



H&K Health Dose: December 12, 2023

A weekly dose of healthcare policy news

LEGISLATIVE UPDATES

Lower Costs, More Transparency Act Passes House

The Lower Costs, More Transparency Act – a legislative package crafted jointly by the House Committee on Energy and Commerce (E&C), House Committee on Ways and Means and House Committee on Education & the Workforce – was unveiled this fall. It initially was scheduled for a U.S. House of Representatives floor vote on Sept. 18, 2023, but it was pulled from the schedule.

The sweeping healthcare package was taken up by the House on Dec. 11, 2023, under suspension of the rules. This voting mechanism limits House floor debate prior to a vote, prohibits all floor amendments, waives points of order against the bill and requires a two-thirds majority vote for final passage. The legislation passed easily in a 320-71 vote, with 166 Republicans and 154 Democrats voting in favor. It will now go to the U.S. Senate. Prospects its passage as a standalone bill are low, but some version of the legislation may be incorporated into a larger bicameral health package early next year.

Among other measures, the legislation would impose a number of price transparency requirements on Pharmacy Benefit Managers (PBMs) and health plans, implement certain payment changes for Medicare providers and extend several federal healthcare programs. Notable provisions of the legislation would:

- implement site neutral payment for Medicare Part B drugs administered in off-campus hospital outpatient departments
- ban spread pricing in the Medicaid program
- delay, for two years, \$8 billion in annual cuts to Disproportionate Share Hospitals (DSHs)

It would also reauthorize funding through 2025 for the Community Health Center (CHC) program, Teaching Health Center Graduate Medical Education (THCGME) program, National Health Services Corps (NHSC), Special Diabetes Program (SDP) and Special Diabetes Program for Indians (SDPI).

More information, including a summary and section-by-section, is available [online](#).

21 Health Bills Approved at House Committee on Energy and Commerce Markup

The House Committee on Energy and Commerce considered 44 pieces of legislation during a marathon, two-day [markup](#) held Dec. 5-6, 2023. The committee voted to advance 21 health-related bills with only a single recorded "nay" – an agreement between Chair Cathy McMorris Rodgers (R-Wash.) and Ranking Member Frank Pallone (D-N.J.) that facilitated a relatively smooth hearing. In his opening statement, Rep. Pallone thanked the majority for "engaging in good faith negotiations" and a "willingness to make changes to several bills to address Democratic concerns."

Health legislation approved at the markup generally related to Medicare provider payment policies, Medicare Part D cost-sharing, PBM transparency and reporting requirements, biosimilar access, U.S. Food and Drug Administration (FDA) national and local coverage determination authorities, and medical device coverage, among other issues. Rep. Pallone has repeatedly stated that many of the measures will need to be refined to address technical and implementation challenges before any next steps: "Some of these policies, in particular



H.R. 4881 [a measure to limit beneficiary cost-sharing under Medicare Part D to a drug's net price], need a substantial amount of additional work before they are ready for floor consideration."

SUPPORT Act: House Legislation; Senate Committee on HELP Holds Markup

Both chambers took steps this week to reauthorize provisions of the Support for Patients and Communities Reauthorization (SUPPORT) Act that provides funding for opioid treatment and prevention programs. Those programs expired Sept. 30, 2023. Differences between the two chambers' versions will have to be reconciled.

The House passed its version of reauthorizing legislation (H.R. 4531) on Dec. 12, 2023, in a 386-37 vote. It includes a provision to permanently place xylazine in Schedule III of the Controlled Substances Act. Reclassifying xylazine previously stalled a floor vote on the legislation, with Democrats expressing concerns over the impacts of criminalizing possession. H.R. 4531 also permanently extends the state plan amendment (SPA) option, which allows a state to amend a Medicaid plan to provide for exceptions to the Medicaid Institutions for Mental Diseases (IMD) exclusion.

In the Senate, similar legislation (S. 3393) was approved 19-1 by the Senate Committee on Health, Education, Labor and Pensions (HELP). The panel also advanced a measure that would allow addiction doctors to prescribe methadone outside of specialized clinics. It did not consider an amendment that would have permanently extended flexibility, allowing opioid use disorder medications to be prescribed via telehealth. S. 3393 also does not include the xylazine provision passed by the House.

