

McDermottPlus Check-Up: May 27, 2022

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This Week's Dose

This week, the nation was once again faced with a horrific tragedy as 19 students and two adults were murdered in Uvalde, Texas. Senate Majority Leader Chuck Schumer (D-NY) held off on pushing for procedural steps to place two gun control bills on the Senate's legislative calendar, both of which passed the House earlier this year. Instead, he is giving time to Senator Chris Murphy (D-CT) and others to negotiate with Republican Senators on possible shared reforms, such as background checks or red flag legislation, to be taken up when the Senate returns from the Memorial Day recess. Additionally, several hearings on the infant formula shortage garnered lawmakers' attention. As the number of legislative days remaining in 2022 dwindles, these continued crises create unknowns for the health policy agenda in the coming months.

Congress

FDA Acknowledges Shortcomings Leading to Infant Formula Shortage. Top officials from the Food and Drug Administration (FDA) testified before the [House Energy and Commerce Oversight Subcommittee](#) and the [Senate Health, Education, Labor, and Pensions \(HELP\) Committee](#) this week, sharing a timeline of the agency's response to plant closures last fall that contributed to the infant formula shortage this spring. FDA Commissioner Robert Califf noted that mailroom issues led to a delay in top agency officials receiving a report detailing these supply chain issues, which didn't reach leadership until February 2022 despite being originally sent in October 2021. Lawmakers from both sides of the aisle were unsatisfied with the agency's explanation of its delayed response, with numerous Members of Congress calling on FDA leadership to take greater responsibility for the shortage, which has left parents searching for new options for obtaining formula. Formula supplies from overseas have begun to arrive here in the U.S. to address the current supply challenges. Relatedly, the FTC launched a [probe](#) this week to further investigate the shortage, looking to "identify the factors that created such a fragile market."

Finance Committee Releases a Bipartisan Draft Proposal for Telehealth Policies for Mental Health. Marking progress toward broader committee legislation on mental health, Senator Finance Committee Chair Wyden (D-OR), Senior Committee Republican Senator Crapo (R-ID), Senator Cardin (D-MD) and Senator Thune (R-SD) joined together to release bipartisan draft text of a bill that would remove Medicare's in-person visit requirement for tele-mental health services, establish benefit transparency for mental health services delivered via telehealth, preserve audio-only mental

health coverage, direct Medicare and Medicaid to promote and support provider use of telehealth, and incentivize CHIP programs to develop local solutions to better serve behavioral health services in schools, including via telehealth, among other things. Their press release can be seen [here](#). Both the Senate Finance and HELP Committees are working to develop broader bipartisan mental health bills. The House Energy and Commerce Committee approved a bipartisan mental health package last week.

Bipartisan PBM Transparency Legislation Introduced in the Senate. On May 24, Senate Commerce Committee Chair Maria Cantwell (D-WA) and Senate Judiciary Committee Ranking Member Chuck Grassley (R-IA) [introduced](#) the Pharmacy Benefit Manager Transparency Act, legislation that would increase oversight of pharmacy benefit management companies (PBMs). The bill would prohibit PBMs from engaging in “spread pricing” (clawing back fees charged to pharmacies after the drug is dispensed); incentivize transparency practices; improve competition by requiring PBMs to report on the amount of money they make from spread pricing; and enhance Federal Trade Commission (FTC) enforcement to hold bad actors accountable. A summary can be found [here](#) and the full bill text is available [here](#).

Administration

CMS Holds Webinar on Medicaid and the End of the PHE. The Centers for Medicare & Medicaid Services (CMS) held its first in a series of planned webinars on the end of the public health emergency (PHE). This first discussion focused on how to wind down Medicaid and CHIP Continuous Enrollment redetermination and renewal processes. As background, the Families First Coronavirus Response Act (FFCRA) allows states to qualify for the temporary Medicaid Federal Medical Assistance Percentage (FMAP) increase during the COVID-19 PHE. To receive the enhanced FMAP, states must maintain continuous Medicaid coverage for enrollees until the end of the month when the COVID-19 PHE ends. Based on current estimates, up to 15 million people could lose their current Medicaid or CHIP coverage, as states will be required to restart the annual Medicaid and CHIP eligibility reviews through a process known as “unwinding” when the PHE ends.

