Highmark's Weekly Capitol Hill Report

Issues for the week ending August 18, 2023

Federal Issues

Regulatory

Appeals Court Finds Oklahoma PBM Laws Preempted by Federal Law

The U.S. Court of Appeals for the Tenth Circuit issued a unanimous decision finding that certain provisions of an Oklahoma state law governing how PBMs operate are preempted under both ERISA and the Medicare Part D statute. The case, PCMA v. Mulready, reverses an earlier decision by the district court upholding those same provisions.

Why this matters: The decision is a significant and important outcome that better clarifies the preemptive scope of state activity around both ERISA and Part D plans.

Background: The case on appeal involved four provisions of Oklahoma's recent PBM law. Those include provisions establishing: (1) various any willing provider standards; (2) retail-only access standards; (3) cost-sharing discount prohibitions (collectively "network restrictions"); and (4) a provision regarding pharmacist probation-related requirements.

- The Tenth Circuit found that the network restrictions are preempted under federal law because they "govern a central matter of plan

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administration" by either directing or forbidding an element of plan structure or benefit design. It also found that the probation-related restriction is preempted under ERISA because it "dictat[es] which pharmacies must be included in a plan's PBM network" and therefore forces plans to adopt a particular scheme of coverage. The Tenth Circuit also rejected Oklahoma's view that the Supreme Court's earlier Rutledge decision largely excluded PBMs from ERISA preemption.

- In addition, the court found that the Medicare Part D statute's preemption provision is "broad", "sweeping", and "akin to field preemption." Accordingly, the court concluded that the provision "precludes States from regulating Part D plans except for licensing and plan solvency." This reading squarely rejects the approach advocated by Oklahoma that Medicare Part D preemption only exists if there is an overlapping or on-point federal standard.

Next Steps: We will continue to monitor any developments in this case, including whether Oklahoma either seeks a rehearing by the full Tenth Circuit and/or review by the Supreme Court.

- **Pharmacy Benefit Manager Regulation Proposed**

Guidance on Annual Redetermination and Re-enrollment for Marketplace Coverage for 2024 and Later Years

On August 14, CMS published guidance outlining the eligibility redetermination procedures Marketplaces on the federal eligibility and enrollment platform (Healthcare.gov) will follow for the upcoming benefit year and later. The guidance replaces 2019 renewal guidance, reflecting current law and Marketplace operations. State-based exchanges may follow the same procedures or alternative procedures outlined in regulation. The guidance does not update the reenrollment hierarchy.

Examples of updated renewal procedures include the following:

- The Marketplace will not end APTC/CSR for enrollees whose Medicaid eligibility is pending verification with the state.
- The Marketplace will not end APTC/CSR for enrollees whose income has risen above 500% FPL and who have not contacted the Marketplace. Because the American Rescue Plan Act and Inflation Reduction Act lifted the previous APTC eligibility limit of 400%, this process is not currently needed.
- The Marketplace will end APTC and income-based CSR for enrollees who fail to reconcile their tax credits two consecutive years, per the NBPP for 2024.

CFPB Request for Information on Medical Payment Products

Last month the Consumer Financial Protection Bureau (CFPB), Centers for Medicare & Medicaid Services, Department of Health and Human Services (HHS), and Department of the Treasury (Treasury) released a **request for information** (RFI) on medical payment products.

The agencies are seeking data and comments on the scope, prevalence, terms, and impacts of medical payment products, including medical credit cards and loans, as well as the downstream consequences of these products and what actions can be taken to address any harm caused by these products.

Comments are due on Monday, Sept. 11.

Effectuated Enrollment: Early 2023 Snapshot and Full Year 2022 Average

CMS published an effectuated enrollment report reflecting the total number of people with active (paid) policies in both the federal and state-based Marketplaces.

Key findings from the report include the following:

- Effectuated enrollment through the Marketplaces for February 2023 was 15.7 million, a 13% increase over February 2022 effectuated enrollment. While most states saw enrollment increases between February 2022 and 2023, including increases over 10% in 23 states, enrollment fell in 13 states.
- In February 2023, 14.3 million Marketplace enrollees, 91% of Marketplace enrollees, received APTC, a 15% increase from February 2022. CSR enrollment increased by 11% over this same time period.
- The average total monthly premium consumers paid after APTC fell by 3% from February 2022 to February 2023.
- In 2022, the average monthly effectuated enrollment total was 13.5 million, a 15% increase over the average monthly enrollment in 2021.

- In 2022, 90% of Marketplaces received APTC, a 2-percentage point increase from 2021.

CMS Issues IRA Anniversary Fact Sheet

CMS recently issued a fact sheet on the one-year anniversary of the Inflation Reduction Act, highlighting changes made under the law. The fact sheet also provides links to previously released guidance implementing the law as well as public education resources.

