



H&K Health Dose July 6, 2021 A weekly dose of healthcare policy news

Legislative Updates

Congress This Week

The Senate is out this week before coming back for a hectic period ahead of the (possibly delayed) August recess.

Senate Budget Committee Chairman Bernie Sanders is working on a draft budget resolution that Senate Majority Leader Chuck Schumer wants to be presented to the full Democratic Caucus when the Senate returns next week. House and Senate Leadership are said to be playing an unusually active role in the drafting of budget legislation given the White House's and Democratic leadership's strategic plan to use it as a vehicle to move key Democratic "human infrastructure" priorities that did not make it into the bipartisan infrastructure package including family care, education, climate change, and Medicare expansion. The big questions are what the top-line figure will be and what (if any) pay-fors will be included. Senator Joe Manchin has thrown out \$2 trillion while Sanders has mentioned \$6 trillion. The remaining provisions of President Biden's budget that didn't make it into the bipartisan agreement total around \$3 trillion. House Budget Chair John Yarmuth (D-KY) said he is "waiting to see what the Senate does."

After some damage control, President Biden appears to have enough Republican votes on the bipartisan infrastructure agreement, for now. The group of 21 senators has divided up responsibility for drafting the legislative language. It's unclear when the text will be ready; some are saying as early as this week. The bipartisan House Problem Solvers Caucus endorsed the package and called for a separate and timely vote, though that is unlikely as House Speaker Nancy Pelosi reaffirmed her commitment to holding the infrastructure agreement until a larger reconciliation package is ready.

Fiscal Year 2022 Appropriations Update

Democratic appropriators in the House of Representatives released their fiscal year (FY) 2022 top-line spending allocations for each of the 12 annual appropriations bills. So far, the House Appropriations Committee has advanced half of the 12 appropriations bills, including the Agriculture-FDA appropriations bill, which would give the FDA an 8% funding boost for FY 2022 to help advance priorities like addressing the opioid crisis, advancing rare disease research, resuming inspections, advancing development and approval of biosimilars and generics, increasing diversity in clinical trials, expanding rural broadband, enhancing domestic production of medical products, and modernizing the FDA's data infrastructure. The House Labor-HHS-Education bill would receive a total of \$237.5 billion, an increase of \$61 billion over current funding levels. Markup is scheduled for July 16. The Committee will continue to advance the remaining appropriations bills with the goal to bring all 12 to a vote on the House floor by the end of the month. Republicans have generally opposed the bills, calling defense spending too low and nondefense discretionary figures too high. The Senate Appropriations Committee is expected to pass a few non-controversial appropriations bills before August recess and pick up steam in the fall.

Administrative/Regulatory Updates

Administration Releases First Rule on Surprise Medical Billing

The Biden administration announced an interim final rule with comment period (IFC) last Thursday designed to largely end surprise medical billing and balance billing, taking the first step to implementing the *No Surprises Act* that passed Congress at the end of last year. The IFC focuses on the methodology for calculating the qualifying payment amount and the notice/consent criteria. Forthcoming regulations will deal with the independent dispute resolution (IDR) process and other aspects of the law. To accompany the IFR, HHS released a [fact sheet](#) on what patients need to know about their rights regarding surprise bills, as well as a [fact sheet](#) on requirements for meeting the rule. The [411-page IFC](#) will be



open for public comment until **September 7th, 2021 at 5 p.m. E.T.** Please find Holland & Knight's high-level summary [here](#).

\$250 Million Awarded to Fight COVID-19 and Improve Health Literacy Among Vulnerable Communities

HHS will [award](#) \$250 million to 73 local governments to improve health literacy among minority and vulnerable communities as part of a new, two-year initiative to identify and implement best practices for improving health literacy to enhance COVID-19 vaccination and other mitigation practices among underserved populations. The *Advancing Health Literacy (AHL) to Enhance Equitable Community Responses to COVID-19* initiative is part of the Biden/Harris Administration's National Strategy for the COVID-19 Response and Pandemic Preparedness.

Provider Relief Portal Open & Updated FAQs

The Provider Relief Fund (PRF) reporting portal was opened by the Health Resources and Services Administration (HRSA) last week. If you have not done so already, you may register [here](#). The registration process will take approximately 20 minutes to complete and must be completed in one session. HRSA published updated [reporting requirements](#) on June 11, including phased reporting deadlines depending on when the money was distributed. For the first phase, providers who received an aggregate payment exceeding \$10,000 between April 10, 2020, and June 30, 2020 have until June 30, 2021, to use their funds and from July 1-Sept. 30, 2021, to submit their reports. A [webcast](#) is scheduled for July 8 to assist providers in understanding the reporting process. HHS also released [updated FAQs](#) regarding the PRF, particularly clarifying questions around eligible expenses and lost revenue.

