Highmark's Weekly Capitol Hill Report

Issues for the week ending February 17, 2023

Federal Issues

Legislative

Senate Committee Ramps Up Scrutiny of PBMs

On Thursday, the Senate Commerce Science, and Transportation Committee held a hearing titled "Bringing Transparency and Accountability to Pharmacy Benefit Managers (PBMs)." The discussion largely centered around the "Pharmacy Benefit Manager Transparency Act," which would expand the Federal Trade Commission's (FTC) authority over PBMs, ban spread pricing arrangements and pharmacy "claw backs," and increase PBM reporting requirements.

During the hearing, Committee Chair Maria Cantwell (D-WA) used harsh rhetoric to describe PBMs, expressing concern over rebates not being passed along to the patient, a lack of transparency, and market consolidation/vertical integration. Ranking Member Ted Cruz (R-TX) urged members to consider the tradeoffs of the legislation and highlighted the importance of PBMs but agreed with Cantwell that the relationship between drug manufacturers, PBMs and health insurers is too opaque. Generally, Senators were uniform in their desire to see more transparency. Members on both sides of the aisle expressed concerns with pharmacy "claw backs," the impacts that

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large PBMs have on community pharmacies, and the role PBMs play in driving up the cost of drugs for patients.

Next steps: It is likely the committee will take up this bill soon given its bipartisan support in the last Congress, when the committee advanced the bill by a vote of 19-9.

- **Senate Committee Advances Insulin Cap Legislation**
- **Senate Advances Dental Medical Loss Ratio Legislation**

Industry Trends

Policy / Market Trends

- **Study Finds Medicare Advantage Rate Notice Would Increase Premiums by $540 on Average and Reduce Benefits in 2024**
- **MEDCAC Discusses Recommendations for Coverage with Evidence Development Criteria**
- **CMS Conducting Webinars Regarding Key Changes to the PY2024 QHP Certification Process**

Senate Committee Examines Health Care Workforce Shortages

The Senate Committee on Health, Education, Labor & Pensions (HELP) held a full Committee hearing on Thursday entitled "Examining Health Care Workforce Shortages: Where Do we Go From Here?" Witnesses at the hearing highlighted existing workforce challenges across the health care landscape.

Why it matters: With Sen. Bernie Sanders (I-VT) taking the helm of the HELP Committee for the first time, bipartisan legislation may be hard to come by. However, addressing worsening workforce shortages across clinician types – physicians, nurses, dentists, pharmacists, mental health providers, etc. could be an area of agreement between he and Ranking Member Bill Cassidy (R-LA).

Ideas proposed in the hearing included increasing the number of Medicare Graduate Medical Education (GME) slots, loan forgiveness, visa reform to allow foreign health care workers to come to the United States and targeting investments in historically black colleges and universities (HBCUs).

Federal Issues

Regulatory

Administration Releases COVID-19 Transition Guidance, Vaccine Schedules

HHS recently published a fact sheet outlining its COVID-19 public health emergency (PHE) transition roadmap, which highlights changes to COVID-19 policies and flexibilities as well as what policies will not be impacted by the end of the PHE declaration.

- **HHS Sec. Becerra also officially gave governors a 90-day notice of the PHE ending as well as the fact sheet.**

Why it matters: The fact sheet will help Plans prepare coverage, payment and operational policies as the federal government begins to unwind requirements and flexibilities allowed under the PHE, which will end May 11.

The details: HHS notes once the PHE ends, the following key COVID-19 policies will change or end:

- **Coverage of COVID-19 testing** under Medicare Part B, Medicaid and commercial insurance
- **Certain Medicare and Medicaid** waivers and broad flexibilities for health care providers
- **Some Medicaid COVID-19 PHE waivers** and flexibilities will end May 11, while others will remain in place for six months

What will not be impacted:

- Access to COVID-19 vaccinations and certain treatments
- Major Medicare telehealth flexibilities
- Medicaid telehealth flexibilities and redeterminations will be handled independently from the PHE ending

Yes, and… The CDC's Advisory Committee on Immunization Practices (ACIP) published the approved schedules for recommended child and adolescent immunizations as well as immunizations for adults.

