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H&K Health Dose: June 7, 2022A weekly dose of healthcare policy news

Legislative Updates

What's Next on Capitol Hill?

Lawmakers returned from Memorial Day recess this week, with the Senate taking up legislation to address healthcare and benefits for veterans exposed to toxic substances. The legislation would expand U.S. Department of Veterans Affairs (VA) healthcare eligibility for veterans exposed to toxic burn pits by creating a presumption of service connection to certain cancers and respiratory illnesses.

The House plans to vote on a gun violence prevention package advanced by the Judiciary Committee last week (the *Protecting Our Kids Act*) and a separate bill to implement a nationwide extreme risk – or red flag – law. House Majority Leader Steny Hoyer (D-Md.) intends to use the eight-bill package to put Republican lawmakers on record regarding their support for gun control measures. Bipartisan discussions have produced slight optimism about a potential compromise on a gun violence prevention bill in the Senate. Initial reporting suggests Democrats may be willing to accept some Republican priorities in exchange for action on guns. There is hope that a limited bill can receive the support it needs to pass the Senate.

This evening (June 7), the House is considering the U.S. Food and Drug Administration (FDA) user fee amendment (UFA) package (H.R. 7667). House leaders plan to hold a vote under an accelerated suspension of the rules, which requires a two-thirds majority. The Senate Health, Education, Labor, and Pensions (HELP) Committee will mark up its version of UFA legislation (likely next week). The House and Senate bills of the UFA text have different additional provisions, so compromises across the chambers and external stakeholders will be necessary to move this across the finish line by Sept. 30, 2022 (when current user fee agreements expire).

Meanwhile, Congress is working to move mental health and the Advanced Research Projects Agency for Health (ARPA-H) legislation as well. ARPA-H was authorized in the Fiscal Year 2022 omnibus package enacted last March. Congress is working to pass additional legislation with more prescriptive authorizing language. Notably, the week of June 20, the House will consider legislation that aims to establish ARPA-H as an independent agency within the U.S. Department of Health and Human Services (HHS), require the agency to coordinate with FDA and the Centers for Medicare & Medicaid Services (CMS) on product approvals and coverage decisions, and authorize \$5 million in appropriations funding for the new agency. The *Advanced Research Project Agency-Health Act* (H.R. 5585) would override HHS' recent decision to put ARPA-H under the National Institutes of Health.

Regarding mental health, relevant House and Senate committees continue to work on legislation expanding telehealth opportunities, reauthorizing various Substance Abuse and Mental Health Services Administration (SAMHSA) programs, strengthening the mental health workforce and allowing for mental health coverage parity.

Senate Democrats have also restarted talks with Sen. Joe Manchin (D-W.Va) in the hope of passing a reconciliation package before Congress adjourns for August recess. Senate Majority Leader Chuck Schumer (D-N.Y.) and Manchin, dubbed the "Chuck and Joe Show" by Politico, have reconvened negotiations for a package that would invest \$300 billion in energy tax credits, address the Affordable Care Act (ACA) premium subsidies that expire on Dec. 31, 2022, and possibly address drug pricing measures.

Last but not least, House appropriators plan to begin their markup of the Fiscal Year (FY) 2023 appropriations bills in June – aiming for votes to begin in July. Senate appropriators have recently confirmed that they aim to mark up all 12 appropriations bills in July.

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Republican Healthy Future Task Force Releases Proposal to Modernize Healthcare

The Modernization Subcommittee of the House GOP's Healthy Future Task Force released its solutions to harness technological innovations to improve Americans' lives and save taxpayer dollars last week. Created by House Republican Leader Kevin McCarthy (R-Calif.), the 17-member task force aims to develop solutions to modernize the U.S. healthcare system to lower costs, keep Americans healthy, develop better therapies and cures, and provide Americans with more choices. The proposals aim to expand access to innovative healthcare technologies, including telehealth, and utilize software to reduce fraud, waste and abuse in the healthcare system. Additional details on the plan are available on the task force website.

Regulatory Updates

After Complaints, HHS Releases New Checklist to Help Ensure Payer Compliance with No Surprises Act

After receiving a high volume of complaints regarding plan and issuer failures to adhere to new requirements under the No Surprises Act (NSA) concerning initial payments and notices of payment denial, HHS released <u>a new checklist</u> to help ensure that plans and issuers understand their obligations and are fully complying with key requirements under the law. HHS notes the list is not an exhaustive list of all NSA requirements. Additional resources and information <u>can be found</u> on the CMS website, where providers can also <u>submit complaints</u>.

CMS Announces New Quality Improvement Strategy

In a new <u>blog post</u>, CMS announced a new quality improvement strategy. CMS will start by hosting listening sessions with stakeholders early this summer to develop short-term and long-term actions that will help drive goals of the new strategy, which include health equity, patient safety and engagement, digital data exchange, and alignment between behavioral and physical health.

ONC Committee Advances Prior Authorization Recommendations

The Office of the National Coordinator for Health Information Technology's (ONC) Health Information Technology Advisory Committee (HITAC) <u>released a report with 13 recommendations</u> on how the ONC Health IT Certification Program can help to streamline, digitize and improve prior authorization processes. The recommendations were informed by a request for information earlier this year and meetings with several stakeholder groups, with a focus on cross-agency collaboration and centering the process around patients. The report will be used to help inform future rulemaking.

HHS Announces New Office of Environmental Justice

HHS has announced the creation of a new permanent Office of Environmental Justice. It will be led by interim director Sharunda Buchanan, a former Centers for Disease Control and Prevention (CDC) official who specialized in environmental health issues such as lead exposure. The new office will be responsible for creating and implementing a department-wide strategy on environmental justice and health and taking the lead on authoring an annual HHS environmental justice report, among other duties. It intends to bring new resources to communities, especially low-income communities and communities of color, to deal with elevated lead exposure or inadequate waste water treatment.

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Latest Medicare Trust Fund Report Forecasts Funding Shortfall by 2018, Recommends Urgent Action

According to the latest annual Medicare trustee report, Medicare will be unable to pay out full benefits starting in 2028, two years later than previously expected, due in large part to reduced healthcare services during the pandemic. The report calls for legislative action "sooner rather than later" to address the impending financial shortfall.

FDA Vaccine Advisory Committee Meets to Advance COVID Shot Recommendations

The FDA vaccine advisory committee met today (June 7) to discuss Novavax's COVID-19 shot. On June 14-15, the same committee is set to discuss COVID-19 vaccinations for children under age 5, which could set up the children's vaccines to begin as early as June 21, according to White House COVID-19 Response Coordinator Ashish Jha.

WHO Creates New Global Health Crises Committee

To better respond to global health crises, the World Health Organization (WHO) announced the creation of a new 14-person committee that will convene semiannually and immediately after any future international public health emergency declarations.