



Health Policy Briefing

June 20, 2022

Drafting of Gun Violence Bill Continues into Weekend

Senate Minority Leader Mitch McConnell (R-Ky.) stated that he is comfortable with the bipartisan gun violence proposal reached by Senate negotiators and that he will support the final legislation if it is in line with the details of the previously released framework. The tentative deal includes measures to make changes to background checks and funding for state red-flag laws, mental health, and school security. Lawmakers have yet to release legislative text or an estimate of the total cost of the bill. Sen. Chris Murphy (D-Conn.), one of the lead negotiators on the package, stated that a vote on the bill could come as early as this week. Sen. John Cornyn (R-Texas), the head GOP negotiator, noted however that there are still unresolved issues surrounding the red-flag law provisions and language to close the ‘boyfriend loophole’. The Senate is scheduled to adjourn late this week for a two-week July 4 recess.

House to Consider ARPA-H, Mental Health Legislation This Week

The House of Representatives plans to consider [H.R. 7666](#), the *Restoring Hope for Mental Health and Well-Being Act of 2022* on the floor this week. The bill would terminate the special waiver health care providers need to prescribe substance use disorder treatment medication as well as provide more funding for mental health care services and people suffering from drug addiction. The House is also scheduled to consider [H.R. 5585](#), the *Advanced Research Projects Agency-Health Act*, which would establish the President’s proposed new agency to speed the development of medical breakthroughs. The chamber also plans to vote on [H.R. 5407](#), the *Enhancing Mental Health and Suicide Prevention Through Campus Planning Act* under suspension of the rules.

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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.), will be considered by the House Rules Committee on Tuesday. 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 VA's list of service presumptions. It would also mandate more federal research on toxic burn pits. The package would cost \$278.5 billion over the next decade. In response to Republican concerns about the total cost of the package, the Senate's substitute amendment decreased the cost of the bill from \$322 billion by reducing the number of veterans eligible for disability compensation and by delaying the bill's effective date. The legislation is expected to be sent to the President's desk after a final vote is held in the House of Representatives this week.

HELP Advances User Fee Package

Last week, 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 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. Ranking Member Burr expressed concern that several amendments adopted during the markup "would kill innovation, placing the entire bill in jeopardy", likely in response to two amendments adopted related to generic drugs. Additional amendments adopted during the committee markup included provisions to prevent future infant formula shortages, increase transparency around accelerated approval determinations, and allow the FDA to approve predetermined change plans for post-market changes to a medical device during its premarket submission phase. The House already passed its version of the bill ([H.R. 7667](#)) on the floor in a 392-28 suspension vote. The current user fee agreements expire at the end of September. HELP Committee Chair Patty Murray (D-Wash.) stated that she would work with Majority Leader Chuck Schumer (D-N.Y.) on the timing for Senate floor consideration of the reauthorization. House Energy and Commerce Chair Frank Pallone (D-N.J.) has expressed confidence that the two chambers will be able to reconcile the differences between the bills without much difficulty.

House Appropriators to Mark Up FDA Bill This Week

The House Appropriations Subcommittee on Agriculture, Food and Drug Administration (FDA), and Related Agencies marked up its draft fiscal year 2023 spending bill last week. The legislation totals \$27.2 billion, an 8% increase over the previous year. It includes \$3.65 billion in discretionary funding for the FDA, a \$341 million increase and slightly higher than the President's budget request. Appropriations Chair Rosa DeLauro (D-Conn.) stated the extra funds would support the inspection of baby formula and review of new products. The bill was advanced by voice vote, despite GOP opposition to the increases in FDA food safety funding. The full Appropriations Committee is scheduled to meet on Thursday to markup the legislation, which lawmakers hope to bring to the floor of the full House next month.

Senate Finance Leadership Release Youth Mental Health Discussion Draft

Bipartisan leadership of the Senate Finance Committee released a draft [bill](#) to overhaul the youth mental health care system as a part of an expansive mental health care package. The discussion draft would expand mental health programs in schools and proposes to allow health care providers to receive Medicaid payments for the delivery of behavioral and physician health care services on the same day. The proposal, drafted by Chair Ron Wyden (D-Ore.), Ranking Member Mike Crapo (R-Idaho), Sen. Tom Carper (D-Del.), and Sen. Bill Cassidy (R-La.), would compel states to clarify Medicaid guidance on allowable payments, improve screening and diagnostic benefits, and require Medicaid to issue guidance on care for foster youth with mental health care needs.