MedPAC Considers 2025 Payment Recommendations at December Meeting

The Medicare Payment Advisory Commission (MedPAC) hosted its [two-day December meeting](#), during which it discussed payment adequacy for physicians, hospital inpatient and outpatient, hospice, outpatient dialysis, skilled nursing facility, home health and inpatient rehabilitation facility services.

Of note, the commission's draft recommendation includes a 1.3 percent pay increase for Medicare physicians in 2025. This reflects an update to the 2024 Medicare base payment rate by half the projected increase to the Medicare Economic Index (MEI). The commission also discussed recommending an add-on payment for clinical services furnished to low-income Medicare beneficiaries (15 percent for primary care clinicians and 5 percent for non-primary care clinicians). For hospitals, the draft recommendations state that for fiscal year (FY) 2025, Congress should update the 2024 base pay rate with an additional 1.5 percent pay bump (a total of 4.3 percent).

Senate Budget Committee Investigates Private Equity Hospital Ownership

Senate Committee on the Budget Chair Sheldon Whitehouse (D-R.I.) and Ranking Member Chuck Grassley (R-Iowa) launched a bipartisan investigation into the impacts of private equity ownership on hospitals. The bipartisan investigation builds upon a probe initiated by Sen. Grassley in March 2023 that was spurred by a series of assaults that occurred at an Iowa health facility.

Sens. Whitehouse and Grassley sent out a series of letters on Dec. 6, 2023, seeking information from hospitals in several states that currently are or were formerly owned or operated by private equity companies. Per a press release on the committee's website, "Since coming under private equity ownership, many hospitals ... have experienced significant staffing reductions and substandard health care, and have been stripped of valuable assets, including their real estate, leaving them saddled with debt. To assess the impact of these transactions and address their harmful effects, the senators are asking for documents and detailed answers about related-party transactions and the degree to which the private equity firms are calling the shots at these hospitals."



This Week: HHS Officials to Discuss AI Before House E&C Committee

The House Committee on Energy and Commerce will convene on Dec. 13, 2023, for its fifth hearing this year to examine artificial intelligence (AI). During "[Leveraging Agency Expertise to Foster American AI Leadership and Innovation](#)," a multi-agency panel of witnesses – comprised of officials from the U.S. Department of Health and Human Services (HHS), U.S. Department of Commerce and the U.S. Department of Energy (DOE) – will discuss the federal government's role in balancing the risks of AI, without impeding innovation on a sector-by-sector basis. Dr. Micky Tripathi, the HHS national coordinator for health information technology, will speak in support of HHS efforts "to promote the fair, appropriate, valid, effective, and safe use of AI and machine learning (ML) in health care, public health, and human services."

This Week: Senate Committee on HELP to Hold Hearing on Diabetes

The underlying causes of the national diabetes epidemic will be the focus at a Nov. 14, 2023, Senate Committee on Health, Education, Labor, and Pensions (HELP) hearing, "[What Is Fueling the Diabetes Epidemic?](#)" HELP Committee Chair Bernie Sanders (I-Vt.) has long been critical of insulin pricing and manufacturers. The hearing will focus on rising rates of diabetes, especially in children. Sen. Sanders in a Dec. 11, 2023, [announcement](#), indicated he is also interested in discussing "what we can do to lower the outrageously high price of diabetes drugs like Ozempic."

Retirements and Resignations

Former House Speaker Kevin McCarthy (R-Calif.) announced last week his plans to resign from U.S. Congress at the end of the month "[to serve America in new ways](#)," per an op-ed he penned and published in *The Wall Street Journal*. Previously, Rep. McCarthy had stated he planned to finish out his term. Rep. McCarthy's seat will remain vacant until California Gov. Gavin Newsom calls a special election. His departure further narrows an already slim Republican majority.

A special election will be held on Feb. 13, 2024, to fill the seat previously held by Rep. George Santos (R-N.Y.), who was expelled from the House in a vote held on Dec. 1, 2023.

