Highmark's Weekly Capitol Hill Report

Issues for the week ending December 16, 2022

Weekly Capitol Hill Report will not publish next week. The next edition will be issued in January.

Federal Issues

Legislative

Congressional Update

Congress bought itself some additional time to complete a final Fiscal Year 2023 spending bill by clearing a second continuing resolution on Thursday that will fund the government through December 23. While leaders and Senate Appropriators are making progress, including with topline spending numbers, House Republicans and a faction of some Senate Republicans are continuing to push for another short-term resolution into the new year when Republicans will have a narrow House majority and the ability to have more leverage over the legislation.

In addition to the government spending legislation, lawmakers and advocates are hoping **a host of other healthcare policy issues may be included in a large year-end package**: **The issues at play include:**

- Traditional "extenders" of payment policies for providers in Medicare and Medicaid
- Extension of telehealth flexibilities

In this Issue:

- Medicare physician payment relief
- Mental health initiatives
- Prior authorization in Medicare Advantage
- Maternal health initiatives

The ultimate scope of a year-end package remains to be determined but much activity continues as the 117th session of Congress inches toward the finish line.

Federal Issues

Regulatory

CMS Releases Sweeping Medicare Advantage Proposed Rule

On Wednesday, the Centers for Medicare & Medicaid Services released a proposed rule that would significantly change Medicare Advantage marketing, prior authorization, and quality programs, among other changes. The rule also is the first to codify provisions of the Inflation Reduction Act's Part D prescription drug reforms passed in August. The rule was released with an accompanying press release and fact sheet.

Highlighted below are key issues of importance:

- **Changes to the Stars Program.** CMS proposes a health equity index (HEI) reward for the 2027 Star Ratings to further incentivize Parts C and D plans to focus on improving care for enrollees with social risk factors (SRFs). In addition, CMS proposes to remove guardrails (bi-directional caps that restrict upward and downward movement of a measure's cut points compared to the prior year) when determining measure-specific-thresholds for non-Consumer Assessment of Healthcare Providers and Systems (CAHPS) measures; modify the Improvement Measure hold harmless policy; include an additional rule for the removal of Star Ratings measures; and remove the 60 percent rule that is part of the adjustment for extreme and uncontrollable circumstances.

- **Reduction in patient experience weights.** CMS proposes to reduce the weight of patient experience/complaints and access measures by half (from four to two) to further align with other CMS quality programs and the current CMS Quality Strategy that promotes quality outcomes.

- **Health Equity in MA.** To further promote health equity in MA, CMS proposes amendments to the population applicability of current health equity regulations, codification of current best

practices, and updates to quality improvement (QI) program requirements. Additional requirements are proposed for MA organizations to develop and maintain procedures to offer digital health education to enrollees with low digital health literacy to assist in accessing telehealth services. Also included are proposals to make provider directories more accessible for beneficiaries with disabilities, as well as requirements for provider directories to identify providers waived to treat patients with medications for opioid use disorder (MOUD).

- **Utilization Management Requirements.** CMS proposes changes to prior authorization (PA) policies for coordinated care to confirm medical necessity, as well as MA plan compliance with local and national coverage determinations. Further changes are proposed to require MA plans to establish a Utilization Management (UM) Committee to review all UM policies, including prior authorization, annually. CMS also proposes to require a review for medical necessity to be conducted by an expert in the field of medicine that is appropriate for the item or service before an MA plan issues an adverse organization determination decision.

- **MA and Part D Marketing.** CMS proposes changes to further strengthen beneficiary protections and improve MA and Part D marketing, including updates to beneficiary communications, opt-out protocols, and new limits to call recording requirements between third-party marketing organizations (TPMOs) and beneficiaries, amongst other changes.

- **Behavioral Health in MA.** In response to past comments regarding challenges in building MA behavioral health networks, CMS is proposing to expand network adequacy requirements to include additional behavioral health specialty types. Other proposals include codifying wait times based on existing guidance, clarifying that some behavioral health services may qualify as emergency services and, therefore, must not be subject to prior authorization, and requiring MA plans to establish programs to coordinate covered services with community and social services to behavioral health services programs.

- **Medicare Parts A, B, C, and D Overpayment Provisions.** CMS proposes to alter the standard for an "identified overpayment" by removing the existing "reasonable diligence" standard and adopting the terms "knowing" and "knowingly" as defined in the False Claims Act. If finalized, MA plans, PDP sponsors, providers and suppliers have identified an overpayment if it has actual knowledge of the existence of the overpayment or acts in reckless disregard or deliberate ignorance of the overpayment.

