Highmark's Weekly Capitol Hill Report

Issues for the week ending October 1, 2021

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Federal Issues

Legislative

Lawmakers Pass Temporary Government Funding, Reconciliation Talks Continue

On Thursday, Congress passed a nine-week continuing resolution (CR) that keeps government funding levels constant until Dec. 3. The stopgap funding measure was signed by President Biden late Thursday evening.

Why it matters: The move avoids a government shutdown, however, key elements of President Biden's Build Back Better agenda continue to hang in the balance. The path forward remains unclear after House Democrats failed last week to reach a consensus that would have allowed the Senate-passed bipartisan infrastructure bill to move forward with a vote that had been promised by House Speaker Nancy Pelosi (D-CA). Notably, the CR did not include a suspension of the debt ceiling, another issue that will have to be addressed by mid-October.

Progressive Democrats refused to support the bipartisan infrastructure bill unless it is accompanied by the finished reconciliation package. Moderates and progressives in the party continue to remain sharply

In this Issue:

divided on the size, scope and timing of the budget reconciliation package. The House Budget Committee has consolidated elements that were approved by the various committees of jurisdiction in September into a single package. However, negotiations on the package continue and key provisions could be scaled back or changed as the topline spending figure for the package likely shrinks from $3.5 trillion to about $2 trillion.

Industry Trends

Policy / Market Trends

- **AARP Report Finds Prices on Specialty Drugs Increased by More Than 3x the Rate of Inflation**

Federal Issues

Regulatory

Administration Releases Surprise Billing Interim Final Rule

The Biden Administration released a pre-publication version of an interim final rule with comment period (IFC), to further implement two major components of the No Surprises Act which takes effect in January 2022.

Background:

- The No Surprises Act requires health care providers and health plans serving commercially insured consumers to hold the consumer harmless when a service is provided by an out-of-network provider (often without the consumer's knowledge) by only requiring the consumer to pay the in-network cost-sharing amount.
- This is the second IFC the Biden Administration has issued to implement provisions of the No Surprises Act, enacted in December 2020 as part of the Consolidated Appropriations Act.
- The law, and this IFC, provides for a "baseball style" independent dispute resolution (IDR) process in which an arbitrator determines the provider's final payment when the health plan and provider cannot agree during a 30-day open negotiation period.

Why this matters: This IFC addresses the IDR process, good faith estimates for uninsured individuals, the patient-provider dispute resolution process, and expanded rights to external review. Among the issues the insurance industry was closely watching in these rules was the role of the qualifying payment amount (QPA) – generally the plan or issuer's median contracted rate for the same or similar service in the specific geographic area – in the IDR process. In this latest rule, the Departments establish that "[w]hen making a payment determination, certified independent dispute resolution entities must begin with the presumption that the QPA is the appropriate OON amount." That directive in the interim final rule closely aligns with the recommendation the insurance industry offered through trade associations throughout this year.

The regulations in the rule are generally applicable to group health plans and health insurance issuers for plan and policy years beginning on or after January 1, 2022.

CMS also released a fact sheet on the rule as well as technical guidance on calendar year 2022 fees for certified IDR entities. There is also a new CMS website dedicated to ending surprise medical bills, including the application to become an IDR entity. Additionally, the Departments released 11 notices of information collection under the Paperwork Reduction Act for documents related to the IDR process, including a notice to begin the open negotiation period, to initiate IDR, to select an IDR entity, and to submit an offer.

The interim final rule also implements requirements on a provider or facility to provide a good faith estimate of expected charges to an uninsured (or self-pay) patient for a scheduled item or service. If the estimate is $400 less than the actual charges, the consumer has a right to initiate a dispute resolution process handled by "select dispute resolution" (SDR) entities

Comments are due December 6.

- **AHIP President and CEO Matt Eyles** released a statement following the release of the interim final rule. The statement reads, "the Administration's approach signals a strong commitment to consumer affordability and lower health care spending through an independent dispute resolution process that should encourage more providers to join health plan networks. We are particularly encouraged to see the rules conform to the intent of the No Surprises Act and direct that arbitration awards must begin with a presumption that the appropriate out-of-network reimbursement is the qualified payment amount. This is the right approach to encourage hospitals, health care providers, and health insurance providers to work together and negotiate in good faith. It will also ensure that arbitration does not result in unnecessary premium increases for businesses and hardworking American families."

