Holland & Knight

H&K Health Dose: June 25, 2024

A weekly dose of healthcare policy news

The U.S. Senate is in recess until July 8, 2024. The U.S. House of Representatives is in session until its Independence Day break next week. Accordingly, Holland & Knight Health Dose will also be on a break next week.

While in session, the House will consider three appropriations bills for fiscal year (FY) 2025 on defense, homeland security and state-foreign operations. Also, the House Committee on Ways and Means (W&M) Subcommittee on Health will host a hearing on value-based care. The committee is also expected to announce a markup of three bills impacting healthcare innovation related to Medicare coverage of GLP-1 medications for obesity, multi-cancer screening tests and breakthrough devices.

LEGISLATIVE UPDATES

Updated Data Privacy Legislation; Expected E&C Markup

The House Committee on Energy and Commerce (E&C) leadership recently circulated a revised draft of the American Privacy Rights Act (APRA), which was approved by the E&C Committee's Subcommittee on Innovation, Data and Commerce in May 2024. The updated measure is expected to be introduced by E&C Committee Chair Cathy McMorris Rodgers (R-Wash.) and Ranking Member Frank Pallone (D-N.J.) early this week, with a markup planned for June 27, 2024. Notable changes from the version previously approved by the subcommittee include the removal of a section on artificial intelligence (AI) algorithms and civil rights. The bill's scope is broader than healthcare but has healthcare implications.

MedPAC June 2024 Report

The Medicare Payment Advisory Commission (MedPAC) recently released its June 2024 Report to the Congress, "Medicare and the Health Care Delivery System." The report covers the following topics:

- approaches for updating clinician payments and incentivizing participation in alternative payment models
- provider networks and prior authorization in Medicare Advantage (MA)
- assessing data sources for measuring healthcare utilization by MA enrollees
- paying for software technologies in Medicare
- considering ways to lower Medicare payments for select conditions in in-patient rehabilitation facilities
- Medicare's Acute Hospital Care at Home

REGULATORY UPDATES

CMS Announces Conclusion of AAP Program for Change Healthcare Cyberattack

In a recent press release, the Centers for Medicare & Medicaid Services (CMS) announced that after July 12, 2024, CMS will no longer accept new applications for Change Healthcare/Optum Payment Disruption (CHOPD) accelerated or advance payments. CMS notes that any providers or suppliers that are having difficulty billing or receiving claim payment at this point should contact Change Healthcare and/or their Medicare Administrative Contractor. CMS noted that accelerated payments have been issued to more than 4,200 Part A providers, totaling more than $2.55 billion. CMS also notes that it issued 4,722 advance payments, totaling more than $717.18 million, to Part B suppliers, including doctors, non-physician practitioners and durable medical equipment suppliers.

Information Blocking Final Rule

The U.S. Department of Health and Human Services (HHS) released an Information Blocking Final Rule on June 24, 2024, which establishes disincentives for healthcare providers under the 21st Century Cures Act authority. The rule will become enforceable 30 days after it has been posted in the *Federal Register*. Under the rule, if the Office of Inspector General (OIG) investigates a claim of information blocking by a healthcare professional and OIG deems the healthcare professional to have committed information blocking, the healthcare professional will be subject to disincentives under the Quality Payment Program (QPP), the Medicare Shared Savings Program (Shared Savings Program) and the Medicare Promoting Interoperability Program.

Under the QPP, clinicians who are determined to have committed information blocking will not be a meaningful Electronic Health Record (EHR) user under the Promoting Interoperability (PI) performance category of the Merit-based Incentive Payment System (MIPS). Such determination will result in a zero score in the category.

Accountable Care Organizations (ACOs) or healthcare professionals who are part of an ACO that are found to have committed information blocking will be barred from the Shared Savings Program participation for one year.

Hospitals and critical access hospitals (CAHs) who are determined to have committed information blocking will not be a meaningful EHR user under the Medicare Promoting Interoperability Program. Therefore, such hospitals will be barred from earning three quarters of the annual market basket increase (a benefit of meaningful EHR user determination). A CAH found to have committed information blocking will have payment for the corresponding reporting year reduced to 100 percent of "reasonable costs." Various physician and hospital groups have spoken out about the negative impacts this rule will inadvertently create for patient care and administrative burden.

CY 2025 MPFS and OPPS Proposed Rules Forthcoming

CMS is expected to soon release its annual fees schedules impacting Medicare payment rates and policies. Under the Medicare Physician Fee Schedule (MPFS), CMS will likely propose a cut to the 2025 conversion factor (CF) in the calendar year (CY) 2025 PFS proposed rule. U.S. Congress has enacted temporary partial fixes. The most recent is set to expire at the end of this year. Since the total relief that was provided, 2.93 percent, only lasts for one year – CMS must cut at least that amount from the 2025 CF in the CY 2025 physician fee schedule (PFS) proposed rule. While the size of the cut isn't known until CMS announces its proposal, any cut to the conversion factor will be on top of CF cuts in previous years.

Telehealth policies are expected to be addressed in the MPFS. However, due to lack of certainty on Congress' potential extension of COVID-era telehealth waivers, CMS is in a tight spot. Misalignment is likely inevitable, and without congressional action, CMS is forced to proceed under the assumption that the legislation may not be enacted. Both E&C and W&M Committees have recently taken action on the issue, though the length of telehealth coverage extension differs by committee. The probability of any legislation on the issue progressing before August 2024 recess is minute, with an end-of-year package as the most likely vehicle, meaning that CMS would have to address any overlap retroactively. CMS could propose some big changes to the MIPS, the major quality performance program for physicians in Medicare, for the 2025 performance period.

CBO Releases Updated Data on 340B Spending

The Congressional Budget Office (CBO) has released new data on 340B drug discount program spending. CBO's analysis found that spending on cancer treatments, immunosuppressants and anti-infective agents comprised 70 percent of total program spending in 2021, up from 58 percent in 2010. The analysis also found that 88 percent of the growth in program spending stems from drugs prescribed by hospitals and their affiliated clinics. CBO notes that only a portion of the growth in 340B spending can be explained by market-wide trends or by disproportionate growth in spending on certain classes of drugs. Other factors that may have contributed to the growth in 340B spending include integration of hospitals and clinics, expanded facility participation due to the Affordable Care Act (ACA) and expanded use of contract pharmacies.

Impending Supreme Court Rulings

The U.S. Supreme Court is expected to return 10 more rulings this season, including decisions on the Emergency Medical Treatment & Labor Act, *Chevron* deference and whether former President Donald Trump is immune from prosecution in the pending election interference case – all of which will have implications for healthcare. After previously announcing the court would hand down opinions on June 26, 2024, the court's website has been updated to add June 27-28, 2024, as opinion days as well.