Highmark's Weekly Capitol Hill Report

Issues for the week ending November 10, 2023

Federal Issues

Legislative

Senate Finance Committee Approves Legislation on Mental Health, Provider Directories, and PBMs

The Senate Finance Committee marked up the Better Mental Health Care, Lower-Cost Drugs, and Extenders Act on Wednesday by a vote of 26-0.

Why this matters: As reported last week, key provisions in the bill include the establishment of new requirements for Medicare Advantage (MA) provider directories, new requirements for PDP sponsors and pharmacy benefit managers (PBM), and mental health. The package also includes extension of a number of Medicare and Medicaid policies set to expire this year.

The version of the bill that the Committee passed included several modifications to the initial draft of the bill, including technical edits, requiring the Department of Health and Human Services (HHS) to brief Congress periodically on implementation of the Pharmacy DIR Rule (Sec. 201), and directing the Government Accountability Office to

In this Issue:

publish a report on the proposed requirements for certain “discount-eligible” Part D drugs (Sec. 203).

Next steps: Unclear. Some of its provisions could end up in an end of year legislative package. However, the size and scope of any year end package -- if there is one -- will likely depend on how broader issues regarding government funding are resolved.

Hospital Perspective: The legislation includes provisions supported by the American Hospital Association that improves access to behavioral health care and delays Medicaid disproportionate share hospital reductions.

- Specifically, the AHA-supported provisions would provide Medicare incentives to integrate behavioral health and primary care; delay certain Medicaid disproportionate share hospital payment reductions for two years; and permanently grant state Medicaid programs the option to receive federal matching payments for substance use disorder treatment provided in certain institutions for mental diseases.
- The legislation also would ensure timely communication regarding telehealth and interstate licensure requirements and extend certain Medicare payment provisions for physicians and clinical laboratory services.

Industry Trends

Policy / Market Trends

- **New Study Adds to Growing Evidence that Medicare Advantage Leads to Better Quality Outcomes than Original Medicare**
- **White House Reports Enrollment Spike for ACA Marketplaces**

30 House Democrats Seek Increased Oversight of AI Tools Used by MA Plans
On November 3, 30 House Democrats sent a letter to the Centers for Medicare & Medicaid Services (CMS) urging the agency to better evaluate how Medicare Advantage (MA) plans utilize artificial intelligence (AI). The letter, led by Reps. Judy Chu (D-CA) and Jerrold Nadler (D-NY), expresses concerns regarding CMS' prior authorization requirements finalized in the 2024 Part C and D rule.

Why this matters: The letter provides a list of measures they hope CMS will take, including requiring MA plans to give reasons for service denials, assess the frequency of denials, determine the extent to which AI informed the denial process, whether algorithms are self-correcting, and whether plans are inappropriately using race or other factors in algorithms.

- The group said it also wants AI rulings to be compared against traditional coverage decisions and wants assurances from MA plans and contractors that coverage is not more restrictive than traditional Medicare.

Federal Issues
Regulatory

CMS Releases Medicare Advantage & Part D Proposed Rule for 2025
The Centers for Medicare & Medicaid Services (CMS) released the pre-publication version of the Medicare Advantage (MA) and Part D Proposed Rule for CY 2025. The proposed rule will be published in the Federal Register on November 15. CMS has released a related press release and fact sheet. Comments are due to CMS by January 5.

Key provisions included in the MA and Part D proposed rule include the following:

- **Network Adequacy for Behavioral Health Providers**
  - Proposes to add certain behavioral health provider specialties to MA network adequacy time and distance standards. Would add a new facility-specialty type, Outpatient Behavioral Health, to the existing list of facility specialty types evaluated as part of CMS' MA network adequacy reviews.

- **New Standards for Special Supplemental Benefits for the Chronically Ill (SSBCI)**
  - Proposes new requirements for MA plans to demonstrate, by the time they submit bids, that SSBCI items and services meet the legal threshold of having a reasonable expectation of improving the health or overall function of chronically ill enrollees and are supported by research. MA plans would have to establish and maintain bibliographies of relevant research studies or other data to demonstrate that an SSBCI meets these requirements.
  - Proposes new restrictions to SSBCI marketing requirements.

- **Mid-Year Enrollee Notification of Available Supplemental Benefits**
  - Proposes that MA plans provide enrollees with a mid-year, personalized notification that lists supplemental benefits not used during the first six months of the year as well other information on accessing the benefits.

- **Revisions to Agent and Broker Compensation**
  - Proposes to redefine “compensation” for purposes of the cap on fees paid to agents and brokers by setting a single compensation rate for all plans, broadening the scope of items and services included within the cap, and limiting separate payments for other services.

- **Annual Health Equity Analysis of Utilization Management (UM) Policies and Procedures**
  - Proposes updates to the composition of, and responsibilities for an MA plan’s UM committee to require: a member of the UM committee to have expertise in health equity, that the UM committee conduct an annual health equity analysis of prior authorization policies and procedures used by the plan, and that the MA plan make the results of the analysis publicly available on their website.