- **The Coalition Against Surprise Medical Billing** (CASMB) also issued a press statement. The statement reads, "we appreciate that these rules adhere to and reinforce the statute which calls for the qualifying payment amount (QPA) to be the primary and overriding consideration for final payment determinations as part of the independent dispute resolution (IDR) process. For patients to be protected from abuse and misuse of IDR and to achieve the full cost-savings projected by the Congressional Budget Office, it is essential that the final rules maintain limits on arbitration. We look forward to working with the Administration and Congress to ensure that millions of Americans are safeguarded from surprise medical bills and out-of-network charges moving forward."

OCR Issues Guidance on Workplace Vaccinations and Privacy

The U.S. Department of Health and Human Services' (HHS) Office for Civil Rights (OCR) issued guidance on COVID-19 vaccinations, the workplace and the Health Insurance Portability and Accountability Act of 1996 (HIPAA) Privacy Rule. The guidance addresses several workplace scenarios and answers questions about whether and how the HIPAA Privacy Rule applies, such as asking customers if they have received a COVID-19 vaccine or requiring a workforce member to disclose whether they have received the vaccine to the employer, clients, or other parties.

The guidance makes note that the HIPAA Privacy Rule only applies to HIPAA covered entities (health plans, health care clearinghouses, and health care providers that conduct standard electronic transactions), and, in some cases, to their business associates.

CMS Provides First Glimpse at 2022 Medicare Advantage and Part D Plans

The Centers for Medicare & Medicaid Services (CMS) issued a press release and state fact sheets on Medicare Advantage (MA) and Medicare Prescription Drug plan options for 2022.

Why this matters:

- CMS projects MA enrollment to reach 29.5 million people in 2022. In addition, 25% of plans will be offering special supplemental benefits for chronically ill enrollees in 2022, up from 19% of plans in 2021.
- Furthermore, CMS states that the average premium for MA plans will be lower in 2022 at $19 per month, compared to $21.22 in 2021, while projected enrollment continues to increase.
- And, as previously announced, CMS projected the average 2022 premium for Part D coverage at $33 per month, compared to $31.47 in 2021.

Future CMS announcements will likely provide greater detail on the 2022 plans, including more detailed information on supplemental benefits and star ratings. CMS also noted an increase in the number of Medicare Advantage Special Needs Plans focusing on serving so-called "Duals", low-income Medicare beneficiaries who have both Medicare and Medicaid. The data release on next year's plans is part of the normal run of activities CMS undertakes in advance of Medicare's open enrollment season, which runs October 15 to December 7. CMS also released information on its Medicare Advantage value-based insurance design (VBID) model, which will have more than 1,000 participating plans this year—the most ever.

COVID-19 Updates

- Pfizer and BioNTech have submitted data to the Food and Drug Administration on the safety and efficacy of their COVID-19 vaccine in children ages 5-11. The companies said Tuesday that they had shared the data with FDA for "initial review," and planned to apply for an emergency-use authorization in the coming weeks. Pfizer and BioNTech said their COVID-19 shot was safe and provoked a strong antibody response in children 5-11 years old in a late-stage trial. The immune response seen in kids enrolled in the study was similar to that seen in teens and young adults, even though the children were given a smaller dose. The companies have not released detailed data from the study but say that they planned to publish the findings in a peer-reviewed scientific journal.

