



H&K Health Dose: April 24, 2024

A weekly dose of healthcare policy news

LEGISLATIVE UPDATES

U.S. Congress is mostly in recess this week, with the exception of the U.S. Senate returning on April 23, 2024, to consider the U.S. House of Representatives-passed foreign aid package. The House Committee on Energy and Commerce (E&C) Subcommittee on Health will hold a hearing, "Legislative Proposals to Increase Medicaid Access and Improve Program Integrity," on April 30, 2024.

The CEO of the payer impacted by the Change Healthcare Attack will testify on May 1, 2024, at a House E&C Committee Subcommittee on Oversight and Investigations hearing to discuss the Change Healthcare cyberattack and how it has impacted patients and providers.

Sen. Cassidy Questions FDA Oversight of Clinical Decision Support Software

Senate Committee on Health, Education, Labor and Pensions (HELP) Ranking Member Bill Cassidy (R-La.) has [sent a letter](#) to the U.S. Food and Drug Administration (FDA) criticizing the agency's decision in a September 2022 guidance to classify clinical decision support (CDS) software as a medical device and to subject software developers to the FDA's regulatory process. Sen. Cassidy argues that the move is not aligned with the agency's statutory authority, highlighting that Congress excluded CDS software from being categorized as a medical device in the 21st Century Cures Act.

Buchanan Asks MedPAC to Rethink Approach to Digital Health Tools

Rep. Vern Buchanan (R-Fla.), chair of the House Committee on Ways and Means Subcommittee on Health, has [sent a letter](#) to the Medicare Payment Advisory Commission (MedPAC) encouraging the commission to rethink its approach to evaluating digital health tools and the use of artificial intelligence (AI) in the Medicare program. In the letter, Rep. Buchanan expresses concerns that MedPAC's current approach could punish providers for using – and innovators for developing – digital health tools that improve health outcomes and control costs.

Surprise Billing Conversation Reignited

Rep. Brett Guthrie (R-Ky.), chair of the House E&C Committee Subcommittee on Health, recently met with Centers for Medicare & Medicaid Services (CMS) to discuss implementation of the No Surprises Act. He indicated in a recent interview that the subcommittee may consider legislative solutions for No Surprises Act reform, stating "We have to figure out what it's going to take to get it to work."

Last Week: House Committee on E&C Considers Medicare Physician Payment Reform

On April 16, 2024, the House E&C Committee Subcommittee on Oversight and Investigations [convened to discuss](#) "improper payments" within Medicare and Medicaid programs. Gene Dodaro, comptroller general of the United States, testified at the hearing to [the results](#) of a recent U.S. Government Accountability Office (GAO) report estimating a combined total of more than \$100 billion in improper payments in the Medicare and Medicaid programs in fiscal year (FY) 2023. The report also includes recommendations for addressing improper payments (overpayments and underpayments) in Medicare and Medicaid. GAO's recommendations include enacting site neutral payment policies, increased oversight for telehealth services and expanding CMS' review of provider screening and enrollment requirements in Medicaid.



Other witnesses included representatives from MedPAC, as well as the Medicaid and CHIP Payment and Access Commission (MACPAC), along with an individual from the Office of Inspector General (OIG). Suggestions included increased safeguards, improved data sharing between states and the agency, and leveraging AI for claims data analysis.

Lame Duck Health Package May Include PBM, 340B, Medicare PFS Reforms; Telehealth Flexibility Extensions

Discussions surrounding the expected post-election lame duck health package are ongoing. Senate Minority Whip John Thune (R-S.D.) recently indicated that the legislative package will likely contain provisions addressing Medicare physician payments, pharmacy benefit managers (PBMs) and extensions for telehealth flexibilities that are currently set to expire at the end of the year.

Retirements

Rep. Jake LaTurner (R-Kan.) announced on April 18, 2024, that he will not seek reelection in the fall. Rep. Turner sits on the House Committee on Appropriations Subcommittee on Labor, Health and Human Services, and Education.

REGULATORY UPDATES

CMS released a series of highly anticipated Medicaid final rules on April 22, 2024. The Medicaid and [Children's Health Insurance Program Managed Care Access, Finance and Quality Final Rule](#) applies to managed care plans and aims to make transparency-related updates to state directed payments. It would also require states to submit an annual payment analysis that compared managed care plans' payment rates for routine primary care services, obstetrical and gynecological services, and outpatient mental health and substance use disorder services as a proportion of Medicare's payment rates.

