1% average increase requested to 12.4% (a 44% cut) and cut small group rates from an average requested increase of 15.3% to 7.4% (a 52% reduction).

In a statement responding to the announcement, the Health Plan Association pointed out the original rates submitted by plans reflected the underlying factors driving up costs, adding that to provide relief for consumers and employers "greater focus is needed to rein in the escalating costs hospitals, providers and drug companies are charging."

1332 Waiver-Impact on Individual Market Update

The New York State of Health (NYSOH) and DFS last week held several calls with HPA and stakeholders to outline a proposed process for mitigating the premium impact that expanding Essential Plan (EP) eligibility from 200% of the federal poverty level to 250% could have on the individual market.

The approach is designed to compensate insurers for the lost revenue associated with the migration of the 200%-250% FLP population to the EP. NYSOH and DFS have presented the proposal to the Centers for Medicare and Medicaid Services, which has indicated its support. In a comment letter sent to CMS last week, HPA also expressed support for the mitigation process as well as reiterating support for the state's proposed 1332 waiver seeking the EP expansion.

State Issues

Pennsylvania

Legislative

Senate Advances State Budget Code Bills

The state Senate last week passed enabling legislation to finalize parts of the state budget, including reauthorization of the Quality Care Assessment (QCA) and other hospital priorities.

The Senate vote marks a new chapter in a budget impasse between the Democratic-controlled House and Republican-controlled Senate. Lawmakers passed and Governor Josh Shapiro signed a budget bill earlier this summer but key legislation that authorizes spending appropriated in the budget remains unfinished.

Recent action: Senators voted 29–18 to send **House Bill 1300** to the House for consideration. The bill, often referred to as the fiscal code, authorizes programs that are funded by the state budget.

What's included: The legislation enables several priorities for hospitals including:

- Reauthorizing for five years and enhancing the QCA.
- Creating a $50 million grant program through the Department of Community and Economic Development to provide emergency relief for hospitals and health systems that experience unexpected financial distress.
- Increasing funding to county mental health services by $20 million to help increase access to home- and community-based behavioral health care and reduce strain on hospital emergency departments.
- Increasing the ambulance transportation reimbursement rate for providers to the greater of Medicare or Medicaid rates.
- Providing for the continued use of the Tobacco Settlement Fund for health-related initiatives.

QCA enhancements: The legislation includes consensus legislative language—agreed to by the Department of Human Services—that would reauthorize the QCA for five years and increase the benefit of the program to hospitals and the state. That framework:

- Includes an increase in the assessment of approximately $250 million for fiscal year (FY) 2023–2024 and $500 million for the remainder of the reauthorization period.
- Increases state directed payments by $1.179 billion, through the use of the Average Commercial Rate for purposes of rate-setting, which creates additional payment room to increase managed care organization (MCO)-directed payments—generating an aggregate net gain to the hospital community of approximately $679 million annually. The expansion of funding through the QCA will improve hospital payments through Medicaid starting in calendar year (CY) 2024.
- Maintains the existing state and hospital benefit proportion at 30/70, by increasing the contribution to the state by $68 million for FY 2023–2024 and $152 million for the remainder of the reauthorization period—in total, contributing $368 million for FY 2023–2023 and $452 million annually thereafter.
- Maintains disproportionate share hospital payments.
- Maintains the provision that any positive balance remaining in the restricted receipt account over $10 million that is not used for hospital payments shall be used to reduce the assessment rate in the next state fiscal year.

Next steps: The legislation passed the Senate with a mostly party-line vote, with Democratic senators raising concerns about provisions for education funding and other items not related to the hospital priorities. When the House might take up the legislation is uncertain. The House is currently not scheduled to reconvene until September 26 and the chamber is deadlocked at a 101–101 partisan split until the September 19 special election in Allegheny County.

Industry Trends

Policy / Market Trends

Humana Files Complaint Against Medicare Advantage RADV Final Rule

Humana filed a complaint in the United States District Court for the Northern District of Texas, challenging CMS's 2023 final rule for calculating payment recoveries in Medicare Advantage Audits ("Final RADV Rule"). The complaint specifically focuses on the decision, in the final rule, to not use a Fee-for-Service Adjuster or take other steps to meet the statutory requirement of "actuarial equivalence" between Medicare Advantage and Fee-for-Service Medicare.

Why this matters: The complaint seeks declaratory and injunctive relief and explains how the Final RADV Rule violates the Administrative Procedure Act ("APA") in three ways:

- Violating the APA's requirement of reasoned agency decision-making by failing to include any empirical or factual justifications for its decision not to apply a Fee-for-Service Adjuster and relying only on incorrect legal arguments.
- Changing the audit methodology applicable to payment years prior to 2024, in violation of the statutory prohibition against retroactive application of Medicare rules.
- Violating the APA's requirement of notice and comment by relying on a court decision (UnitedHealthcare v. Becerra) without providing a meaningful opportunity for comment on the agency's reliance on this decision.

OIG Releases Strategy for Oversight of Managed Care Organizations

The Office of the Inspector General (OIG) released comprehensive strategy to align its oversight of managed care organizations with current oversight of fee-for-service programs. OIG notes that the strategy is intended to promote access to care, provide comprehensive financial oversight, promote data accuracy and encourage data-driven decisions.

Why this matters: The strategy identifies four phases of a managed care "life cycle" and describes potential oversight activities OIG may pursue during each phase. During the Plan Establishment and Contracting Phase, OIG may review State or CMS contracts, plan benefit design, establishment of plan service area, and accuracy of plan bids. In the Enrollment Phase, OIG may provide oversight of marketing, agent or broker activities, eligibility determinations and accuracy of enrollment data. In the Payment Phase, oversight focus areas may include risk adjustment, payment accuracy, medical loss ratio and the use of value-based care or alternative payment models.

Finally, in the Services to People Phase, oversight focus areas may include network adequacy, ineligible or untrustworthy providers, coverage determinations, and whether enrollees are receiving care that meets clinical guidelines. OIG notes many of these oversight activities are underway, and offers examples of current and completed work in both Medicare and Medicaid managed care oversight throughout the strategy. Read More

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/.**