Highmark's Weekly Capitol Hill Report

Issues for the week ending February 16, 2024

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Federal Issues

Regulatory

FTC & HHS Launch Inquiry into Role of Supply Chain Entities on Drug Shortages

The Federal Trade Commission (FTC) and Department of Health and Human Services (HHS) have issued a joint request for information on the role of group purchasing organizations (GPOs) and pharmaceutical wholesalers on prescription drug shortages.

Why this matters: The agencies assert a lack of competition in the GPO and wholesaler markets and solicit information on how this lack of competition impacts contracting and compensation practices.

Other Information Sought:

- Specific details on the nature of contracting practices, including re-bidding provisions, most-favored nation pricing and similar clauses, rebate, chargeback, and manufacturer administrative fees.

In this Issue:

- The role of exclusive or near-exclusive supply contracts with generic manufacturers, including failure-to-supply clauses, as well as market-share and volume-based contracts with hospitals, pharmacies, and healthcare providers.
- Feedback on how contracting practices may contribute to a reduction in the number of suppliers, less reliable supply chains, and drug shortages.

Comments are due by April 15, 2024.

- **4 Studies Reveal How Medicare Advantage Excels**

Departments Publish FAQs on Implementation of Transparency in Coverage Requirements

Earlier this month, the Departments of Health and Human Services, Treasury and Labor (Departments) issued a set of frequently asked questions on implementation of the Transparency in Coverage (TiC) requirements (FAQs Part 65).

Why this matters: The FAQs reiterated that when using claims data, plans may not be able to provide accurate cost estimates for items or services with limited past data. Very low utilization can result in less predictive and accurate cost estimates.

Consistent with previous guidance, the Departments state they are likely to exercise their discretion, on a case-by-case basis, not to bring enforcement actions against plans that fail to provide cost-sharing information for items and services when based on insufficient past claims data (e.g., in cases where payment is determined retrospectively, as with rates based on a percentage of billed charges) and for which there have been fewer than 20 different claims in total over the past three years.

The Departments clarify that for these items and services, the plan should indicate on the self-service tool that the item or service is covered, but that a specific cost estimate is not available pursuant to the TiC Final Rules because of insufficient data. Additionally, the tool should encourage the member to contact their plan for more information.

CMS Issues Draft Part Two Guidance on the Medicare Prescription Payment Plan

CMS released draft part two guidance related to the Medicare Prescription Payment Plan that was established by section 11202 of the Inflation Reduction Act.

According to the fact sheet, the draft part two guidance is primarily focused "on Part D enrollee education, outreach, and communications related to the Medicare Prescription Payment Plan," building upon what was proposed in the draft part one guidance. CMS states that model documents will be available for public comment through an Information Collection Request.

The guidance also proposes "additional operational requirements for Part D plan sponsors, including guidance for non-retail pharmacies, Part D bidding for Contract Year 2025, and Medical Loss Ratio (MLR) instructions."

Comments are due to CMS by March 16.

Departments Publish No Surprises Act (NSA) Public Use File

The Departments of Health and Human Services, Labor, and the Treasury (the Departments) published a Public Use File on Independent Dispute Resolution (IDR) process operations for the first two quarters of last year.

Why this matters: These files include all data elements required for publication by the NSA and are accompanied by supplemental tables and background. The Departments will release additional IDR PUFs when the data is available.

State Issues

New York

Legislative

Governor Releases 30-day Budget Amendments

Last week, Governor Hochul released the 30-day budget amendments to her 2025 Executive Budget proposal.

Why this matters: Although largely technical, the amendments include restrictions on the state's Consumer Directed Personal Assistance Program (CDPAP), a home care program that allows older New Yorkers and people with disabilities to choose their own caregivers. It has grown significantly and has been subject to criticism. The proposed amendments, expected to save the state $100 million, would give the Department of Health more oversight authority over the program.

Measures discussed include limiting how many hours personal assistants can work, restricting the number of fiscal intermediaries that the state works with and limiting the program to individuals who are capable of hiring and managing CDPA workers on their own – essentially barring people enrolled in CDPAP from using a third party, such as a spouse or parent, to manage their care.

The 30-day amendments also provide the Department of Health with additional contracting flexibilities in relation to the 1115 Medicaid waiver, in order to carry out provisions of the waiver.

Next Steps: In the next major step in the budget process, the Senate and Assembly will issue their "one-house" budget priorities in early March. The Governor, Senate and Assembly will then commence negotiations with the goal of adopting a final budget by April 1.

State Issues

West Virginia
Legislative

Legislative Update
The 2024 Regular Session of the West Virginia Legislature will pass its two-thirds point of completion on Tuesday—leaving just 20 days for legislative activity to occur until the final day of the session—March 10.

HB 4753—Cancer Biomarker Testing
This bill resides with the House Judiciary Committee, where it has the support of health plans but has now prompted the American Cancer Society to oppose its own proposal, largely based on the fact that ACS wants the bill to cover pre-diagnosis testing and non-FDA approved testing and treatment. It appears that the House leadership is siding with House Insurance Committee Chairman Steve Westfall and the health plans and will allow the bill to move forward through the committee next week. ACS will apparently continue to oppose the bill.

