Highmark's Weekly Capitol Hill Report

Issues for the week ending December 31, 2021

Federal Issues

Legislative

Senate Returns to Busy Agenda

The U.S. Senate reconvened this week to an active agenda that includes voting rights legislation, work on an omnibus spending package, and an attempt to restart the stalled Build Back Better talks.

First up is an attempt to pass voting rights legislation, which Senate Majority Leader Chuck Schumer wants to pass by the Martin Luther King holiday. To pass the legislation, Schumer and other Democrats must convince Sens. Joe Manchin (D-WV) and Kirsten Sinema (D-AZ) to vote to eliminate the filibuster, something both have said publicly they would not do.

In addition, appropriators will begin working on the FY 2022 government spending package, with the current funding deadline of February 18 looming. Democratic Senators will also meet as a group this week for the first time since Manchin announced his opposition to the Build Back Better reconciliation package just before Christmas.

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Federal Issues

Regulatory

Surprise Medical Billing Protections Take Effect; CMS Releases Guidance and Information on No Surprises Act

Beginning January 1, 2022, new federal protections will shield millions of consumers from surprise medical bills—unexpected bills from an out-of-network provider, out-of-network facility or out-of-network air ambulance provider. The protections, implemented under the No Surprises Act, ban surprise billing in private insurance for most emergency care and many instances of non-emergency care. Both insured and uninsured/self-pay individuals who are concerned that their rights have been violated now have access to a host of tools, including a help desk and webpage.

In late December, CMS published several guidance and information documents related to the No Surprises Act. Below are a few key documents:

- **External Review**: Guidance for states, plans and issuers on state external review processes regarding requirements in the No Surprises Act.

- **Independent Dispute Resolution (IDR) system and Notice of Consent requirements**: FAQs on implementation of the federal IDR system, notice and consent documents, and No Surprises Act provider applicability.

- **Consolidated Appropriations Act (CAA) Enforcement Letters**: Letters from multiple states that capture CMS' understanding of the Public Health Service Act provisions, as extended or added by the CAA, that each state is enforcing either directly or through a collaborative enforcement agreement, and the provisions that CMS will enforce. These letters also communicate whether the federal IDR process and the federal patient-provider dispute resolution process apply in each state, and in what circumstances. Additional letters will be added to this site in the coming weeks.

- **Guidance for Certified IDR Entities:** Provides certified IDR entities with an overview of the IDR process and their responsibilities as part of the process.

Tri-Agencies Release List of Certified Independent Dispute Resolution (IDR) Entities

The Departments of Health and Human Services, Labor and Treasury (Tri-Agencies) released a list of certified IDR entities for the federal IDR process between providers, facilities or providers of air ambulance services and group health plans, health insurance issuers and Federal Employees Health Benefits program carriers.

- Starting Jan. 1, 2022, if a provider or facility and a health plan cannot agree on the payment amount for an out-of-network service covered by the No Surprises Act, these organizations can be selected to make a payment determination.

- The application process opened Sep. 30, 2021, and the Tri-Agencies will continue to accept applications on a rolling basis. The website will be updated as additional organizations become certified.

HHS Gears Up for Implementation of New Good Faith Estimates

Starting January 1, new regulations require providers, facilities, and providers of air ambulance services to give an uninsured (or self-pay) individual, or their authorized representative, a good faith estimate of expected charges after an item or service is scheduled, or upon request. This process is meant to protect uninsured individuals from unexpectedly high medical bills.

The Department of Health and Human Services (HHS) released several guidance documents on this new process, including Guidance for Providers and Facilities, Guidance about Selected Dispute Resolution Entity, Guidance for Uninsured or (Self-Pay) Individuals and Guidance about the Administrative Fee.

Why this matters: As outlined in the guidance provided by HHS, the good faith estimate must include a list of items and services expected to be provided as part of the primary care in addition to items and services expected to be provided in conjunction with the primary care. If an uninsured (or self-pay) individual receives a bill that is at least $400 more than the expected charges on the good faith estimate, they can choose to initiate a new dispute resolution process, engaging a third-party entity certified by HHS to arbitrate their dispute. This process will decide how much the individual will pay to the provider or facility: the amount on the good faith estimate, the billed amount, or another amount in between the estimated amount and billed amount. There is a $25 administrative fee to utilize this dispute process.

Of note, individuals who have coverage through the commercial market, Medicare, Medicaid and other programs will also be able to request these cost estimates if they choose to not use their insurance for a health care service and instead pay out of pocket.

CMS Issues 2023 Payment Notice Proposed Rule, Payment Parameters Guidance, and Risk Adjustment Transfer Simulation Summary Report

On December 28, CMS issued the 2023 Notice of Benefit and Payment Parameters ("Payment Notice") proposed rule. The 2023 Payment Notice proposed rule will be published in the *Federal Register* on January 5. **Comments are due by January 27.**

CMS simultaneously released guidance on the Premium Adjustment Percentage, Maximum Annual Limitation on Cost Sharing, Reduced Maximum Annual Limitation on Cost Sharing, and Required Contribution Percentage for the 2023 Benefit Year ("Payment Parameters") as well as Summary Results for Transfer Simulations for the HHS-Operated Risk Adjustment Technical Paper, which was published on October 26.

