



H&K Health Dose June 29, 2022

A weekly dose of healthcare policy news

Judicial Updates

Supreme Court Reverses *Roe v. Wade* and Hands Down Numerous Other Healthcare-Related Decisions

The U.S. Supreme Court on June 24, 2022, handed down a controversial decision overturning *Roe v. Wade*, which removed federal abortion protections and leaves states to determine their own abortion laws. Dissenting Justices Stephen Breyer, Elena Kagan and Sonia Sotomayor warned that the high court could be pulled into a growing number of interstate abortion cases as a result. In response to the announcement, the U.S. Department of Health and Human Services (HHS) [released new guidance](#) outlining existing abortion and other reproductive health rights and a White House official says that there will be "several relevant agency announcements" this week. President Joe Biden indicated on June 24 that his administration will focus on protecting women's rights to travel to receive abortions in states where it remains legal and ensure medication abortion is available "to the fullest extent possible." However, both actions may be vulnerable to a potential legal challenges. Additionally, the legal boundaries when it comes to telehealth abortions are largely undefined, which could leave providers in unclear legal territory in many states. Experts warn that the additional pressures could lead to further exodus from the healthcare workforce and that medical training on how to perform an abortion in states with abortion laws on the books may cease altogether, rendering exception-based policies – such as for rape or incest – practically infeasible to implement. Experts also note that the decision could have implications on other nonreproductive elements of the healthcare sector.

The high court also handed down a number of other healthcare-related decisions, including:

- Upholding a 2005 rule that decreased the amount of disproportionate share hospital (DSH) payments low-income hospitals receive for serving a high proportion of poor patient populations.
- Upholding a lower court decision that allows the government to recover billions of dollars' worth of overpayments to insurers for upcoding claims for Medicare Advantage plans.
- Allowing employer-based health plans to designate all dialysis providers as out-of-network, which experts say could prompt coverage changes and lead employees with kidney failure to shift to Medicare coverage.

Legislative Updates

FY 2023 Appropriations Hum Along

The House Appropriations Committee approved six Fiscal Year (FY) 2023 spending bills last week, setting them up for possible floor action in July. The remaining measures, including Labor-Health and Human Services-Education, advanced in their respective subcommittees and are scheduled for full committee markup this week. The draft Labor-HHS-Education language provides \$242.1 billion in total funding, a 13 percent (or \$28.5 billion) increase over FY 2022 enacted levels. This amount includes a \$124.1 billion increase for the U.S. Department of Health and Human Services (HHS), a \$2 billion increase for the Centers for Disease Control and Prevention (CDC), a \$2.5 billion increase for the National Institutes of Health (NIH) and \$2.75 billion for the Advanced Research Projects Agency – Health (ARPA-H). A [summary of the bill](#) is available on the committee's website. These bills are still subject to change as bipartisan topline spending levels for defense and nondefense discretionary appropriations remain unresolved. Of note is the increased activity related to Community Project Funding (CPF) requests (i.e., "earmarks"). This year, the House included more than 4,386 submissions totaling more than \$8.2 billion, including 1,310 requests totaling \$1.4 billion for Labor-HHS-Education-related requests alone.



Historic Gun Safety Bill Signed Into Law

President Joe Biden on June 25, 2022, signed the first major gun safety legislation in 30 years into law. His action follows House passage (234-193) on June 22 and Senate passage (65-33) on June 23. Fifteen Senate Republicans voted for the legislation, which was the product of negotiations co-led by Sens. Chris Murphy (D-Conn.) and John Cornyn (R-Texas). The new law boosts funding for bolstered background checks for those younger than 21 who try to purchase firearms, allows states to establish "red flag" laws, closes the "boyfriend loophole" by prohibiting individuals convicted of misdemeanor domestic violence crimes from purchasing/possessing firearms for five years, and would create a federal clearinghouse on evidence-based practices to improve school safety. The bill also includes several healthcare-related provisions, including various mental health funding grants and directs the U.S. Department of Health and Human Services (HHS) to issue technical guidance to states on improving access to telehealth services for Medicaid and Children's Health Insurance Program (CHIP) beneficiaries.