The Ensuring Access to Medicaid Services [Final Rule](#) sets minimum threshold standards for payments to the direct care workforce. This regulation aims to standardize data and monitoring and create new opportunities for states to promote active beneficiary engagement in their Medicaid programs, with the goal of improving access to care. It also establishes that at least 80 percent of Medicaid Home and Community Based Services payments directly compensate direct care workers rather than "administrative overhead."

CMS also released the Minimum Staffing Standards for Long-Term Care Facilities and Medicaid Transparency Reporting [Final Rule](#) (LTC Staffing Rule) on April 22, 2024. Included in the rule are new comprehensive minimum nurse staffing requirements, which aim to significantly reduce the risk of residents receiving unsafe and low-quality care within LTC facilities.

The U.S. Department of Health and Human Services (HHS) finalized the [340B Administrative Dispute Resolution \(ADR\) Rule on April 18, 2024](#). The rule establishes an alternative dispute resolution (ADR) process that allows all 340B covered entities, regardless of the size of the organization or monetary value of the claim, to avail themselves of this process to address claims at dispute with drug companies.

Lastly, the Biden Administration [announced a final rule](#), "HIPAA Privacy Rule to Support Reproductive Health Care Privacy." The rule comes through the Office for Civil Rights (OCR) at the HHS. The rule strengthens protection established by the 1996 HIPAA rule, including:

- Prohibition of the use or disclosure of protected health information (PHI) when it is sought to investigate or impose liability on individuals, healthcare providers or others who seek, obtain, provide or facilitate



reproductive healthcare that is lawful under the circumstances in which such healthcare is provided, or to identify persons for such activities

- Requirement that a regulated healthcare provider, health plan, clearinghouse or their business associates to obtain a signed attestation that certain requests for PHI potentially related to reproductive healthcare are not for these prohibited purposes
- Requirement that regulated healthcare providers, health plans and clearinghouses to modify their Notice of Privacy Practices to support reproductive healthcare privacy

CBO Releases Analysis of Medicare ACOs' Past Performance and Future Directions

The Congressional Budget Office (CBO) [released a report](#) about the past performance and future directions of Medicare accountable care organizations (ACOs). The report reviews factors limiting savings for Medicare ACOs and discusses certain ACOs associated with greater savings.

CDER Announces New Center For Clinical Trial Innovation

Last week, the FDA's Center for Drug Evaluation and Research (CDER) announced the launch of the Center for Clinical Trial Innovation (C3TI) through a *Federal Register* notice. The new center will focus on promoting innovative clinical trial approaches through internal and external collaboration. New leadership of the center said that "C3TI will help address unmet medical needs for rare disease patients by helping identify the most appropriate trial approaches for small patient populations."

2024 CMS Health Equity Conference Live

The agenda for the 2024 CMS Health Equity Conference, which will be held May 29-30, 2024, is [now live](#). If you are interested in attending and have not yet registered, registration [remains available online](#).

FTC Finalizes Non-Compete Rule

The Federal Trade Commission (FTC) has [finalized a rule](#), which effectively bans most employers from using noncompete clauses. The rule states, "It is an unfair method of competition – and therefore a violation of Section 5 – for persons to, among other things, enter into non-compete clauses ("non-competes") with workers on or after the final rule's effective date. With respect to existing non-competes – i.e., non-competes entered into before the effective date – the final rule adopts a different approach for senior executives than for other workers. For senior executives, existing non-competes can remain in force, while existing non-competes with other workers are not enforceable after the effective date."

ONC Releases Common Agreement 2.0, TEFCA Update

The Office of the National Coordinator (ONC) for Health Information Technology released a Common Agreement Version 2.0 (CA v2.0) on April 22, 2024. According to ONC, CA v2.0 "establishes the technical infrastructure model and governing approach for different health information networks and their users to securely share clinical information with each other – all under commonly agreed-to rules-of-the-road. The seven designated Qualified Health Information Networks™ (QHINs™) under the Trusted Exchange Framework and Common AgreementSM (TEFCASM) can now adopt and begin implementing the new version." In conjunction with CA v2.0, ONC published the Participant and Subparticipant Terms of Participation, which sets the agreement standards for TEFCA participants. According to Micky Tripathi, National Coordinator of ONC, this new version "allows TEFCA to keep pace with the advanced, secure data services approaches used by the tech industry." This update is designed to significantly improve safe data sharing and aims to improve care coordination, the maintenance and accuracy of an individual's health record and reduce physician burden.