Specifically, the Inflation Reduction Act:

- Ensures that people with Medicare pay no more than $35 for a month's supply for each covered insulin product under Medicare prescription drug coverage, Traditional Medicare, or Medicare Advantage.
- Lowers Medicare Part D prescription drug costs and redesigns the prescription drug program (e.g., people enrolled in Medicare prescription drug coverage who have very high drug costs will no longer have to pay cost-sharing for their prescription drugs in the catastrophic phase of the program starting in 2024, and caps annual out-of-pocket prescription drug costs at $2,000 for 2025).
- Makes adult vaccines, recommended by the ACIP, available at no cost for people with Medicare prescription drug coverage starting January 1, 2023, and later in 2023 for people with Medicaid coverage.
- Allows Medicare to negotiate directly with participating drug companies to improve access to innovative treatments for people with Medicare and lower costs for the Medicare program.
- Requires drug companies that raise their drug prices faster than the rate of inflation to pay Medicare a rebate and reduces coinsurance for these drugs for people with Medicare under certain circumstances.
- Provides more assistance in affording Medicare prescription drug coverage premiums and out-of-pocket drug costs by expanding the low-income subsidy program (LIS or "Extra Help") under Medicare Part D to 150% of the federal poverty level starting in 2024.
- Extends increased financial help to purchase affordable, comprehensive health insurance plans through HealthCare.gov and the state-based Marketplaces.

CMS Issues State Guidance on Claiming Methodologies for Medicaid Managed Care

The Centers for Medicare & Medicaid Services (CMS) released a new State Medicaid Director Letter (SMDL) with guidance to states on claiming federal financial participation (FFP) matching funds for Medicaid managed care expenditures through capitation payments.

In certain circumstances, a portion of capitation payments may be eligible for FFP at a "differential match rate" that varies from a state's standard Federal Medical Assistance Percentage (FMAP). For benefits or populations subject to a differential match rate -- such as family planning services, community-based mobile crisis intervention services, and Indian Health Service facility services – that are provided through managed care programs, states must develop separate claiming methodologies for each program to ensure they receive the appropriate match rate. The SMDL provides guidance for states on how to develop claiming methodologies with illustrative examples.

Cost Determination for Medicare Coverage of Monoclonal Antibodies for the Treatment of Alzheimer's.

On Aug. 17, CMS issued a memo to provide information on the significant cost determination for Medicare coverage of monoclonal antibodies for the treatment of Alzheimer's disease.

Why this matters: CMS has determined the cost of coverage under National Coverage of Determination (NCD 200.3) does not meet the significant cost threshold. Therefore, MA Plans are required to assume the costs and cover anti-amyloid monoclonal antibody treatments for Alzheimer's based on the coverage criteria set forth under NCD 200.3. MA plans must collect the applicable registry trial number on each claim or encounter for monoclonal antibodies that receive traditional approval from the FDA. Additional information on available registries for physicians can be found on CMS webpage.

CMS Extending Spousal Impoverishment Rules for Married HCBS Applicants and Recipients

CMS issued an informational bulletin stating the Consolidated Appropriations Act, 2023 modifies section 2404 of the Patient Protection and Affordable Care Act (ACA) to require state Medicaid agencies apply the spousal impoverishment rules to married home and community-based services (HCBS)-eligible applicants and beneficiaries through Sept. 30, 2027. States should continue to follow spousal impoverishment guidance published in State Medicaid Director Letter #15-001. Read More

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CMS Seeks Comment on MLTSS Measure Development

CMS issued a request for public comment and feedback on the updated technical specifications of managed long-term services and supports (MLTSS) quality measures. CMS will accept comments on the measure specifications through 11:59 PM ET on Monday, Aug. 28, 2023. Read More

State Issues

New York

Regulatory

1132 Waiver Update and Impact on Individual Market

New York continues to await a final decision from the Centers for Medicare and Medicaid Services on the state's 1132 waiver application that seeks to expand Essential Plan eligibility from 200% of the federal poverty level to 250%. The NY State of Health staff has indicated that CMS is generally supportive of the proposal aimed at increasing affordability of coverage in New York. However, part of the ongoing discussion between CMS and NYSOH has been the potential impact of expanding the EP on the individual market and how that could be mitigated. The goal is to have the waiver approved when DFS announces the 2024 ACA rates in late August.

Pharmacy Benefit Manager Regulation Proposed

DFS last week issued a proposed regulation to govern the conduct of PBMs operating in New York. The proposal includes definitions and licensing of PBMs as well as establishing rules for PBMs' contracting with pharmacies and network adequacy, requirements for audits and investigations of pharmacies, and various consumer protections. In announcing the regulation, DFS said "Our proposed regulation is a significant milestone in stopping unfair practices that have fueled years of runaway prescription drug prices." DFS' press release can be found here.

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/.**
If you have any questions about a DE, NY, PA, WV, or congressional bill, contact the Government Affairs Department at (717).302.3978.