ARPA-H Bill Passes House with Overwhelming Support as Key Details Remain Undecided

On June 22, 2022, the House overwhelmingly passed the Advanced Research Project Agency-Health (ARPA-H) Act (H.R. 5585). Disagreements have been ongoing about whether to house the new agency within the National Institutes of Health (NIH) or separately within U.S. Department of Health and Human Services (HHS). The House bill, spearheaded by House Energy and Commerce Health Subcommittee Chair Anna Eshoo (D-Calif.), would permanently place ARPA-H under the guise of the HHS Secretary and made several other changes, including removing the requirements for Senate approval of the ARPA-H Director and prohibiting the ARPA-H Director from awarding any funding or contracts to foreign research entities.

Mental Health and Substance Abuse Remains a Focus

The House on June 22, 2022, passed a bipartisan package by a vote of 402-20 that seeks to address mental health and substance abuse in the U.S. Among other changes, the legislation – the Restoring Hope for Mental Health and Well-Being Act (H.R. 7666) – would reauthorize national suicide and maternal mental health screening and treatment programs, and improve integration of evidence-based behavioral healthcare into primary care settings.

On June 27, the House Oversight and Reform Committee [held a hearing](#) on the federal response to the addiction crisis featuring President Joe Biden's drug czar, Dr. Rahul Gupta, who spoke to the administration's focus on harm reduction strategies.

PBM Remains Under Scrutiny

Last week, the Senate Commerce Committee advanced the Pharmacy Benefit Manager (PBM) Transparency Act to the full Senate, which aims to empower the Federal Trade Commission (FTC) to shed light on and crack down on certain PBM practices that may inflate drug prices. Three Republican members of the House Education and Labor Committee also [sent a letter](#) to the Government Accountability Office requesting a study on PBMs and their role in pharmaceutical pricing and supply. Separately, the FTC [announced a new policy](#) of ramped up enforcement against any "illegal rebate schemes [or] bribes to prescription drug middleman that block cheaper drugs," citing insulin as an example.



Pressure Mounts for Congress to Extend Enhanced ACA Subsidies

Centers for Medicare & Medicaid Services (CMS) Administrator Chiquita Brooks-LaSure urged Congress to extend enhanced Affordable Care Act plan subsidies sooner than later, warning time is of the essence as payers look to set their rates for the 2023 plan year and that rates and the number of uninsured could both skyrocket otherwise. The enhanced rates are currently set to expire in October, just before midterms. Sen. Joe Manchin (D-W.Va.) recently expressed his openness to extending the subsidies as part of a skinnier Build Back Better package provided some degree of "means-testing" – i.e., the credits would be extended only for the lowest-earning enrollees.

Regulatory Updates

FDA Issues Proposed Rule to Make Prescription Drugs More Readily Available for Consumer Use

On June 27, the U.S. Food and Drug Administration (FDA) [issued a proposed rule](#) that would make it easier for prescription drugs to become available over-the-counter. The proposal can apply to new or existing drugs and would establish an additional condition for nonprescription use (ACNU), which is needed for nonprescription drugs that require additional labeling for consumer use purposes.

CMS Issues 2023 Home Health Proposed Payment and ESRD Rules

On June 17, Centers for Medicare & Medicaid Services (CMS) issued the Home Health Prospective Payment System Rate Update [proposed rule](#) for CY 2023, which would lead to an estimated decrease in aggregate payments of minus-4.2 percent or minus-\$810 million compared to CY 2022. On June 21, CMS released its End-Stage Renal Disease (ESRD) Prospective Payment System [proposed rule](#) for renal dialysis services for Calendar Year (CY) 2023, which is expected to yield an overall 3.1 percent pay bump due in part to a \$6.19 increase to the current base rate.

Colorado Becomes First State with Federally Backed Public Option

U.S. Department of Health and Human Services (HHS) approved a Section 1332 State Innovation Waiver request for the state of Colorado to create a state-specific health plan, making it the first-of-its-kind in the nation. According to the HHS [press release](#), Colorado projects that approximately 32,000 Coloradans will gain health insurance under the waiver by 2027, an increase of approximately 15 percent of the individual market.