- **Changes to an Approved Part D Formulary – Immediate Substitutions**. Consistent with current substitution requirements for generic drugs, CMS proposes to permit Part D sponsors to immediately substitute: (i) a new interchangeable biological product for its corresponding reference product; (ii) a new unbranded biological product for its corresponding brand name biological product; and (iii) a new authorized generic for its corresponding brand name equivalent.

- **Expanding Eligibility for Low-Income Subsidies (LIS) Under Part D of the Medicare Program.** CMS is implementing the Inflation Reduction Act change to expand eligibility for the full LIS to individuals with incomes up to 150 percent of the FPL beginning on or after January 1, 2024.

Comments to the rule are due February 13, 2023.

Proposed 2024 Notice of Benefit and Payment Parameters Seeks Major Changes to Advance Biden Administration Priorities

CMS issued the 2024 Notice of Benefit and Payment Parameters Proposed Rule to advance the Biden administration's goals to increase access to and simplify choice for Exchange coverage, mitigate expected coverage losses from the looming expiration of the COVID-19 public health emergency, address the mental health crisis, and advance concrete health equity policies.

Why this matters: The rule comes as enrollment in Exchange coverage has never been higher and continues to outpace 2023's strong numbers.

- First, CMS, operator of the Federally facilitated Exchange, proposes to effectively become an active purchaser by limiting the number of non-standardized plan options to two per product network type and metal level (excluding catastrophic plans), in any service area, for 2024 and beyond, as a condition of QHP certification.

- CMS also proposes to optimize the default re-enrollment logic used to map renewing enrollees by selecting a silver-level QHP with cost-sharing reductions in the same product for the many low enrollees who are eligible for cost-sharing reductions who would otherwise be enrolled in a bronze plan without CSRs.

- To respond to potential coverage gaps for those enrolled in Medicaid coverage who lose it when they are redetermined, CMS proposes to expand the special enrollment period to select Exchange coverage to 60 days before through 90 days after the loss of Medicaid coverage.

- Further, Exchange-funded Navigators will be permitted to conduct unsolicited door-to-door outreach and enrollment in hard-to-reach communities, a change from the prior requirement to only conduct outreach and received consent to follow up for enrollment assistance later.

Comments to the rule are due 45 days after the rule is published in the Federal Register.

SAMHSA Proposes Home Use of Medications for the Treatment of Opioid Use Disorder

On Friday, the Federal Register posted a proposed rule from SAMHSA to make the pandemic rules that allowed take-home drugs to help fight opioid addiction permanent. HHS has issued this notice of proposed rulemaking (NPRM) to solicit public comment on its proposal to modify its regulations regarding medications for the treatment of opioid use disorder. The proposed rule would make it easier for patients with opioid use disorder to access drugs like methadone for home use and for providers to prescribe them via telehealth for patients with opioid use disorder. Additionally, the proposed rule would widen the scope of who is able to prescribe treatment drugs to permanently include any provider licensed to dispense medications such as physician assistants or nurse practitioners.

Comments to the rule are due February 14, 2023.

CMS Submits Innovation Report to Congress

On December 13, the Center for Medicare and Medicaid Innovation (CMMI) released its 2022 report to Congress. This report launched more than 50 alternative payment and care delivery model tests, with 33 models now or still operational, according to CMMI's sixth report to Congress on its progress. Over the two-year period covering the report, CMMI reports that operational model tests have included over 314,000 healthcare providers and/or plans alone that have impacted the medical care of more than 41.5 million Medicare and Medicaid beneficiaries, as well as commercially insured individuals. CMMI uses alternative payment and care delivery model tests to improve the quality of healthcare for participants while attempting to make the delivery of medical care more affordable for all. According to CMMI reports, just six model tests have delivered statistically significant savings, net of any incentive or operational payments. Only two of those six models have shown significant improvements in quality and four have met the criteria to be eligible for expansion. CMMI plans to broaden the definition of success for its models, adding metrics around health equity, person-centered care, and health system transformation.

CMS Releases Details of Ground Ambulance and Patient Billing Advisory Committee

On Dec. 13, the Administration announced the names of those selected to join the Ground Ambulance and Patient Billing (GAPB) Advisory Committee. The Committee's first meeting will be on Jan. 17 and Jan. 18, 2023. As established by the No Surprises Act, the GAPB Advisory Committee will make recommendations to improve the disclosure of charges and fees for ground ambulance services, better inform consumers of insurance options for such services, and protect consumers from balance billing.