CMS Issues Updates to Issuer Toolkit on COVID-19 Vaccines

CMS recently issued an update to the Toolkit on COVID-19 Vaccine—Health Insurance Issuers and Medicare Advantage Plans. CMS issued this toolkit to help health insurance issuers and Medicare Advantage plans identify issues to consider and address when providing coverage and reimbursement for COVID-19 vaccine administration. This version updates various information, including clarifying that "for CY 2022, Medicare payment for the COVID-19 vaccine (if providers do not receive it for free) and its administration for beneficiaries enrolled in a Medicare Advantage plan will be made by the beneficiary's Medicare Advantage plan."

Coalition Advocates to Renew Expiring CARES Act Telehealth Provision

The Alliance to Fight for Health Care, sent a letter to Treasury Secretary Janet Yellin and IRS Commissioner Charles Rettig asking for their support to help keep telehealth services affordable for workers with certain high-deductible health plans (HDHP) coupled with a health savings account (HSA). A key provision of the Coronavirus Aid, Relief, and Economic Security Act (CARES) Act of 2020 helped to make telehealth more affordable and flexible for those with a health savings account, but this flexibility expired on December 31, 2021.

The Alliance to Fight for Health Care is a broad-based coalition comprised of businesses, patient advocates, employer organizations, unions, health care companies, consumer groups and other stakeholders that support employer-provided health coverage.

A post on the AFHC website calls on the Treasury and the IRS to provide a policy of non-enforcement while Congress considers legislative solutions. There is currently bipartisan/bicameral legislation in Congress, the Telehealth Expansion Act of 2021 (S.1704/H.R. 5981), to extend this flexibility. The full text of the letter is available here.

IRS Issues Guidance on FY 2022 PCORI Fee

The Internal Revenue Service (IRS) issued Notice 2022-04, which provides the adjusted dollar amount for calculating the annual fee to fund the Patient-Centered Outcomes Research Institute ("PCORI Fee").

The applicable dollar amount that must be used to calculate the PCORI Fee imposed for plan years that end on or after October 1, 2021, and before October 1, 2022 is $2.79.

COVID-19 Updates

- President Biden announced that his Administration will purchase 500 million rapid, at-home COVID tests with the aim of providing free tests directly to Americans who want them beginning in January. This action is separate from the White House's earlier announcement that health insurers would be required to reimburse for over the counter (OTC) COVID-19 tests.

- The President also announced that they would be taking steps to increase hospital support and expanding vaccination capacity. A thousand military doctors, medics, and nurses will be deployed to COVID-burdened hospitals during the first two months of 2022 and the Federal Emergency Management Agency (FEMA) will set up new pop-up vaccination clinics nationwide alongside federal vaccination providers.

- The Food and Drug Administration (FDA) authorized two oral antivirals for treatment of COVID-19. The FDA first issued an emergency use authorization (EUA) for Pfizer's Paxlovid for treatment of mild-to-moderate COVID-19 for individuals 12 years and older who have tested positive and are at high-risk of developing severe illness. The FDA also issued an EUA for Merck's molnupiravir for treatment of mild-to-moderate COVID-19 for individuals 18 years and older at high-risk for severe illness. The agency did note that molnupiravir is not recommended for use during pregnancy.

- The Office for Civil Rights (OCR) at the U.S. Department of Health and Human Services (HHS) issued guidance on federal non-discrimination policies in COVID-19 vaccination programs. The guidance, which specifies enforcement of Section 1557 of the Affordable Care Act and Title VI of the Civil Rights Act of 1964, is intended to improve equity and COVID-19 vaccine disparities among communities most at risk.

State Issues

New York

Legislative

Pending Bills from 2021 Session Signed into Law

Amid a flurry of last-minute action on pending legislation from the 2021 session, Governor Hochul approved a handful of bills. The bills enacted were:

Mid-year formulary (A4668/S4111) - signed with chapter amendment
What it does: Generally prohibits a health care plan that provides essential benefits under the Affordable Care Act ("ACA") from, beginning on the same date as open enrollment and continuing through the end of the plan year: (1) removing a drug from its formulary; (2) moving a drug to a tier subject to increased cost sharing; and (3) adding utilization management restrictions, except at the time of enrollment or issuance.

A plan would be able to move a drug to a tier with higher cost-sharing if either: (1) an AB-rated generic or interchangeable biologic was simultaneously added to the formulary, or (2) if such change did not apply to insureds who either currently take such medication or have had, since the beginning of the plan year, a condition for which such drug is prescribed. Further, a plan would be permitted to remove a drug from its formulary or implement utilization review practices mid-year if the Federal Food and Drug Administration ("FDA") either removed a drug from the market or issued safety concerns, respectively.