MedPAC June 2022 Report to the Congress

The Medicare Payment Advisory Commission (MedPAC) released its June 2022 [Report](#) to Congress last week. The report asserts that the Medicare program would have spent \$6.6 billion less in 2019, and beneficiaries would have saved \$1.7 billion in out-of-pocket costs, if payment rates between hospital outpatient departments, ambulatory surgical centers, and doctors' offices were aligned. The report also recommends that the Centers for Medicare and Medicaid Services (CMS) consider using a population-based payment approach that reduces the number of accountable care organization model tracks, transitioning to periodic administrative updates of benchmarks using a growth factor, and using a mandatory national episode-based payment model for certain clinical episodes to reduce the number of Medicare alternative payment models. In response to the rising launch prices of certain drugs approved with limited clinical evidence, MedPAC recommends that Congress give the U.S. Department of Health and Human Services (HHS) Secretary the discretion to use coverage with evidence development and to cap a drug's price based on existing evidence. The report also recommends that the HHS Secretary be granted the authority to use internal reference pricing to establish a maximum reimbursement level for a group of drugs. Other topics covered in the report include vulnerable Medicare beneficiaries' access to care; a framework for identifying safety net providers and whether new funding may be warranted; and options to improve the accuracy of Medicare Advantage payments.

WH to Release New Pandemic Preparedness Plan

The Biden administration is getting ready to release a new plan to prepare for future pandemics and other biological threats, according to a senior administration official. The plan to improve the nation's framework for preparedness, response, and recovery is the result of more than a year of work by national security and public health officials. The administration could release the National Biodefense Strategy as soon as this month. It will outline an approach for countering biological threats to humans, animals, environments, and crops. The Strategy aims to more clearly delineate the responsibilities of federal agencies in pandemic response. The first iteration of the National Biodefense Strategy was released in September 2018 by the Trump administration.

Becerra, Fauci Test Positive in Breakthrough COVID Cases

U.S. Department of Health and Human Services (HHS) Secretary Xavier Becerra tested positive for COVID-19 last week after taking an antigen test. He is fully vaccinated and boosted against COVID-19 and was experiencing mild symptoms. He previously tested positive for COVID-19 last month. He was not considered a close contact of President Joe Biden or Vice President Kamala Harris and planned to work in isolation in accordance with the Centers for Disease Control and Prevention guidance. This is the second time in about a month that the HHS Secretary has tested positive for COVID-19.

President Joe Biden's Chief Medical Officer and Director of the National Institute of Allergy and Infectious Diseases Anthony Fauci has also tested positive for COVID-19. He is fully vaccinated and has been boosted twice and was experiencing mild symptoms of the virus. Fauci planned to isolate and work from his home and was not considered a close contact for President Biden or other senior government officials.

COVID Vaccines Authorized for Nation's Youngest Children

The U.S. Food and Drug Administration authorized emergency use of the Moderna COVID-19 vaccine and the Pfizer-BioNTech COVID-19 vaccine for the prevention of COVID-19 to include use in children down to 6 months of age last week. 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. The two vaccines for this population use different dosages, a different number of shots, and different intervals between shots. While severe disease and death from COVID-19 remain uncommon in children compared to adults, COVID-19 is still a leading cause of death among children and adolescents, including children aged one to four.

Upcoming Congressional Hearings and Markups

House Rules Committee meeting for H.R. 7666, **Restoring Hope for Mental Health and Well-Being Act**; H.R. 5585, **Advanced Research Projects Agency-Health (ARPA-H) Act**; H.R. 4176, **LGBTQI+ Data Inclusion Act**; and Senate amendment to H.R. 3967, **Honoring our PACT Act**; 2:00 p.m.; June 21

House Veterans' Affairs Subcommittee on Health hearing on H.R. 291, **COST SAVINGS Enhancement Act**; H.R. 345, **Reproductive Health Information for Veterans Act**; H.R. 1216, **Modernizing Veterans' Health Care Eligibility Act**; H.R. 1957, **Veterans Infertility Treatment Act**; H.R. 6273, **VA Zero Suicide Demonstration Project Act**; and H.R. 7589, **REMOVE Copays Act**; 10:00 a.m.; June 22

Senate Environment and Public Works Committee hearing to examine Toxic Substances Control Act amendments implementation; 10:00 a.m.; June 22

Senate Commerce, Science, and Transportation executive session to consider several pieces of legislation, including S. 4293, **Pharmacy Benefit Manager Transparency Act of 2022**; 10:00 a.m.; June 22

House Appropriations markup of FY 2023 Defense Funding; 10:00 a.m.; June 23

House Appropriations markup of FY 2023 Agriculture/Food and Drug Administration Funding; 10:00 a.m.; June 23

House Judiciary Subcommittee on Courts, Intellectual Property, and the Internet hearing "The Patent Trial and Appeal Board After 10 Years: Impact on Innovation and Small Businesses;" 10:00 a.m.; June 23

House Oversight and Reform Select Subcommittee on the Coronavirus Crisis "A Hearing with Trump White House Coronavirus Response Coordinator Dr. Deborah Birx;" 10:00 a.m.; June 23