HB 5417—NCOIL model bill on dental plan expenditure reporting
The House Health Committee has control over this bill and the West Virginia Dental Association has now pulled its support for a proposal that was agreed to at NCOIL by the American Dental Association. It is not clear how or if HB 5417 will advance in light of the dental association's new position.

EMS-Ambulance Reimbursement
SB 444 and SB 533 both are moving forward toward passage in the Senate and would require payment for service by health plans even if no transport occurs. Air ambulance services are specifically excluded from the mandate proposed in this bill. HB 5103 has also been endorsed by the Fire and Emergency Services Committee on to the Finance

Committee and is written in a manner that would propose to hold health plans liable for certain fees that are permissibly imposed on residents by a county commission—but if not paid by that resident could be submitted for payment to the resident's health plan.

HB 5379—Fairness in Cost-sharing calculations
This bill is proposed to create technical corrections to the co-pay maximizer legislation originally enacted in 2018.

HB 4956—Oral Health and Cancer Rights
This bill was advanced by the House Insurance Committee on to the House Health Committee last week pertaining to oral health and cancer rights—mandating coverage that would fall outside of the EHB under ACA. The Senate version of this bill has not been considered and is referred to two committees.

HB 5310—Broadband providers/Health plan cooperative agreements
This bill proposes to establish a statutory framework for broadband providers and health plans to voluntarily partner in delivering services to plan members for purposes of improving patient access to telemedicine services and remote health monitoring. It was advanced from one committee and is now in the possession of the House Judiciary Committee. The proposal imposes no requirements on either broadband providers or health plans but it would establish a precedent for future state action in this area that could eventually become a service mandate on both industries.

HB 5338—Data Privacy Protection Act
This bill is within the jurisdiction of the House Finance Committee.

HB 4809—Health Sharing Ministries Act
This measure is now moving forward in both houses without controversy or opposition and will be enacted into law by the conclusion of the legislative session.

Industry Trends
Policy / Market Trends

AHIP Urges Stability for Medicare Advantage Beneficiaries in 2025
AHIP President and CEO Mike Tuffin published a blog in response to the Medicare Advantage (MA) & Part D 2025 Advance Notice recently released by CMS, urging stability for the 32 million MA beneficiaries in 2025. Tuffin highlights the value of Medicare Advantage, the significant policy changes already underway within MA and Part D, and the policymaker and stakeholder support for the program – as well as the growing evidence seniors will have elevated care needs in 2025. Blog highlights include:

"… This combination of better care at lower costs has made Medicare Advantage an increasingly popular choice. As Medicare Advantage has grown in popularity, policymakers' interest in this part of Medicare has grown as well.

“Over the past three years, the Administration has made a series of fundamental changes to Medicare Advantage, including revising the Star Ratings system, finalizing new rules on how plan payments are audited, restricting and modernizing the prior authorization process, and issuing strong new marketing regulations. This year, CMS began to phase in a new Medicare Advantage risk model, removing 2,000 diagnosis codes over a three-year period, and reducing funding. Taken together, the program is in the midst of the most significant reforms since passage of the Affordable Care Act.

“Further, CMS is now implementing very significant changes to the Part D benefit for 2025, including a new benefit and subsidy structure, an updated risk model, and a new program enabling seniors to spread their prescription drug out-of-pocket costs over the course of a calendar year. These changes meaningfully impact Medicare Advantage because nearly all Medicare Advantage beneficiaries are in plans providing Part D prescription drug coverage as part of their integrated benefits package.

“In addition to these far-reaching policy changes, recent months have seen a clear spike in seniors’ care utilization that is widely expected to continue into 2025. Reports indicate that the return of elective procedures deferred during the pandemic has been one key driver. Moreover, the Medicare Trustees recently reported they expect Medicare costs on a per capita basis to grow 5.8% for 2025.

“It is against that backdrop that the Medicare Advantage policies recently proposed by CMS for 2025 must be evaluated.”

“Numerous media outlets and independent analysts are in agreement this proposal will result in reduced Medicare Advantage funding for 2025. …”

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4 Studies Reveal How Medicare Advantage Excels

AHIP published a new article spotlighting 4 recent studies that demonstrate how Medicare Advantage (MA) provides cost savings and higher quality care to beneficiaries while delivering value for the government:

1. The Avalere study shows how **MA can help advance trust fund solvency**.

2. The study from Wakely Consulting Group shows that when compared on apples- to-apples basis, the original Medicare program costs more than government estimates, which suggests **MA delivers savings to the Medicare program**.

3. The Healthcare Effectiveness Data and Information Measures Study shows that **MA plans provide superior quality of care and better rates of preventive services** while maintaining greater cost efficiency.

4. The MA Demographics Study shows that **more Americans from more diverse populations chose MA** for their health care coverage this past year than ever before.

The bottom line: The results underscore that Medicare Advantage provides more affordable, higher quality care while serving a more diverse population and delivering more value compared to original Medicare.

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/.**