CMS Issues Clarifying Guidance on Agent/Broker Compensation

On December 14, CMS issued a clarifying guidance on the Frequently Asked Questions (FAQ) on Agent/Broker Compensation and Guaranteed Availability of Coverage that was first published on June 7, 2022. The June 7th guidance clarified that arrangements that pay reduced (or no) commissions and other forms of compensation to agents and brokers who assist consumers with enrollment in individual market coverage during a Special Enrollment Period (SEP) and pay higher amounts for Open Enrollment Period (OEP) enrollments for the same benefit year violate the guaranteed availability provisions of the Affordable Care Act. This clarifying guidance supplements and does not supersede the FAQ published on June 7, 2022.

Monkeypox Public Health Emergency Expected to End Jan. 31

The U.S. Department of Health and Human Services (HHS) Secretary, Xavier Becerra, released a statement on the ongoing mpox outbreak, announcing that "given the low number of cases today, HHS does not expect that it needs to renew the emergency declaration when it ends on January 31, 2023." Mpox, formerly called monkeypox, was first declared a public health emergency by HHS on August 4, 2022.

CMS publishes the Qualified Health Plan Data Submission and Certification Timeline for the 2024 Plan Year

CMS released the Key Dates for Calendar Year 2024, Proposed Timing of Submission of Rate Filing Justifications for the 2023 Filing Year, and Proposed Timing of Qualified Health Plan (QHP) Data Submission and Certification for the 2024 Plan Year.

- **Proposed Key Dates for Calendar Year 2024: Qualified Health Plan (QHP) Data Submission and Certification, Rate Review; and Risk Adjustment.** The Key Dates document provides Proposed Key Dates for Calendar Year 2024 for 1) Qualified Health Plan (QHP) Certification in the Federally-facilitated Exchanges (FFEs); 2) Rate Review; and 3) Risk Adjustment. The proposed Key Dates document is available on the CMS Regulations and Guidance Page here.

- **Proposed Timing of Submission of Rate Filing Justifications for the 2023 Filing Year for Single Risk Pool Coverage Effective on or after January 1, 2024.** The 2023 Rate Review bulletin proposes guidance for purposes of establishing the submission deadlines under 45 CFR 154.220 for Rate Filing Justifications for single risk pool coverage in the individual and small group markets effective on or after January 1, 2024. The 2023 Rate Review Proposed Bulletin is available on the CMS Regulations and Guidance Page at directly at here.

- **Proposed Timing of Qualified Health Plan (QHP) Data Submission and Certification for the 2024 Plan Year (PY) for Issuers in the FFE.** The QHP Certification bulletin proposes submission deadlines for health insurance issuers applying to offer QHPs on the FFEs, including the timeline for PY 2024 QHP certification. The QHP Certification bulletin is available on the CMS Regulations and Guidance Page at here.

Coalition Highlights, Responds to Surprise Billing Lawsuits

The Coalition Against Surprise Medical Billing (CASMB) continues to shine a spotlight on attempts to weaken the No Surprises Act (NSA) through ongoing litigation and harmful practices that are overloading the Independent Dispute Resolution (IDR) system.

Why it matters: There is growing bipartisan concern that ongoing legal challenges to the law will delay, overturn or weaken implementation of the NSA, which would erode patient protections in the law.

The details: CASMB highlighted an article from Bloomberg discussing the harm being caused to health care systems across the country due to continued lawsuits against the NSA, including a third lawsuit recently filed by the Texas Medical Association. The lawsuit, which is against the Departments of Health and Human Services, Labor, and Treasury, challenges use of the Qualifying Payment Amount (QPA) in the arbitration process, arguing that there are certain aspects of the QPA calculation methodology that artificially deflate the QPA and financially harm providers.

- **An additional cause for concern** is a major backlog of unresolved claims due to the large influx of claims by providers and private equity-backed groups that are prioritizing higher payments in the arbitration process.

CASMB also sent a multi-stakeholder letter, including over 50 groups, to the tri-agencies expressing concern over continued litigation efforts attempting to undermine the NSA—a sentiment it echoed when air ambulance provider LifeNet filed the latest lawsuit challenging portions of the NSA final rule.

- **The letter additionally** highlighted the recent data from BCBSA and AHIP finding that the NSA prevented 9 million surprise medical bills in the first 9 months of 2022.

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/.**