House Appropriations Subcommittee on Labor/Health and Human Services/Education markup of FY 2023 Funding; 5:30 p.m.; June 23

House Appropriations markup of FY 2023 Labor/Health and Human Services/Education Funding; 10:00 a.m.; June 30

H.R.8038 — To authorize the Food and Drug Administration to require manufacturers of infant formula to warn about a discontinuance or interruption in the production of infant formula, and for other purposes. Sponsor: Rep. Johnson, Dusty [R-SD-At Large]; Committees: House - Energy and Commerce

H.Res.1171 — Supporting the designation of the week of June 13 through June 19, 2022, as “National Men’s Health Week”. Sponsor: Rep. Payne, Donald M., Jr. [D-NJ-10]; Committees: House - Oversight and Reform

S.4386 — A bill to allow for devices with a predetermined change control plan to be marketed without submitting a supplemental application or premarket notification if the changes to such devices are consistent with such plan. Sponsor: Sen. Braun, Mike [R-IN]; Committees: Senate - Health, Education, Labor, and Pensions

S.4385 — A bill to amend the Federal Food, Drug, and Cosmetic Act to allow waivers of annual establishment registration fees for small businesses, and for other purposes. Sponsor: Sen. Braun, Mike [R-IN]; Committees: Senate - Health, Education, Labor, and Pensions

S.4381 — A bill to amend titles XVIII and XIX of the Social Security Act with respect to nursing facility requirements, and for other purposes. Sponsor: Sen. Warner, Mark R. [D-VA]; Committees: Senate – Finance

S.4378 — A bill to reauthorize a provision of the Federal Food, Drug, and Cosmetic Act pertaining to drugs containing single enantiomers. Sponsor: Sen. Marshall, Roger [R-KS]; Committees: Senate - Health, Education, Labor, and Pensions

S.4396 — A bill to require the Secretary of Defense to conduct a study on providing benefits under TRICARE Reserve Select and the TRICARE dental program to members of the Selected Reserve and their dependents Sponsor: Sen. Duckworth, Tammy [D-IL]; Committees: Senate - Armed Services

S.4395 — A bill to allow grantees under the HIV Health Care Services Program to allocate a portion of such funding for services to individuals at risk of acquiring HIV. Sponsor: Sen. Scott, Rick [R-FL]; Committees: Senate - Health, Education, Labor, and Pensions

S.4391 — A bill to establish rules for export certification of devices manufactured outside of the United States. Sponsor: Sen. Cassidy, Bill [R-LA]; Committees: Senate - Health, Education, Labor, and Pensions

S.4390 — A bill to require summary approval information with respect to certain approved drugs and biological products. Sponsor: Sen. Hickenlooper, John W. [D-CO]; Committees: Senate - Health, Education, Labor, and Pensions

S.4388 — A bill to amend title 10, United States Code, to waive cost-sharing under the TRICARE program for three mental health outpatient visits per year, and for other purposes. Sponsor: Sen. Ossoff, Jon [D-GA]; Committees: Senate - Armed Services

S.Res.672 — A resolution expressing support for the designation of May 2022 as “Stroke Awareness Month”. Sponsor: Sen. Lujan, Ben Ray [D-NM]; Submitted in the Senate, considered, and agreed to without amendment and with a preamble by Unanimous Consent.

H.R.8063 — To amend title XVIII of the Social Security Act to repeal the private cause of action for damages in the case of a primary plan which fails to provide for primary payment or appropriate reimbursement. Sponsor: Rep. Schneider, Bradley Scott [D-IL-10]; Committees: House - Ways and Means; Energy and Commerce

H.R.8058 — To require the Attorney General to propose a program for making treatment for post-traumatic stress disorder and acute stress disorder available to public safety officers, and for other purposes. Sponsor: Rep. Joyce, David P. [R-OH-14]; Committees: House – Judiciary

H.R.8057 — To amend the Foreign Assistance Act of 1961 to implement policies to end preventable maternal, newborn, and child deaths globally. Sponsor: Rep. Jacobs, Sara [D-CA-53]; Committees: House - Foreign Affairs

H.Res.1174 — Supporting the goals and ideals of “Deep Vein Thrombosis and Pulmonary Embolism Awareness Month”. Sponsor: Rep. Burgess, Michael C. [R-TX-26]; Committees: House - Energy and Commerce

H.R.8081 — To amend title 10, United States Code, to preserve the authority of the Secretary of the military department concerned over a member of the Armed Forces undergoing medical treatment or evaluation for medical disability, and for other purposes. Sponsor: Rep. Mast, Brian J. [R-FL-18]; Committees: House - Armed Services

H.R.8078 — To ensure that prior authorization medical decisions under Medicare are determined by physicians. Sponsor: Rep. Green, Mark E. [R-TN-7]; Committees: House - Ways and Means; Energy and Commerce