CMS Approves Expanded Medicaid Maternal Health Coverage for Four Additional States

Centers for Medicare & Medicaid Services (CMS) has [approved](#) four additional states for expanded Medicaid maternal health coverage for up to one year after birth. Maine, Minnesota, New Mexico and Washington, D.C., join 10 other states and bring the total number of people covered on an annual basis to more than 250 million. CMS Administrator Chiquita Brooks-LaSure noted to the media that the agency is in the process of finalizing extension proposals for nine additional states.

ONC Launches New HITAC Task force To Review ONC Standards and Specifications

U.S. Department of Health and Human Services' (HHS) Office of the National Coordinator (ONC) for Health Information Technology (HIT) [launched a new Standards Task Force](#) as part of its existing HIT Advisory Committee (HITAC) to review and make recommendations on ONC standards and specifications. The Task Force satisfies a requirement set forth in the 21st Century Cures Act and will include current HITAC members as well as additional industry experts. All Task Force meetings will be open to the public. Stakeholders can also provide written or verbal comments. The Task Force is expected to issue a final report in the fall, which will help to inform future HITAC recommendations and ONC work.



COVID-19 Vaccine Update

Following the Centers for Disease Control and Prevention's (CDC) recommended use of Moderna and Pfizer COVID-19 vaccines for children age 6 months and older, approximately 2.7 million U.S. children under age 5 received their first dose of a COVID-19 vaccine. CMS also announced coverage for children enrolled in Medicaid or CHIP with zero cost sharing. On June 24, the agency recommended the Moderna shot for adolescents age 6-17, which joins Pfizer as the second shot approved for that age group.

The FDA's vaccine advisory committee met June 28 to discuss whether COVID-19 vaccines should be updated to combat emerging variants ahead of an anticipated fall/winter surge.

CMS Announces Next Iteration of Medicare Oncology Model

On June 27, Centers for Medicare & Medicaid Services (CMS) [announced](#) a new Enhancing Oncology Model (EOM) to replace its Oncology Care Model, which ends this month. EOM offers two separate risk tracks and places an increased emphasis on individualized, whole-patient focused care including health-related social needs. Applications are due by Sept. 30 and CMS will host a series of webinars starting with an overview webinar on June 30. For more information, visit the CMS [EOM webpage](#).

Monkeypox on the Rise

In an attempt to curb the emerging monkeypox outbreak, the Biden Administration announced that it will expand testing to five of the nation's largest commercial laboratories. The official tally currently stands at 156 cases but experts fear the true total could be higher. Also this week, the World Health Organization declared monkeypox an "evolving threat," but stopped short of deeming it a global health crisis, the same level as the COVID-19 pandemic. Notably, monkeypox is typically transmitted through sexual contact.

President Biden names Permanent Director of White House Office of Science and Technology

The White House [announced](#) that President Joe Biden intends to nominate Dr. Arati Prabhakar for director of the White House Office of Science and Technology. In that role, Prabhakar would be the president's chief advisor for Science and Technology and serve as a member of the president's Cabinet. Prabhakar was previously the first woman to lead the National Institute of Standards and Technology (NIST) after being unanimously confirmed by the Senate and later directed the Defense Advanced Research Projects Agency (DARPA). Prabhakar replaces Dr. Francis Collins, who has been in the role on an interim basis since February after stepping down from his longtime role as NIH Director.

Biden Administration Comes Down Hard on Cigarette Companies

The U.S. Food and Drug Administration (FDA) issued formal marketing denial orders to e-cigarette giant Juul, which will force the company to pull all of its e-cigarette products from U.S. shelves, though a federal appeals court has granted Juul a temporary stay of the FDA's decision. Juul has asked the court for a permanent stay. According to the [press release](#), following a nearly two-year review of the company's premarket tobacco product applications, the FDA determined that the applications lacked sufficient evidence to demonstrate that marketing of the products would be appropriate for the protection of the public health. In particular, some of the company's study findings "raised concerns due to insufficient and conflicting data."

Separately, the Biden Administration [signaled plans](#) for impending rulemaking that would require tobacco companies to reduce nicotine levels in cigarettes sold in the United States, which would be an unprecedented move. May 2023 is listed as the intended timeframe, though the administration is not held to this.