Effective date: 1/1/23 *pending chapter amendment agreement

Anti-mail order (A5854/S3566) - signed
What it does: Modifies current law requiring insurers to permit enrollees to fill prescriptions at in-network retail, as opposed to mail order, pharmacies at the "same reimbursement amount" as provided to a network mail order pharmacy. The bill strikes language from current law which required such a retail pharmacy to consent "in advance, through a contractual network agreement" to the same reimbursement amount and to agree to the "same applicable terms and conditions" as an in-network mail order pharmacy. Further, the bill defines "same reimbursement amount" to mean that a plan must apply the same benchmark index (including average wholesale price), maximum allowable cost, and national prescription drug codes to all participating pharmacies.

Effective date: immediately

Rx EOBs (A3516/S7075) – signed with chapter amendment
What it does: Requires all insurers and HMOs to provide an EOB for all "pharmaceutical expenses" claims. It is our understanding that the chapter amendment will allow plans to provide these EOBs electronically and on a quarterly basis.

Effective date: 60 days after enactment (late Feb) *pending chapter amendment agreement

PBM Licensure & Registration (A1396/S3762) – signed with chapter amendment

What it does: Includes provisions that: (1) establish a duty to covered individuals, health plans, and providers; (2) establish a private right of action for providers and covered individuals to collect damages or seek injunctive relief; (3) prohibit the substitution of drugs; (4) preclude PBMs from requiring specialty pharmacies to become accredited by independent organizations; (5) require PBMs to disclose "all financial and utilization information" to payers or providers; (6) require registration with, and payment of a $1,000 annual fee to, the Department of Financial Services ("DFS"); and (7) authorize DFS, in consultation with the Department of Health ("DOH"), to issue regulations establishing standards for licensure, addressing conflicts of interest, and pertaining to consumer protection. Further, the bill establishes grounds for revocation of a license – including fraudulent or deceptive practices.

Effective date: 90 days after enactment (late March) *pending chapter amendment agreement

Early Intervention services covered lives assessment (A5339/S5560) – signed
What it does: Restructures the payment system for EI services by creating a statewide pool, funded by an increase to the covered lives assessment, from which municipalities and the State would be provided monies to cover related costs. For the fiscal year beginning in April 2022, the fund would contain $40 million, to be allocated amongst the State and municipalities in proportion to their respective shares of EI expenditures that were not reimbursed by Medicaid in the last 12-month period for which data is available. The bill also eliminates the obligation of private health coverage to cover EI services.

Effective date: 1/1/22

Industry Trends

Policy / Market Trends

Insurers Return $2 Billion in Rebates to Consumers in 2020

The Centers for Medicare and Medicaid Services (CMS) released additional information on the Affordable Care Act's (ACA) Medical Loss Ratio (MLR) for the 2020 reporting year. These files include 2020 MLR rebates by state and market, a list of issuers owing MLR rebates for 2020, and Public Use Files (PUFs) containing data from all health insurers' final MLR filings. According to CMS, the ACA MLR provisions resulted in approximately $2 billion in rebates for 9.8 million consumers for 2020. Of these consumers, 4.8 million were individual market consumers, 2.6 million were small group employees, and 2.4 million were large group employees. Rebates paid in 2021 for the 2020 reporting year reflect financial data for plan years 2018, 2019, and 2020.

CMS Reports Record Open Enrollment Gains through December 15

CMS announced 13.6 million people enrolled in individual market coverage for the 2022 plan year by the December 15 deadline for January 1 coverage. Of those, 9.7 million people enrolled in the 33 states using Healthcare.gov and nearly 3.9 million enrolled in the 18 states with State-based Marketplaces. Ninety-two percent of people who enrolled in Healthcare.gov states will receive premium tax credits for 2022 coverage and more than 400,000 of those receiving tax credits would have been ineligible for premium subsidies prior to the American Rescue Plan Act. The announcement of Marketplace enrollment through Week 6 of Open

Enrollment show enrollment gains are higher than the previous all-time high enrollment number reported for Healthcare.gov in 2018 and SBMs in 2021, respectively.

Open enrollment will continue through January 15, 2022, for coverage beginning on February 1.

CMS Releases Latest Enrollment Figures for Medicare, Medicaid, and CHIP

The Centers for Medicare & Medicaid Services (CMS) released the latest enrollment figures for Medicare, Medicaid, and the Children's Health Insurance Program (CHIP).

The June 2021 Medicaid and CHIP enrollment snapchat shows more than 83 million individuals have coverage through Medicaid and CHIP – an enrollment increase of over 430,000 individuals compared to May 2021 numbers. Additionally, CMS indicates that as of October 2021, the total Medicare enrollment is almost 64 million individuals and enrollment in Medicare Advantage is more than 27 million individuals. CMS also indicates that Medicare Part D enrollment is over 49 million, including enrollment in stand-alone Part D plans as well as MA plans with prescription drug coverage.

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/.**