H.Res.1177 — Expressing the sense of the House of Representatives regarding the Centers for Medicare & Medicaid Services developing a mobility metric to guide providers in preventing mobility loss among hospitalized older adults. Sponsor: Rep. Pence, Greg [R-IN-6]; Committees: House - Energy and Commerce

H.Res.1176 — Expressing support for the designation of June 19, 2022, as “World Sickle Cell Awareness Day” in order to increase public alertness across the United States and global community about sickle cell disease, the continued need for empirical research, early detection screenings for sickle cell trait carriers, novel effective treatments leading to a cure, and preventative care programs with respect to complications from sickle cell anemia and conditions related to sickle cell disease. Sponsor: Rep. Davis, Danny K. [D-IL-7]; Committees: House - Energy and Commerce

S.4414 — A bill to require the Secretary of Health and Human Services to publish a list of hospitals found to be non-compliance with the hospital price transparency rule. Sponsor: Sen. Braun, Mike [R-IN]; Committees: Senate - Health, Education, Labor, and Pensions

S.4412 — A bill to authorize the Secretary of Health and Human Services to award grants to States, Indian Tribes, Tribal organizations, and urban Indian organizations to provide safety measures to social workers, health workers, and human services professionals performing services placing such individuals in high-risk and potentially dangerous situations, and for other purposes. Sponsor: Sen. Sinema, Kyrsten [D-AZ]; Committees: Senate - Health, Education, Labor, and Pensions

S.4434 — A bill to protect the privacy of personal reproductive or sexual health information, and for other purposes. Sponsor: Sen. Hirono, Mazie K. [D-HI]; Committees: Senate - Commerce, Science, and Transportation

S.4425 — A bill to amend the Public Health Service Act to authorize a scholarship and loan repayment program to incentivize physicians to enter into the field of sickle cell disease research and treatment, and for other purposes. Sponsor: Sen. Van Hollen, Chris [D-MD]; Committees: Senate - Health, Education, Labor, and Pensions

S.Res.683 — A resolution supporting the goals and ideals of World Sickle Cell Awareness Day. Sponsor: Sen. Booker, Cory A. [D-NJ]; Committees: Senate - Foreign Relations

H.R.8100 — To amend title 38, United States Code, to improve the authority of the Secretary of Veterans Affairs to hire psychiatrists; Sponsor: Rep. Cartwright, Matt [D-PA-8]; Committees: House - Veterans' Affairs

H.R.8111 — To protect the privacy of personal reproductive or sexual health information, and for other purposes; Sponsor: Rep. Jacobs, Sara [D-CA-53]; Committees: House - Energy and Commerce

- H.R.8113 — To amend title 10, United States Code, to eliminate certain charges under the TRICARE dental program for members of the Selected Reserve of the Ready Reserve, and for other purposes; Sponsor: Rep. Kim, Andy [D-NJ-3]; Committees: House - Armed Services
- H.R.8129 — To give the Federal Trade Commission authority over certain tax-exempt organizations; Sponsor: Rep. Spartz, Victoria [R-IN-5]; Committees: House - Energy and Commerce
- H.R.8130 — To direct the Assistant Secretary for Planning and Evaluation of the Department of Health and Human Services to conduct an annual study on health care competition and consolidation at the State level; Sponsor: Rep. Spartz, Victoria [R-IN-5]; Committees: House - Energy and Commerce
- H.R.8131 — To amend the Pension Funding Equity Act of 2004 to repeal the antitrust exemption applicable to graduate medical resident matching programs; Sponsor: Rep. Spartz, Victoria [R-IN-5]; Committees: House – Judiciary
- H.R.8132 — To amend title XVIII of the Social Security Act to repeal the Obamacare ban on provider-owned hospitals, and for other purposes; Sponsor: Rep. Spartz, Victoria [R-IN-5]; Committees: House - Energy and Commerce; Ways and Means
- H.R.8133 — To amend title XVIII of the Social Security Act and title XXVII of the Public Health Service Act to address incorrect billing by off-campus hospital locations, and for other purposes; Sponsor: Rep. Spartz, Victoria [R-IN-5]; Committees: House - Energy and Commerce; Ways and Means
- H.R.8134 — To eliminate the inpatient-only service list; Sponsor: Rep. Spartz, Victoria [R-IN-5]; Committees: House - Energy and Commerce; Ways and Means
- H.R.8135 — To require the Government Accountability Office to evaluate the effects of anticompetitive contracting clauses in contracts between health insurers and health care providers and to determine actions taken by the Federal Trade Commission and the Department of Justice relating to the use of such clauses in such contracts and to assess their ability to effectively enforce the Federal antitrust laws with respect to such use; Sponsor: Rep. Spartz, Victoria [R-IN-5]; Committees: House - Energy and Commerce; Judiciary