Enforcement Bodies Target Health Fraud and Violations Including Improper Use of COVID Relief Dollars and Elder Abuse

The Justice Department opened a record of more than 900 new matters, including 580 health fraud matters, of which 366 were potential False Claims Act violations. The department intends to zero in on misuse of electronic health records, contributors to the opioid epidemic, senior citizen abuse allegations, manipulations of Medicare's managed care program, and improperly claiming COVID-19 relief funds.

The HHS Office of Inspector General (OIG) will soon seek feedback on making its guidance more timely, actionable, and useful and looking into developing a database that would list individual providers or entities that are excluded from federally funded health programs due to violations. The Agency also identified four priority areas, including ensuring the integrity and effectiveness of the pandemic response and recovery, ensuring the quality of care and patient safety in nursing homes, realizing the potential of telehealth, and advancing health equities.

Center for Medicaid and CHIP Services (CMCS) and Center for Medicare Leads Announced

The Biden Administration recently named Meena Seshamani to run CMS's Medicare office and Daniel Tsai to lead Medicaid services. A physician and former Obama-era health official, Seshamani will oversee Medicare policymaking. She will also serve as a deputy administrator at CMS. During the Obama administration, Seshamani was director of the HHS Office of Health Reform that focused on implementing the Affordable Care Act. Tsai most recently held the roles of Assistant Secretary for MassHealth (Massachusetts' Medicaid and CHIP agency) and state Medicaid Director, where he served for six years and implemented value-based reforms and programs that enhanced supports for social determinants of health. Tsai will hold the titles of Deputy Administrator of CMS and Director for CMCS.



Supreme Court to Consider Four High-Profile Healthcare Cases Next Term

The Supreme Court has announced that it will hear four healthcare-related cases during its next term. The high court will consider the nearly 30% cut in reimbursement for 340B drugs under the Trump administration. They will also review a Centers for Medicare and Medicaid Services (CMS) rule setting Medicare payments for disproportionate share hospitals (DSH) as well as a case to decide whether a state Medicaid program can claim part of a tort settlement for past medical expenses. Finally, the court will consider whether the Affordable Care Act allows a disparate impact claim from plaintiffs alleging disability discrimination.

CMS Proposes First Direct Effort to Close Equity Gaps in ESRD Rule

On July 1, the Centers for Medicare & Medicaid Services (CMS) released the [calendar year \(CY\) 2022 proposed rulemaking for end-stage renal disease \(ESRD\)](#). The rule includes the annual update to the ESRD prospective payment system and the ESRD Quality Incentive Program. The rule also includes proposed changes to the ESRD Treatment Choices (ETC) Model in an effort to address health equity issues, including testing a new approach that rewards participants for significant improvement in the rates of home dialysis and kidney transplants for lower-income beneficiaries. If finalized, these changes would take effect Jan. 1, 2022.

New Study Reveals Physician Compensation Down with Pandemic

Physicians generally experienced modest salary gains in 2020, according to Modern Healthcare's annual Physician Compensation Survey, a 0.5% increase on average, compared with 2.7% in 2019. The decline was primarily attributed to declines in productivity-based compensation, reflecting decreased demand for patient services during the pandemic.

COVID Update

As the Delta variant continues to spread, the Biden administration will deploy response teams made up of CDC and FEMA officials to areas in the U.S. with high levels of the variant.

New Israeli data suggests the Pfizer vaccine appears to be less effective in halting the spread of the delta strain, though it remains highly effective at preventing severe illness. It protected 64% of people against COVID between June 6 and early July, down from 94% between May 2 and June 5, but kept 93% of those infected out of the hospital, down only 5%.

In a statement about getting more American's vaccinated after falling slightly shy of its July 4 target to have at least 70% of Americans have at least one shot, the administration identified five key strategies, including expanding the availability of vaccines in mobile clinics, at workplaces, and in primary care offices, as well as ramping up door-to-door outreach.

Some Johnson & Johnson shot recipients reportedly seek out additional doses of the Pfizer or Moderna vaccines, which have higher efficacy rates. While some preliminary findings have suggested that mixing vaccines can be effective, the FDA warns against mixing vaccines until more conclusive data about efficacy and potential side effects.

White House pandemic response coordinator Jeff Zients says the U.S. government is ready to deploy booster shots if scientists and health officials determine they're needed.

The Biden administration is coming under increasing pressure to ease travel bans for international tourists as many European countries are reopening.