Rep. Patrick McHenry (R-N.C.) will also retire when his term ends in January 2025. McHenry currently chairs the House Committee on Financial Services. He has served in the House since 2005.

On the other side of the aisle, Rep. Kathy Manning (D-N.C.) announced on Dec. 7, 2023, that she would not seek re-election next year. A running list of members of Congress who are retiring or seeking other office is available [online](#).

REGULATORY UPDATES

Administration Publishes Fall 2023 Unified Agenda

The unified agenda, which details various federal departments and agencies' rulemaking priorities, can be found on the Office of Management and Budget (OMB) [website](#). The HHS fall 2023 agency rule list can be found [online](#).

CMS Issues Interim Final Rule on Medicaid Unwinding

The Centers for Medicare and Medicaid Services (CMS) issued an interim final rule (IFR) on Dec. 6, 2023, with a request for comments, "[Medicaid; CMS Enforcement of State Compliance with Reporting and Federal Medicaid Renewal Requirements Under Section 1902\(tt\) of the Social Security Act](#)." The IFR implements CMS' authorities



under the Consolidated Appropriations Act of 2023 to enforce penalties for states for noncompliance with federal Medicaid eligibility rules and reporting requirements during the post-continuous coverage Medicaid eligibility redetermination period. The enforcement authorities include requiring states to submit a corrective action plan, suspending disenrollments from Medicaid for procedural reasons and imposing civil money penalties (CMPs). They also include reducing the state-specific Federal Medical Assistance Percentage (FMAP) for failure to meet reporting requirements.

FDA Approves Two Milestone Treatments for Sickle Cell Disease

The U.S. Food and Drug Administration (FDA) has approved the first cell-based gene therapies for treating sickle cell disease (SCD) in patients 12 years and older. Sickle cell disease is a group of inherited blood disorders affecting approximately 100,000 people in the U.S. The FDA approved Casgevy from Vertex Pharmaceuticals and CRISPR Therapeutics, along with Lyfgenia from Bluebird Bio., for treating the disease on Dec. 8, 2023. Casgevy is the FDA-approved treatment to use the genome-editing technology CRISPR. Lyfgenia is a cell-based gene therapy that uses a lentiviral vector (gene delivery vehicle) for genetic modification. More information is available [online](#).

White House Announces New March-In Framework, Other Actions

The Biden Administration released a fact sheet, "New Actions to Lower Health Care and Prescription Drug Costs by Promoting Competition," on Dec. 7, 2023, announcing a set of new actions to "stop anticompetitive mergers and anticompetitive practices by dominant corporations in health care markets" and "increase Americans' access to life-saving medications." In the publication, it announced a controversial Department of Commerce-HHS [draft framework](#) asserting that the high price of a drug (or other product) may be used as a justification for an agency to exercise "march-in rights" – authorities for the government to license inventions developed using federal funds. The draft framework is open for public comment through Feb. 6, 2023.

Among other actions, the fact sheet outlines a new data-sharing initiative between HHS, the Federal Trade Commission (FTC) and the U.S. Department of Justice (DOJ) to help identify anticompetitive behavior. Those agencies will issue a request for information (RFI) soliciting stakeholder feedback on the impact of private equity in healthcare.

HHS Releases Concept Paper on Cybersecurity in Healthcare, Public Health Sectors

The HHS released a concept paper on Dec. 6, 2023, outlining its ongoing activities and strategic plan to improve cybersecurity in the healthcare sector. The concept plan details four broad "pillars" of the strategy:

- publish guidance setting voluntary cybersecurity performance goals for healthcare institutions
- ask Congress for new authorities and funding to incentivize and cover the upfront costs of cybersecurity planning and implementation for healthcare facilities
- propose enforceable cybersecurity standards for CMS
- establish within the Administration for Strategic Preparedness and Response (ASPR) a "one-stop shop" to provide industry with health cybersecurity expertise and capabilities

In addition, HHS will seek to increase civil monetary penalties for Health Insurance Portability and Accountability Act (HIPAA) violations.