- **Amendments to Part C and Part D Reporting Requirements**
  - Proposes to affirm and clarify CMS authority related to MA and Part D data reporting, to allow for future expanded data reporting requirements.

- **Enhanced Enrollees' Right to Appeal an MA Plan's Decision to Terminate Coverage for Non-Hospital Provider Services**
  - Proposes to require that Quality Improvement Organizations rather than the MA plan review untimely fast-track appeals of a plan's decision to terminate services in a skilled nursing facility, comprehensive outpatient rehab facility, or home health agency.
  - Proposes to eliminate the requirement that an enrollee forfeit the right to appeal a service termination decision when the enrollee leaves the facility.

- **Additional Changes to an Approved Formulary—Substituting Biosimilar Biological Products**
  - Proposes to include substitutions of biosimilar biological products other than interchangeable biological products for their reference products as "maintenance changes."

- **Changes to Enrollment Options for Medicare-Medicaid Dually Eligible Enrollees**
  - Proposes to replace the current quarterly special enrollment period (SEP) with a new SEP that allows dually eligible individuals and people enrolled in the Part D low-income subsidy program to elect a standalone prescription drug plan (PDP) on a monthly basis.
  - Proposes to create a new integrated care SEP to allow dually eligible individuals to elect an integrated dual eligible special needs plan (D-SNP) on a monthly basis.
  - Proposes to limit enrollment in certain D-SNPs to those individuals who are also enrolled in an affiliated Medicaid MCO.
  - Proposes to limit the number of D-SNPs that affiliated organizations can offer in the same service area.

- **Limit on Out-of-Network Cost Sharing for D-SNP PPOs**
  - Proposes to limit out-of-network cost sharing for certain professional services provided to preferred provider organization (PPO) D-SNP members to the in-network cost-sharing limits for such services, starting

in 2026. Permissible cost-sharing limits would be determined in part by the Maximum Out-Of-Pocket (MOOP) limits selected by the D-SNP PPO in its bid.

- **Contracting Standards for Dual Eligible Special Needs Plan "Look-Alikes"**
  - Proposes to lower the threshold for determining that an MA plan is a D-SNP "look-alike" plan from the current threshold of 80 percent Medicare-Medicaid dual eligibles to 60 percent dual eligibles incrementally over a two-year period. For contract year 2025, the limitation would apply to non-SNP MA plans with 70 or greater percent dually eligible individuals. For contract year 2026, CMS proposes to further reduce the threshold from 70 percent to 60 percent or greater dually eligible enrollment as a percentage of total enrollment.

- **Standardized MA Risk Adjustment Data Validation Appeals Process**
  - Proposes to require that MA organizations exhaust all three levels of appeal for medical record review determinations before beginning the payment error calculation appeals process.

- **Star Ratings** (changes would apply for the 2025 measurement period and the 2027 Star Ratings unless otherwise noted)
  - Proposes to update the Medication Therapy Management (MTM) Program Completion Rate for Comprehensive Medication Review (CMR) measure (Part D).
  - Proposes to revise the process for identifying data completeness issues and calculating scaled reductions for the Part C appeals measures.
  - Proposes to update how the categorical adjustment index (CAI) and health equity index (HEI) are calculated in the case of contract consolidations.
  - Proposes to revise an aspect of the quality bonus payment (QBP) appeals process.
  - Proposes to add to the Star Ratings program that a sponsor may request CMS review of its contract's administrative claims data used for the Part D Patient Safety measures no later than the annual deadline set by CMS for the applicable Star Ratings year.

- **Other Changes:**
  - Proposes to clarify past performance criteria related to a plan being under intermediate sanctions and allow CMS to deny applications for plans under federal bankruptcy proceedings.
  - Proposes to allow CMS to share MA encounter data with state Medicaid agencies to support the Medicaid program, including sharing such data in advance of the final risk adjustment reconciliation to support care coordination for dually-eligible enrollees.

CMS Releases Bulletin on Medicaid and CHIP Managed Care Monitoring and Oversight Tools

The Centers for Medicare & Medicaid Services (CMS) released the third in a series of Center for Medicaid and CHIP Services (CMCS) Information Bulletins (CIB) concerning oversight of Medicaid managed care programs. The new CIB provides updates and reminders on the web-based reporting portal and the reporting requirements for Medicaid managed care programs. The guidance also provides an update on CMS' process for review and approval of managed care contracts, rate certifications, and state-directed payments; and announces the release of several new technical assistance toolkits.

A June 2021 CIB introduced a reporting template for Managed Care Program Annual Reports (MCPAR) and the development of a web-based reporting portal for the collection of all required managed care reports. The second CIB in July 2022 provided an update on the web-based reporting portal and introduced two additional reporting templates for the Medical Loss Ratio (MLR) Report and the Network Adequacy and Access Assurances Report (NAAAR).

