Highmark's Weekly Capitol Hill Report

Issues for the week ending October 27, 2023

Federal Issues

Legislative

House Elects New Speaker

On Wednesday, House Republicans elected Rep. Mike Johnson (R-LA) as the next Speaker of the House of Representatives in a 220-209 vote. The vote ended the weeks-long search for a new Speaker that revealed significant discord among House Republicans, after they removed former Speaker Kevin McCarthy (R-CA-20) and rejected three subsequent nominees.

Why this matters: With the election of the new Speaker, the House can now resume regular legislative activity. Speaker Johnson sent a Dear Colleague to the Conference laying out House Republicans' agenda between now and the end of the year. On that list is a potential continuing resolution to fund the government into next year.

Speaker Johnson was first elected to the House in 2016. He is the former chairman of the Republican Study Committee (RSC) and currently serves as the Vice Chair of the Republican Conference. He also serves on the Armed Services and Judiciary Committees. Prior to his election to the House, he worked as a constitutional litigator and served in the Louisiana Legislature from 2015-2017. While not

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much is known of his health care positions, he published a policy paper during his time at the RSC - A Framework for Personalized, Affordable Care. Regardless, he will likely defer to committee chairs and the broader conference as to any health care agenda in this Congress.

Federal Issues

Regulatory

Administration Releases Surprise Billing IDR Operations Proposed Rule

On Oct. 27, The Departments of Health and Human Services, Labor and Treasury (Departments) released a Notice of Proposed Rulemaking (NPRM) and corresponding Fact Sheet on the operations of the No Surprises Act (NSA) Independent Dispute Resolution (IDR) process. This NPRM is intended to resolve existing challenges in the IDR process and facilitate improved communications and between payers, providers and certified IDR entities.

The NPRM includes the following key components:

- Establishes new requirements for the information that health plans must include at the time of their initial payment or notice of denial of payment for certain items and services
- Establishes new batching requirements to allow certain items to be batched in the same payment determination under additional circumstances. The Departments also propose limiting batched determinations to 25 line items in a single dispute
- Amends certain requirements related to the open negotiation period, including centralizing the process through the federal IDR portal and adjusting the content included in the open negotiation notice
- Amends the payment and collection of administrative fees and IDR entity fees. The Departments propose to collect the non-refundable administrative fee directly from the disputing parties and lay out requirements for when the initiating and non-initiating parties would be required to pay the fee. Additionally, the Departments propose a reduced administrative fee structure and amounts for parties in low-dollar disputes, as well as a reduced administrative fee for non-initiating parties in ineligible disputes.
- Requires plans to communicate information using claim adjustment reason codes (CARCs) and remittance advice remark codes (RARCs) when providing any paper or electronic remittance advice to an entity that does not have a contractual relationship with the plan

- Requires IDR entities to determine eligibility within five business days of final IDR entity selection and notify both parties.

- Defines bundled payment arrangements

- Amends the rules for extensions of timeframes due to extenuating circumstances

Next Steps: The proposed rule has a 60-day comment period, with comments expected to be due on or around Jan. 2, 2024.

COVID Commercialization: HHS Releases Therapeutics Sunsetting Guidance

The U.S. Department of Health and Human Services (HHS) released a COVID-19 treatments transition operational guide to assist with preparations for the transition of COVID-19 therapeutics, specifically nirmatrelvir packaged with ritonavir, Paxlovid, manufactured by Pfizer; and molnupiravir, Lagevrio, manufactured by Merck, from a U.S. government-managed distribution process to traditional commercial distribution.

The guide provides new national drug codes (NDCs) for commercial products, information about inventory and disposal management, transition timelines, and patient assistance programs.

Ordering and Distribution Timelines: The guide provides a projected timeline based on manufacturers' commercialization plan but notes that timing is subject to change.

On November 1, 2023, Lagevrio and Paxlovid commercial products will be available for purchase through commercial channels using unique NDCs relative to the USG-procured supply. However, HHS instructs that for both products, USG-procured products should be dispensed to patients until depletion or expiration, whichever comes first.

Patient Assistance Programs

Paxlovid: A patient assistance program operated by Pfizer will be available for eligible patients. Health care providers and dispensing locations can share information with patients regarding eligibility and enrollment in the program to obtain free product.

- *Uninsured and federally covered individuals:* This program will use USG supply and will be available starting around December 1, 2023, through December 31, 2024. More information is expected around December 1.

  Through December 31, 2024, individuals covered under federal programs, such as Medicare or Medicaid, and uninsured patients are eligible for the patient assistance program and can receive Paxlovid at no cost. Starting January 1, 2025, eligible uninsured and underinsured patients can receive USG procured, NDA-labeled Paxlovid at no cost. Participating dispensing sites will be sent replacement product for any dispensed product within this program.

- *Commercially insured individuals:* Pfizer will also be operating a Paxlovid co-pay savings program for eligible commercially insured patients. This is estimated to become available on November 1.

Lagevrio : As USG supply is depleted, a Merck Patient Assistance Program (a 501c3 Foundation) intends to provide Lagevrio free of charge to eligible patients who, without assistance, could not otherwise afford the product. HHS reports information will be available on November 1.

Administration Files Appeal in Surprise Billing Court Decision

The Department of Justice (DOJ) filed a notice of appeal in the *Texas Medical Association v. HHS* (TMA III) court decision, which was primarily a challenge to the qualifying payment amount (QPA) calculation methodology under the No Surprises Act (NSA). The DOJ did not include a request for a stay of the court decision.