- Non-grandfathered group plans and individual insurance must provide coverage without cost-sharing for vaccines included in the routine schedule.
- Health plans typically have a year to implement new recommendations.

HHS Secretary Responds to President's Executive Order on Lowering Drug Costs

CMS announced that the Secretary of the HHS has selected three new models for testing by the CMS Innovation Center (CMMI) to help lower the high cost of drugs, promote accessibility to life-changing drug therapies, and improve quality of care. This announcement is in response to Executive Order 14087, "Lowering Prescription Drug Costs for Americans."

Why it matters: CMS released a report describing the models, selection criteria, test questions, evaluation strategy and implementation plans. **The models are:**

- **The Medicare $2 Drug List**: Under this model (the Medicare High-Value Drug List Model), Part D plans would be encouraged to offer a low, fixed co-payment across all cost-sharing phases of the Part D drug benefit for a standardized Medicare list of generic drugs that treat chronic conditions.
- **The Cell and Gene Therapy Access Model**: Under this model, state Medicaid agencies would assign CMS to coordinate and administer multi-state, outcomes-based agreements with manufacturers for certain cell and gene therapies.
- **The Accelerating Clinical Evidence Model**: Under this model, CMS would develop payment methods for drugs approved under accelerated approval, in consultation with the Food and Drug Administration, to encourage timely confirmatory trial completion and improve access to post-market safety and efficacy data.

The report also directs CMMI to evaluate three additional areas of research: accelerating biosimilar adoption, data access changes to support price transparency, and cell and gene therapy access in Medicare fee-for-service. A fact sheet and frequently asked questions are also available.

CMS Issues Medicaid Drug Rebate Program Reminders for States

The Centers for Medicare & Medicaid Services (CMS) issued a program notice to remind states of Medicaid Drug Rebate reporting and certification requirements. The notice reiterated that states must report certain data about their value-based purchasing arrangements under a CMS authorized supplemental rebate agreement by March 1, 2023 and that states must certify their state drug utilization data (SDUD) records submitted after Jan. 1, 2022.

CMS Proposes Medicare Benefit Expansion for Mobility Devices

On February 15, the Centers for Medicare & Medicaid Services (CMS) released a proposed National Coverage Determination (NCD) that would, for the first time, expand coverage for power seat elevation equipment on certain power wheelchairs to Medicare-covered individuals.

Why it matters: If the NCD is finalized, power seat elevation equipment would be covered by Medicare for individuals with a Group 3 power wheelchair, which are designed to meet the needs of people with Medicare with severe disabilities, in order to improve their health as they transfer from the wheelchair to other surfaces.

CMS stated the NCD follows an evidence-based clinical analysis CMS initiated in August 2022 to examine whether the use of power seat elevation equipment on power wheelchairs: 1) falls within a Medicare benefit category and, 2) if yes, whether it is reasonable and necessary. The proposed National Coverage Determination decision memorandum is available to review and the 30-day comment period will close March 17, 2023.

CMS Proposes Requiring Nursing Home Disclosure of Private Equity Ownership

The Centers for Medicare & Medicaid Services (CMS) issued a new proposed rule requiring Nursing Homes to disclose additional ownership and management information to highlight private equity ownership. Specifically, the proposed rule provides definitions of “private equity company” and “real estate investment trust” to assist nursing homes when reporting data. According to CMS, these definitions will “lead to the disclosure of whether direct and indirect nursing home owners are private equity companies or real estate investment trusts.”

CMS also issued a press release and fact sheet upon release of the proposed rule. Read the proposed rule here.

State Issues

New York

Regulatory

Regulatory Updates

- **Draft PBM Filing Regulation Posted for Comment**
  The Department of Financial Services (DFS) last week issued a proposed regulation clarifying the electronic filing requirements for PBMs. Comments are due April 16.

