



H&K Health Dose: December 17, 2024

A weekly dose of healthcare policy news

Congress has made a deal on government funding, with the health section text released earlier today. Since the CR is expected to move this week, Speaker Johnson has indicated he may waive the 72-hour rule, which designates the timeframe before a vote can be held. The health section covers a myriad of issue areas including provisions on Medicaid, Medicare, FDA, public health extenders, pandemic response, PBM reform, drug pricing, women and maternal health, substance abuse treatment, and mental health. According to the text, telehealth flexibilities are to be extended through December 31, 2026. The SUPPORT Act, Accelerating Kids' Access to Care Act, and a 5-year reauthorization of the Rare Pediatric Disease Priority Review Voucher Program are also included. See the section-by-section and full health bill text for greater detail.

HEARINGS

The Senate Committee on the Judiciary, Subcommittee on Intellectual Property is holding a [hearing](#) tomorrow at 2 pm titled *The RESTORE Patent Rights Act: Restoring America's Status as the Global IP Leader*.

LEGISLATIVE UPDATES

House Releases AI Taskforce Report

The House Task Force on Artificial Intelligence (AI) unveiled its comprehensive end-of-year report today (see attached), providing a detailed roadmap to guide Congress in developing policies for the rapidly evolving technology.

Spanning 253 pages, the report explores how AI can be leveraged across social, economic, and health sectors while addressing the potential risks and challenges associated with misuse or unintended consequences.

2024 Unified Agenda

OMB's Office of Information and Regulatory Affairs (OIRA) posted the Fall 2024 HHS Unified Agenda ([HERE](#)). As a brief reminder, the Unified Agenda (UA) is a list of regulatory and deregulatory actions that Departments intend to issue in the "near and long term" which is interpreted to mean over the next 12 months with additional insights in the 12 – 24-month horizon. The UA is maintained by OMB's Office of Information and Regulatory Affairs (OIRA) and is updated twice per year (Spring and Fall). Of note, there are 30 total regulations that are being published for the first time.

CMMI 2024 Report to Congress

CMS published the Center for Medicare and Medicaid Innovation's (CMMI's) 2024 Report to Congress ([HERE](#)). This report provides updates on 37 models and initiatives (including 9 newly announced models), 52 evaluations, and activities from October 1, 2022 through September 30, 2024.

MedPAC and MACPAC Hold December Public Meetings

The Medicare Payment Advisory Commission (MedPAC) convened its December meeting to evaluate payment adequacy and discuss potential updates for various healthcare services. Topics included physician payments, hospital inpatient and outpatient services, rural emergency hospitals, skilled nursing facilities, inpatient rehabilitation facilities, home health services, hospice services, and outpatient dialysis services.



Meanwhile, the Medicaid and CHIP Payment and Access Commission (MACPAC) addressed a range of issues during its December meeting. Agenda items included oversight of Medicaid managed care organizations, home and community-based services (HCBS), the Medicare Advantage calendar year 2026 proposed rule, and care transition strategies for children and youth with special healthcare needs.

REGULATORY UPDATES

ASTP/ONC Releases HTI-2 and “HTI-3” Final Rules

The *Health Data, Technology, and Interoperability: Trusted Exchange Framework and Common Agreement (TEFCA)* (HTI-2) final rule introduces policies related to the TEFCA Manner Exception and provisions designed to enhance reliability, privacy, security, and trust within the national exchange network. It also includes corrections and updates to existing regulatory provisions of the ONC Health IT Certification Program.

Notably, the final rule omits several policies included in the July 2024 HTI-2 proposed rule, which remain under further review and development. The final rule is available for public inspection in the *Federal Register* and is scheduled for official publication on December 16, 2024.

The timeline for review, development, and potential finalization of the omitted policies remains uncertain. The incoming Trump Administration is expected to take a cautious approach to increased regulation of technological innovation. Meanwhile, a separate final rule addressing the Protecting Care Access proposals is currently under review by the Office of Management and Budget.

The final rule finalizes information blocking regulatory enhancements that were proposed in the HTI-2 Patient Engagement, Information Sharing, and Public Health Interoperability proposed rule.

In addition to HTI-2, CMS [released](#) the *Health Data, Technology, and Interoperability: Protecting Care Access (HTI-3) Final Rule* today which finalized the addition of a definition of “reproductive health care” to the defined terms for purposes of the information blocking regulations, finalized revisions to two previously established information blocking exceptions, and finalized the new Protecting Care Access Exception.

CMS Releases Update on the Progress Toward Advanced Explanation of Benefits (AEOB)

On December 13th, CMS released an update on the Progress Toward Advanced Explanation of Benefits (AEOB) Rulemaking and Implementation (December 2024). This update follows a previous April 2024 [update](#) and provides updates from the Departments of Labor, Health and Human Services, the Treasury, and the Office of Personnel Management (OPM) on developing AEOB rulemaking and the implementation of AEOB requirements.

CMS Releases CAA Implementation FAQ

CMS also [released](#) FAQs about Consolidated Appropriations Act (CAA), 2021 Implementation on Good Faith Estimates (GFE) for Uninsured or Self-Pay Individuals (PART 5). HHS prepared these FAQ to address the provision of GFEs for uninsured (or self-pay) individuals, as described in Public Health Service Act (PHS Act) section 2799B-6 and implementing regulations at 45 CFR 149.610. CMS also released a [fact sheet](#) “*Health Insurance? Determining When Uninsured (or Self-Pay) Good Faith Estimate Rules Apply*,” which provides more information about determining whether an individual is considered insured, uninsured, or self-pay for GFE purposes.