



## H&K Health Dose: June 22, 2022 A weekly dose of healthcare policy news

### Legislative Updates

#### **FDA User Fee Bill Advances in Senate HELP Committee**

On June 14, the Senate Health, Education, Labor, and Pensions (HELP) Committee advanced the Food and Drug Administration Safety and Landmark Advancements (FDASLA) Act ([S. 4348](#)), reauthorizing medical product user fees at the U.S. Food and Drug Administration (FDA) for another five years. The package was approved in a 13-9 vote, with Ranking Member Richard Burr (R-N.C.) joining eight other Republicans in voting against the measure because of amendments adopted during the markup.

There are significant differences between S. 4348 and the FDA user fee bill passed by the House on June 8 ([H.R. 7667](#)) – including that the Senate bill includes the Verifying Accurate Leading-edge IVCT Development (VALID) Act, which would give the FDA authority over in vitro clinical tests (IVCTs) – a new category of products, which would include both in vitro diagnostic products and laboratory developed tests (LDTs). Differences between the House and Senate bills will need to be reconciled before a bill can be finalized and reach President Joe Biden's desk to be signed into law.

The HELP Committee also advanced four other bills during the June 14 executive session: the Maximizing Outcomes through Better Investments in Lifesaving Equipment (MOBILE) Health Care Act (S. 958); the Retirement Improvement and Savings Enhancement to Supplement Healthy Investments for the Nest Egg (RISE & SHINE) Act (S. 4353); the Cardiovascular Advances in Research and Opportunities Legacy (CAROL) Act (S. 1133); and the Early Hearing Detection and Intervention Act (S. 4052).

#### **Senate Finance Committee Releases Mental Health Draft**

On June 15, Senate Finance Committee leaders released a [discussion draft](#) focused on youth mental health. This discussion draft is the second of five subject areas under development to be released as the committee seeks to advance a comprehensive mental health reform package this year. The first [discussion draft](#) – focused on telehealth policies – was released on May 26, and additional pieces on workforce, parity and care integration are expected in the coming weeks.

#### **Senate Passes Bill to Support Veterans Exposed to Burn Pits**

The Senate voted 84-14 to pass a substitute amendment to the House-passed Sergeant First Class Heath Robinson Honoring Our Promise to Address Comprehensive Toxics (PACT) Act (H.R. 3967). The legislation would support veterans who have been exposed to toxic substances during military deployments. The bill, introduced by House Veterans Affairs Committee Chair Mark Takano (D-Calif.), was to be considered by the House Rules Committee on June 21. The bill would increase access to medical care and disability benefits for veterans by establishing presumptions of service connection related to toxic exposure, and by adding 23 burn pit and toxic exposure-related conditions to the Veterans Affairs' list of service presumptions. It would also mandate more federal research on toxic burn pits. The legislation is expected to be sent to the president's desk after a final vote is held in the House this week.



## Health Policies Facing Expiration

With narrowing legislative days in 2022, questions loom about Congressional action around health-related policies facing expiration. The below list is not exhaustive but sheds some light on policies that Congress may elect to address before the end of the year.

- Medicare Sequester: Increases back to 2 percent on July 1, 2022; permanently canceling the Medicare sequester would cost roughly \$200 billion over 10 years, according to Congressional Budget Office (CBO).
- User Fees (see first article): Expires Sept. 30, 2022.
- Temporary Assistance for Needy Families (TANF): Expires Sept. 30, 2022; CBO estimates that the cost of extending TANF over a 10-year period would be roughly \$167.3 billion.
- Maternal, Infant, and Early Childhood Home Visiting Program: Expires Sept. 30, 2022; CBO estimates that enacting such a provision would cost roughly \$2 billion over 10 years.
- Affordable Care Act (ACA) Premium Subsidies: Expires Dec. 31, 2022; according to CBO, making these subsidies permanent is projected to cost \$209.5 billion over 10 years.
- Medicaid Federal Medical Assistance Percentage (FMAP) for Territories: Enhanced FMAP expires on Dec. 13, 2022; CBO estimated that the 2022 extension of territories' FMAP increased federal outlays by \$319 million.
- Medicare Access and CHIP Reauthorization Act/Alternative Payment Models (MACRA/APM) Bonus (2022 last performance year, 2024 payment year): Expires Dec. 31, 2022; Centers for Medicare & Medicaid Services (CMS) estimated that APM incentive payments for the 2022 performance year would total between \$600 million and \$750 million.
- Radiation Oncology Model: Delay Expires on Dec. 31, 2022; Center for Medicare & Medicaid Innovation (CMMI) models are budget neutral.
- Medicare Physician Bonus Payments: A 3 percent increase expires on Dec. 31, 2022; in 2022, CBO projected that the 3 percent boost would cost \$1.4 billion for that year. The future cost of cutting bonus payments would depend on future Medicare expenditures.
- Pay-As-You-Go (PAYGO): A 4 percent PAYGO is set to begin Jan. 1, 2023; CBO had estimated that implementing the cuts in Fiscal Year (FY) 2022 would have resulted in a \$36 billion reduction in Medicare spending. Notably, PAYGO Cuts have never been implemented since their inception.