- **DFS Issues Circular Letter on Psychiatry E/M Codes**
  Also last week, DFS posted its Circular Letter relating to Evaluation and Management (E/M) codes. The CL was issued to remind insurers of their obligation to accept and initiate processing of claims submitted by psychiatrists pursuant to, and consistent with, the current version of the American Medical Association (AMA) current procedural terminology (CPT) codes, including E/M CPT codes. The Department indicated it had received information that some insurers' reviews of E/M codes submitted by psychiatrists did not comport with the most recent version of the AMA CPT codes.

State Issues

West Virginia
Legislative

Senate Committee Advances Insulin Cap Legislation
On Thursday, February 16, the Senate Health Committee advanced Senate Bill 577 (Maroney, R-Marshall). Senate Bill 577 proposes $35 copay cap on insulin per 30-day supply and further seeks to impose a $100 copay cap on diabetic devices per 30-day supply.

Senate Advances Dental Medical Loss Ratio Legislation
On Monday, February 13, the Senate advanced Senate Bill 290 (Takubo, R-Kanawha). Senate Bill 290 proposes to require small group and individual dental plans to have a 70% medical loss ratio and for large group plans to have a 75% loss ratio. Senate Bill 290 now awaits consideration from the House Banking and Insurance Committee and House Health Committee.

There was a stakeholder meeting convened on the bill Friday by House Insurance Chairman Steve Westfall, who announced his decision to propose a legislative and OIC study of the issue rather than move the bill forward.

Industry Trends
Policy / Market Trends

Study Finds Medicare Advantage Advance Rate Notice Would Increase Premiums by $540 on Average and Reduce Benefits in 2024

A new study conducted by Avalere discusses the implications for the Centers for Medicare & Medicaid Services (CMS) 2024 Advance Notice for proposed payment and coverage policies for Medicare Advantage (MA) plans in 2024. The study finds that the changes could lead to an average of $45 decrease in monthly savings (a total of $540 for 2024) for each member per plan.

The study suggests that two key proposals will impact the 2024 plan payments and MA enrollee premiums or benefits, including a proposal to remove medical education payments in the non-end stage renal disease (ESRD) US per capita costs (USPCC) baseline and a proposal to update the MA CMS Hierarchical Condition Category (HCC) risk adjustment model. Additionally, changes made to the 2023 Star Ratings will impact payment cuts.

Why it matters: The analysis finds that enrollment-weighted average rebates would be $45 per member per month lower (29%) in 2024 than in 2023. If the proposed changes are finalized, the study projects that beneficiaries could see plans reduce their 2024 benefits to keep premiums at their 2023 rate, increase their 2024 premiums to offer the same 2023 benefits, or a combination of both. The full study can be found here.

MEDCAC Discusses Recommendations for Coverage with Evidence Development Criteria

The Medicare Evidence Development and Coverage Advisory Committee (MEDCAC) recently held a two-day meeting to discuss and make recommendations to CMS regarding the coverage with evidence development (CED) criteria to be used when a CED decision is issued by the Centers of Medicare & Medicaid Services (CMS) as part of a National Coverage Decision (NCD) – a nationwide determination of whether Medicare will pay for an item or service. The CED pathway is used by Medicare to cover items and services on the condition that they are furnished in the context of approved clinical studies or with the collection of additional clinical data.

Why it matters: The MEDCAC panel used an AHRQ report with recommendations on revising the CED criteria as a basis for its discussion. At the conclusion of the meeting, the MEDCAC panel voted on the importance of the proposed criteria changes recommended in the AHRQ report. Key themes included data quality and security, communication of milestones, net benefit to patients, diversity of study population, and reporting of results. CMS will consider the panel's discussion and suggestions in any proposal to update the CED criteria. Additional detail and meeting materials can be found here.

CMS Conducting Webinars Regarding Key Changes to the PY2024 QHP Certification Process

The Qualified Health Plan (QHP) Certification Webinar Series provides stakeholders with guidance on various activities and policies related to the QHP certification process for the forthcoming plan year. In the coming months, several of these webinar sessions will focus on key changes to the PY2024 QHP certification process, including enhancements and updates to QHP certification systems, QHP Application submission, and QHP Application review results. Plans and issuers are encouraged to enroll in the series, which can be found on RegTap.

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/.**