Why this matters: *TMA III*, comprising lawsuits filed by the Texas Medical Association and various air ambulance providers in the Eastern District of Texas, involves challenges to regulations and guidance establishing the methodology used to calculate the qualified payment amount (QPA) and other independent dispute resolution (IDR) processes under the *No Surprises Act*. The lower court's decision, while mixed, largely favored providers, with the court finding many of the challenged portions of the regulations conflict with the plain terms of the Act and should be set aside and vacated.

Next Steps: Given the recency of the appeal, a briefing schedule has not yet been set and it remains to be seen whether the federal government will seek to fast-track the proceedings.

This appeal follows the frequently asked questions (FAQs) recently released by the Departments of Health and Human Services, Treasury and Labor, which addressed updates to QPA calculations and other elements of the NSA following the *TMA III* court decision.

CDC Revises RSV Immunization Recommendation Amid Drug Shortages

The Centers for Disease Control and Prevention (CDC) issued a Health Alert Network Health Advisory to provide options for clinicians in the context of a limited supply of nirsevimab, the monoclonal antibody product recommended for infants and young children to protect against respiratory syncytial virus (RSV)-associated lower respiratory tract disease. The recommendations include:

- Prioritizing available nirsevimab 100mg doses for infants at the highest risk for severe RSV disease, including infants (age <6 months) and young children with underlying conditions that place them at the highest risk for severe RSV disease.

- Providers are advised against using two 50mg doses for infants weighing 11lbs or more to preserve the supply of 50mg doses for those most in need.

- Providers should suspend use of nirsevimab in palivizumab-eligible children, aged 8 to 19 months for the 2023-2024 RSV season; these children should receive palivizumab per American Academy of Pediatrics recommendations.

- Prenatal providers should discuss potential nirsevimab supply concerns when counseling pregnant people about the maternal RSV vaccine (Abrysvo), as maternal vaccination is effective and will reduce the number of infants requiring nirsevimab during the RSV season.

Mandy Cohen, Director of the CDC, indicated that the agency is working with nirsevimab's manufacturers to try to alleviate shortages.

CMS Publishes Key 2024 Open Enrollment Information for ACA Marketplaces

The Centers for Medicare & Medicaid Services (CMS) launched Healthcare.gov window shopping ahead of the 2024 Open Enrollment period. Consumers can begin to preview plans and prices on Healthcare.gov in advance of Open Enrollment, which begins on November 1 and runs through January 15.

CMS released information on 2024 issuer participation, consumer choice, average premiums, and financial assistance in the states using Healthcare.gov in the 2024 Qualified Health Plan (QHP) Landscape Report and Open Enrollment Fact Sheet. Key takeaways include:

- **Consumer Choice**: The average American will have a choice of just under 7 QHP issuers, similar to 2023, and 96% of enrollees have access to three or more issuers.

- **Issuer Participation:** 210 QHP issuers will participate in the HealthCare.gov Marketplaces. In 2024, 8 states and 23 counties will have more QHP issuers participating compared to 2023.

- **Average Premiums:** The average second lowest cost silver plan (SLCSP) premium increased by 4% from plan year 2023 to 2024. This matches the increase from plan year 2022 to 2023.

- **Subsidies**: As a result of the extension of enhanced premium subsidies through the passage of the Inflation Reduction Act, four in five HealthCare.gov customers will be able to select a QHP for $10 or less per month after subsidies.

CMS released additional resources including Plan Year 2024 State-based Marketplace Open Enrollment information.

Similar to last year, CMS plans to release enrollment snapshots for HealthCare.gov and State-based Marketplaces throughout the Open Enrollment Period.

Biden Administration Rolls Out Cybersecurity Toolkit for Health Care Industry

The Biden Administration is ramping up efforts to harden defenses around the U.S. health care infrastructure, releasing an updated cyber "toolkit" to help the sector better defend against hackers. This year alone, the Cybersecurity and Infrastructure Security Agency (CISA) provided pre-ransomware notifications to roughly 65 U.S. health care organizations to stop ransomware encryption and warn entities of early-stage ransomware activity.

Why this matters: The Health and Human Services Department (HHS) and CISA jointly released the toolkit that includes ways for the health sector to mitigate risk, such as vulnerability scanning, best

practices, and a framework for accessing and improving cyber resiliency. HHS Deputy Secretary Andrea Palm stated that it's part of a broader set of tools HHS has been releasing over the last year to help improve cyber hygiene across the sector.

CMS Releases Resource Guide on Medicaid Redeterminations

The Centers for Medicare & Medicaid Services (CMS) released a policy and operational resource guide slide deck highlighting different options that a state may pursue during the Medicaid redetermination process. For example, the memo discusses different options available to a state during an ex parte review, including holding the review to gather more information, treating the ex parte determination as final, or a combination of both. This information is intended to provide an order of operations for redetermination practices. Read More

Industry Trends

Policy / Market Trends

New Study Highlights Growing Concerns of Workforce Shortages

A strained health care system may be heading in a dangerous direction in the pandemic's aftermath, according to a new report published this month by Kaufman Hall. Since the pandemic, hospitals and health systems have struggled to attract and retain enough staff. 2/3 of respondents, comprising hospitals, health systems, and medical groups, said staffing shortages have forced them to run at less than full capacity at some point over the past year. According to the report:

- 63% of respondents said they are struggling to meet patients' demand for care,
- Nearly 1/3 of respondents said patients' concerns and complaints about access to care are increasing,
- Patients are having a harder time getting appointments; and
- Nearly half of practicing U.S. physicians are older than 55, meaning while the demand for care is increasing, the number of providers is diminishing.

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/.**