The webinar did not provide new information regarding the Medicaid PHE unwinding but instead provided background information and a review of current resources and guidance for both [States and Partners](#) as well as for [Medicaid and CHIP Enrollees](#). CMS will be posting the webinar recording, and we will share that when available.

CMS plans to hold webinars on unwinding different PHE flexibilities monthly. The Administration is expected to renew the PHE again in mid-July, and we believe that they will do so again in October when that next extension expires, meaning the PHE is expected to remain in effect at least through the end of 2022, and possibly longer. Nonetheless, CMS is socializing plans for a post-PHE world to apprise stakeholders of impending changes.

CMS Launches Probes into Hospitals with High-Levels of COVID. CMS Principal Deputy Administrator and Chief Operating Officer Jon Blum, announced that the agency would be investigating hospital facilities with high COVID-19 transmission rates, prioritizing these probes into facilities with high numbers of patient or health worker safety complaints. Hospitals are currently required to report data about suspected hospital acquired infections to the Department of Health and Human Services (HHS), but CMS will be implementing a more rigorous surveying process to identify and cite facilities with particularly lenient COVID protocols. The agency will be requesting additional funds from Congress to support these activities, with Blum noting he is hopeful congressional lawmakers would approve his recent budget request to support augmented agency processes.

ARPA-H Established Within NIH. This week, the National Institutes of Health (NIH) noticed in the [Federal Register](#) that the agency has modified its structure to include the Advanced Research Projects Agency for Health (ARPA-H). This new agency is modeled after the Defense Advanced Research Projects Agency (DARPA), which is famed for backing high risk/reward innovations like the internet. President Biden called for the formation of ARPA-H in his April 28, 2021, [remarks](#) to a Joint Session of Congress. Since that time, the Administration and Congress have been working to develop and stand up an agency to conduct innovative, high-risk/high-reward biomedical research. On May 25, Secretary Becerra [announced](#) that Adam Russell, former DARPA program manager, will serve as acting deputy director of the newly established agency, beginning in June.

This formal establishment of the new agency under NIH for administrative purposes, but reporting directly to the Secretary of HHS, comes following an opposing viewpoint from congressional leaders on the House Energy and Commerce Committee, who have argued that the agency should be fully independent. While the funding and initial structure of the agency was included and approved in the FY22 Omnibus with bipartisan support, debate continues around consideration of the “[ARPA-H Act](#)” (H.R. 5585), which would clarify where ARPA-H will be located from a governance perspective. If the legislation were to pass, ARPA-H would no longer be part of NIH and instead would become a fully autonomous agency within HHS.

Quick Hits

- The Food and Drug Administration [announced](#) it will meet on June 15 to review data for Pfizer and Moderna COVID-19 vaccines for children under 5 years.
- Leaders of agencies across the HHS issued a joint [letter](#) to states, tribes, and jurisdictions encouraging them to prioritize and maximize their efforts to strengthen children’s mental health and well-being.
- The Congressional Budget Office (CBO) issued a [report](#), presenting its baseline projections for the federal budget over one and ten years respectively, if spending and taxes remain generally unchanged. Per the report, CBO expects this year’s budget shortfall to shrink significantly to \$1 trillion down from \$2.8 trillion in 2021.
- U.S. Surgeon General Vivek Murthy issued an [advisory](#), calling for additional support for healthcare workers as burnout, an aging physician workforce, and nationwide workforce shortages threaten the healthcare sector.
- Four states – California, Florida Kentucky, and Oregon – are extending [Medicaid coverage](#) for postpartum healthcare services from 60 days to twelve months.
- The Medicare Payment Advisory Commission (MedPAC) announced [five new appointments](#) and two reappointments.
- The Biden Administration announced it has withdrawn the [Securing Updated and Necessary Statutory Evaluations Timely \(SUNSET\)](#) rule, which would have required agencies to review healthcare regulations every ten years and rescind, amend or extend the policies.

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