

H&K Health Dose: September 12, 2023

A weekly dose of healthcare policy news

LEGISLATIVE UPDATES

This Week: Pivotal Week on Spending

There is much to accomplish before the Sept. 30, 2023, deadline for U.S. Congress to act to fund the federal government. The two chambers remain in vastly different places on government funding levels. It also remains to be seen if a continuing resolution (CR) can be reached in time, if emergency funding – including increases for Ukraine and the Federal Emergency Management Agency (FEMA) – will be included or if a government shutdown is imminent.

Congress has used CRs to extend government funding through December over the last three years. This year, the U.S. House of Representatives has passed just one of the 12 annual appropriations bills – legislation to fund military construction, veterans affairs and related agencies – while the U.S. Senate has passed none, but reported all 12 bills out of committee before the August 2023 recess. Republicans in the House continue to have internal disagreements regarding overall spending levels and policy riders. Government funding negotiations could be further complicated by the need to attach the administration's supplemental funding request. The latest debt limit deal included a provision to trigger a 1 percent across-the-board discretionary spending cut if the government is not fully funded by Jan. 1, 2024.

Lower Cost, More Transparency Act Health Bill Released

On the healthcare front, movement is taking shape in the House. Last week, House Committee on Energy and Commerce Chair Cathy McMorris Rodgers (R-Wash.), Ranking Member Frank Pallone Jr. (D-N.J.), House Committee on Ways and Means Chair Jason Smith (R-Mo.) and House Committee on Education and the Workforce Committee Chair Virginia Foxx (R-N.C.) introduced the Lower Costs, More Transparency Act (a section-by-section summary is available). This bill incorporates bipartisan policy provisions that have advanced from the three committees. Key provisions in the bill include:

- Codify and enhance hospital price transparency requirements
- Health insurance and health plan price transparency requirements
- Site-neutral payments related to ambulatory payment classification (APC) groups for drug administration performed at off-campus outpatient departments
- Pharmacy benefit managers (PBMs) and drug pricing reform, including requirements for group plan sponsors and a ban on Medicaid spread pricing
- Extension of community health center funding and the Special Diabetes Program
- Elimination of Medicaid disproportionate share hospital cuts for fiscal years (FYs) 2024-2025

While the House will likely to take action quickly on the aforementioned bill, it is unlikely that the Senate will act on it immediately. Instead, it will inform negotiations with the Senate on what would likely be a year-end healthcare package.

Sen. Cassidy Releases White Paper of Artificial Intelligence

On Sept. 6, 2023, the Senate Committee on Health, Education, Labor, and Pensions (HELP) Ranking Member Bill Cassidy (R-La.) released a white paper on artificial intelligence (AI) entitled "Exploring Congress' Framework for the Future of AI: The Oversight and Legislative Role of Congress Over the Integration of



Artificial Intelligence in Health, Education, and Labor." Sen. Cassidy is seeking feedback on regulating the Al industry and how to ensure Al technology is designed, developed and deployed in a manner that protects Americans' rights and safety. Comments are due by Sept. 22, 2023.

Sen. Cassidy Releases RFI on Improving Health Data Privacy

Sen. Cassidy (R-LA) requested information from stakeholders on Sept. 7, 2023, on how to enhance the privacy protections of health data to safeguard sensitive information while balancing the need to support medical research. He emphasized that health data that is collected from new technologies such as wearable and smart devices, as well as health and wellness apps are not protected under the Health Insurance Portability and Accountability Act (HIPAA). Sen. Cassidy said that the aim of this request for information (RFI) is to use stakeholder feedback to identify solutions to modernize HIPAA and ensure all health data is properly safeguarded. Comments are due by Sept. 28, 2023.

Committee on Ways and Means Seeks Comment on Disparities in Rural and Undeserved Communities

House Committee on Ways and Means Chair Jason Smith (R-Mo.) requested on Sept. 7, 2023, that the healthcare community comment and contribute solutions to address disparities in access to care that exist for millions of Americans – particularly those in rural and underserved communities. As part of the RFI, Rep. Smith highlights five key areas of interest: 1) payment disparities between different geographic areas, 2) the long-term financial health of providers and facilities, 3) payments for identical care provided in varying sites of service, 4) bringing new professionals into the healthcare workforce and 5) innovative care models and technology to improve patient outcomes. Comments are due on Oct. 5, 2023.

REGULATORY UPDATES

CMS Allows Submitted IDR Requests to Continue

The Centers for Medicare & Medicaid Services (CMS) said on Sept. 5, 2023, that independent dispute resolution (IDR) entities could continue processing eligibility determinations for single and bundled disputes submitted on or before Aug. 3, 2023. CMS said the IDR portal remains closed for new disputes following a recent court ruling.

HHS OIG Releases Report on Medicare Drug Pricing

The U.S. Department of Health and Human Services (HHS) Office of Inspector General (OIG) released a report, "Medicare Part B Drug Payments: Impact of Price Substitutions Based on 2021 Average Sales Prices." The report found that since 2013, Medicare and its enrollees have saved \$73.4 million as a result of CMS' price-substitution policy for Part B covered drugs. In 2021, CMS lowered Medicare payment amounts for 13 drugs, resulting in \$273,000 in savings. The report further noted that in 2021, Medicare and its enrollees could have realized an additional \$889,000 in Medicare savings if CMS had expanded the price-substitution criteria.

CMS Proposes Minimum Staffing Standards for LTC Facilities

CMS released a proposed rule on Sept. 1, 2023, "Medicare and Medicaid Programs; Minimum Staffing Standards for Long-Term Care (LTC) Facilities and Medicaid Institutional Payment Transparency Reporting." The proposed rule would establish comprehensive nurse staffing requirements to hold nursing homes accountable for providing safe and high-quality care in Medicare- and Medicaid-certified LTC facilities.



The proposal would require at least one registered nurse onsite 24 hours a day and require each resident to have 0.55 hours of attention a day from a registered nurse and 2.45 hours from nurse aides. CMS estimates that about 75 percent of nursing homes would have to increase staffing in their facilities under the proposed standards. For more information, the CMS press release and fact sheet are available. For a detailed look at the proposal, see Holland & Knight's alert, "CMS Proposes Minimum Staffing Standards for Long-Term Care Facilities," Sept. 7, 2023.

HHS Issues Nondiscrimination Proposed Rule

The HHS Office for Civil Rights (OCR) issued a proposed rule on Sept. 7, 2023, to update and clarify nondiscrimination requirements for recipients of HHS funding (e.g., Medicare providers). The proposed rule clarifies the application of Section 504 of the Rehabilitation Act of 1973, which implements the prohibition of discrimination on the basis of disability to several areas not explicitly addressed through the existing regulation, including medical treatment decisions; the use of value assessments; web, mobile and kiosk accessibility; and accessible medical equipment. Comments are due on Nov. 13, 2023.

CMMI Unveils New AHEAD Multi-Payer Payment Model

The Center for Medicare & Medicaid Innovation (CMMI) announced on Sept. 5, 2023, a new voluntary multipayer payment model that seeks to replicate global budget, total cost of care or models used in other states to increase investment in primary care. As part of the States Advancing All-Payer Health Equity Approaches and Development (AHEAD) Model, up to eight states will receive up to \$12 million to implement the model via a cooperative agreement with CMS, which will operate for a total of 11 years, from 2024 through 2034. CMS anticipates releasing a Notice of Funding Opportunity (NOFO) in late Fall 2023, with a subsequent application period in Spring 2024. For more information, read the CMS frequently asked questions and press release. CMS will also hold a webinar on Sept. 18, 2023.