CMS Launches 'Birthing Friendly' Designation on Care Compare

The Centers for Medicare & Medicaid Services (CMS) began displaying the 'Birthing-Friendly' designation icon on CMS's Care Compare online tool.

Why this matters: CMS created the new designation to identify hospitals and health systems that participate in a statewide or national perinatal quality improvement collaborative program and that implement evidence-based care to improve maternal health. The public can use the Care Compare tool to identify hospitals that have been designated as "Birthing-Friendly." This is the first-ever hospital quality designation by HHS that specifically focuses on maternal health. This proposal was made in conjunction with Vice President Harris' nationwide call to action to reduce maternal mortality and morbidity, which included CMS' intention to establish this proposed hospital designation.

In addition to displaying this information on Care Compare, over 25 health plans have agreed to post information on the Birthing-Friendly designation in their provider directories. This collaboration between CMS and private plans ensures over 150 million Americans will have access to this information. For more information, please see CMS's release.

State Issues

Pennsylvania

Regulatory

Pennie's 2024 Open Enrollment Period Begins

Pennsylvania's official state-based health insurance marketplace is now open for Pennsylvanians to enroll in health insurance coverage for 2024. This annual Open

Enrollment Period offers consumers the opportunity to compare health plans through Pennie. Pennie's Open Enrollment Period began on November 10 and closes on Dec. 15. For those who enroll during this open enrollment period, coverage will become effective on January 1, 2024. Because plans and prices may change every year, anyone who needs coverage should review their options. Those currently enrolled through Pennie should make sure their family size, income, and contact information are up to date.

Pennie advises consumers that health plans offered outside of Pennsylvania for purchase may not have the same protections as plans available through Pennie. Consumers who no longer qualify for Medicaid because of changes in income may find affordable private health plans through Pennie.

Pennie encourages anyone seeking coverage to go to Pennie.com before December 15 and enroll.

CSRxP Issues Statement in Support of FTC Crackdown on Patent Abuse

The Campaign for Sustainable Rx Pricing (CSRxP), of which BCSA, AHIP & the AHA are members, released a statement in response to an announcement from the Federal Trade Commission (FTC). The Commission announced they are challenging more than 100 patents listed in the U.S. Food and Drug Administration's (FDA) "Approved Drug Products with Therapeutic Equivalence Evaluations" publication, otherwise known as the "Orange Book."

The FTC sent letters to several drug makers including brand name drug giants AbbVie, AstraZeneca, and Glaxo-Smith Kline. The FTC letters challenge patents on several different types of brand name products including inhalers and EpiPen injectors. CSRxP Executive Director, Lauren Aronson issued the following statement in support of the move:

"Big Pharma's egregious and longstanding abuse of the patent system blocks competition from more affordable alternatives, keeps prescription drug prices high, and costs patients and the entire U.S. health care system billions of dollars each year. CSRxP commends the FTC for taking proactive steps to crack down on Big Pharma's egregious anti-competitive tactics by challenging flimsy patents designed to game the system and boost profits, not protect or foster innovation."

Read the announcement from the Federal Trade Commission as well as the letters to brand name drug companies HERE and HERE.

Industry Trends

Policy / Market Trends

New Study Adds to Growing Evidence that Medicare Advantage Leads to Better Quality Outcomes than Original Medicare

A new study published by Harvard Medical School and Inovalon found Medicare Advantage (MA) members experience better quality outcomes than original Medicare members, including having fewer preventable hospitalizations, fewer readmissions and lower rates of high-risk medication.

Why this matters: The study found:

- Avoidable hospitalizations in original Medicare were **7 times** higher than in MA.
- Original Medicare readmissions were **8 times** higher than MA.
- Rates of inappropriate high-risk medication use were **4 times** higher in original Medicare than MA.

The study adds to the growing body of evidence that shows MA provides better value than original Medicare. Other recent studies have demonstrated that, when comparing MA and original Medicare, MA costs less and outperforms its counterpart on cost protections for low-income and diverse populations.

White House Reports Enrollment Spike for ACA Marketplaces

After the first week of open enrollment, the White House is reporting strong enrollment numbers for the Affordable Care Act (ACA) health insurance marketplaces, with 300,000 new customers signing up for individual market plans. President Biden wrote on X, the platform formerly known as Twitter, “In the first week of Open Enrollment, 1.6 million people have signed up for a plan at HealthCare.gov, including 301,000 new consumers — that’s a 50% increase from last year.”

Enrollment rates through HealthCare.gov have gone up year-over-year since 2020. The pressures of the pandemic led to more people seeking out health insurance and maintaining coverage. This year’s enrollment numbers are expected to exceed last year’s — 16.3 million — once again. The Inflation Reduction Act also extended pandemic-era enhanced subsidies to last through 2025, lowering premiums and making plans more accessible for more people.

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/.**