State Issues

Delaware

Legislative

Primary Care Bill Signed Into Law

Governor John Carney last week signed Senate Substitute 1 for Senate Bill 120 into law. Citing shortfalls in primary care resources and assessing that current Delaware law does not ensure adequate investment in primary care health care structures and services, Senate Substitute No. 1 for Senate Bill No. 120 is intended to strengthen the primary care system in Delaware by:

(1) Directing the Health Care Commission to monitor compliance with value-based care delivery models, and develop and monitor compliance with alternative payment methods that promote value-based care;
(2) Requiring rate filings limit aggregate unit price growth for inpatient, outpatient, and other medical services to certain percentage increases over the next 5 years;
(3) Requiring an insurance carrier to spend a certain percentage of its total cost on primary care over the next 4 years;
(4) Requiring the Office of Value-Based Health Care Delivery ("OVBHCD") to establish mandatory minimums for payment innovations, including alternative payment models, and evaluate annually whether primary care spending is increasing in compliance with the established mandatory minimums for payment innovations.

The legislation also revises the appointment process for members of the Primary Care Reform Collaborative who are not members by virtue of position.

State Issues

New York

Regulatory

DFS Issues Circular Letter to Suspend Utilization Review

Yesterday, the Department of Financial Services (DFS) finalized a Circular Letter requiring health plans to suspend utilization review (UR) activities at hospitals which certify they have a staffing shortage. This followed last week's meeting between hospital and health plan associations that ended with no consensus on the issue. Suspension of UR was one of the provisions in Governor Hochul's 9/27 Executive Order aimed at mitigating staff shortages due to the state's vaccine mandate.

The Circular Letter provides that health plans must suspend retrospective review and prior authorization for inpatient and outpatient services for 30 days (until 10/27) at hospitals certifying they have a staff shortage. It was accompanied by a certification template hospitals must submit to plans.

State Issues

Pennsylvania

Legislative

State Lawmakers Approve Critical Emergency Waivers and Flexibilities

Pennsylvania lawmakers last week agreed to preserve critical COVID-19 emergency waivers and flexibilities through March 2022. Governor Wolf signed House Bill 1861 (now Act 73 of 2021) to preserve the regulatory waivers and flexibilities that have supported the hospital response during the pandemic.

In addition to extending many of the COVID-19 related waivers and administrative flexibilities, House Bill 1861 also requires final reports to be issued by each authority that initially authorized an extended regulatory statute suspension no later than May 1, 2022. The report shall include a list of each suspension extended, including a reference to the suspended statute, order, rule, or regulation. For each suspension, the termination date shall also be included in the report.

The Department of Health updated its guidance to acute care providers and facilities to reflect the extension through March 31, 2022.

Why this matters: Hospitals urged lawmakers to take action before the September 30 deadline to preserve expanded access to telehealth, pharmacy vaccines, and other essential regulatory relief that have supported the hospital response during the pandemic.

In related action, Pennsylvania lawmakers last week approved Senate Bills 397 and 398. The legislation has been placed on Governor Wolf's desk and is awaiting his signature. This legislation will:

- Ensure physician assistants can practice immediately upon the filing of an executed supervisory agreement, eliminating administrative approval delays that can extend 120 days or longer
- Allow physicians to supervise up to six physician assistants
- Give physician assistants and physicians more flexibility to decide how they want to work together in their daily practice
- Place a physician assistant on the medical and osteopathic boards with a permanent seat

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Industry Trends

Policy / Market Trends

AARP Report Finds Prices on Specialty Drugs Increased by More Than 3x the Rate of Inflation

A new blog post from the Campaign for Sustainable Rx Pricing highlights the latest Rx Price Watch report from AARP. The report finds price hikes have "consistently exceeded" the general rate of inflation since 2006 and that between 2019 and 2020 this rate of increase was almost three-and-a-half times greater than inflation. According to the report, drug manufacturers hiked prices on 180 selected specialty medications in 2020 by an average rate of 4.8%, while the rate of inflation during that same period was only 1.3%.

Why this matters: These price hikes are contributing to a crisis of affordability, as Americans across the country continue to be unable to afford prescription drugs they need. As the report states, "In 2020, the average annual cost of therapy for a single specialty prescription drug, based on the market basket used in this study, was $84,442 per year. This average annual cost was almost $20,000 higher than the median US household income and nearly three times the median income for Medicare beneficiaries."

The report builds the case that brand name drug makers are targeting price hikes on specialty medications, as these medications are increasingly being used to treat common chronic conditions.

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/.**