## Regulatory Updates

### Supreme Court Rules Against Government on Drug Reimbursement

On June 15, the U.S. Supreme Court overturned a significant pay cut for hospitals, finding that the U.S. Department of Health and Human Services (HHS) improperly failed to gather crucial pricing information. The unanimous opinion reversed a D.C. Circuit ruling that upheld HHS' \$1.6 billion annual cuts to reimbursement in the 340B program. The decision was a win for the American Hospital Association; the group led an industry challenge. Oral arguments in the case discussed possibly overturning *Chevron* deference (a Supreme Court precedent that requires judicial deference to reasonable agency readings of ambiguous statutes). However, the decision didn't address *Chevron*. HHS' move to



reduce 340B drug reimbursement originated in 2017, when it issued a final rule reducing hospital reimbursement under the 340B Program for 2018 from 6 percent over each drug's average sales price to 22.5 percent below the average sales price.

Notably, the ruling did not provide a specific remedy. The case will now go back to a lower court for further deliberations, including remedies. The decision could allow hospitals participating in the 340B program to reclaim some of the 340B payments that were withheld. How CMS will finance those retroactive payments remains to be determined. Since the original policy was budget-neutral and HHS already redistributed the savings, clawing back that money will be complicated.

## **HHS Released Guidance on Telehealth and HIPAA**

The U.S. Department of Health and Human Services (HHS), through the Office for Civil Rights (OCR) released guidance surrounding telehealth and Health Insurance Portability and Accountability Act (HIPAA) compliance following the eventual conclusion of the COVID-19 public health emergency (PHE). While not entirely new information, HHS' guidance provides clarifications surrounding when OCR will stop utilizing enforcement discretion, as well as clarifications on audio-only telehealth visits, which were not reimbursable under Medicare before the pandemic. Of note, HIPAA enforcement discretion was not one of the waivers extended by Congress for five months following the conclusion of the PHE.

## **MACPAC, MEDPAC Release June Reports to Congress**

The Medicaid and CHIP Payment and Access Commission (MACPAC) released its June 2022 Report to Congress, with recommendations for: access monitoring; directed care payments; vaccine access for adults; behavioral health IT; integrated care strategies; and health equity.

The Medicare Payment Advisory Commission (MEDPAC) also released its June 2022 Report to Congress discussing: alternative payment models, medically underserved areas, safety-net providers, Part B prices, MA risk adjustment, payment alignment and stand-alone Part D segmentation.

## **OIG Finds Major Inaccuracies in Medicare's Race and Ethnicity Data**

The U.S. Department of Health and Human Services (HHS) Office of Inspector General (OIG) [issued a report](#) titled "Inaccuracies in Medicare's Race and Ethnicity Data Hinder the Ability To Assess Health Disparities," which includes several recommendations to CMS focused on improving its race and ethnicity data.

## **Request for HITACH Nominations**

The U.S. Government Accountability Office (GAO) [issued a request for nominations](#) for the Health Information Technology Advisory Committee (HITAC). GAO intends to appoint at least four new members to serve three-year terms beginning Jan. 1, 2023.. Nominations are due no later than July 22, 2022.

## **COVID-19 Vaccines Authorized for Children Under Age 5**

The U.S. Food and Drug Administration (FDA) authorized emergency use of the Moderna COVID-19 vaccine and the PfizerBioNTech COVID-19 vaccine for the prevention of COVID-19 to include use in children down to 6 months of age. The emergency use authorization was followed by the Centers for Disease Control and Prevention's endorsement of a unanimous recommendation from the Advisory Committee on Immunization Practices (ACIP) to vaccinate all children as young as 6 months old with one of the two vaccines.