



## Health Policy Briefing

May 31, 2022

### Senate to Consider Gun Control Legislation

President Joe Biden is demanding that Congress pass new gun control measures following the killing of 19 children and two teachers during a mass shooting at an elementary school in Uvalde, Texas last week. Senate Majority Leader Chuck Schumer (D-N.Y.) has moved to put two gun background check bills on the Senate calendar but stated that he is not optimistic about their prospects given continued Republican opposition to any firearm restrictions. While most Republicans, including Minority Leader Mitch McConnell (R-Ky.), are not inclined to examine legislative solutions to gun violence, a few GOP senators appeared more open to exploring areas of possible compromise. Sens. Roy Blunt (R-Mo.), Lindsey Graham (R-S.C.), Susan Collins (R-Maine), and Mitt Romney (R-Utah) have highlighted the potential of red flag proposals and efforts to address mental health. Majority Whip Dick Durbin (D-Ill.) confirmed that the chamber will debate and vote on legislation mandating background checks for gun sales following the Memorial Day recess, but there appears little chance for movement in the evenly divided Senate where at least 10 Republican votes would be required to avoid a filibuster. Sen. Joe Manchin (D-W.Va.) has also confirmed that he remains opposed to changing the Senate’s filibuster rules to pass gun restrictions by a simple majority.

### COVID-19 Aid Back to Negotiating Table

The senators working to draft the latest package of COVID-19 response funding will return to the negotiating table amidst reports that offsets for the \$10 billion agreed to in April have been spent given the delay in taking up the bill. According to a Republican aide, between \$2 and \$4 billion in funds previously designated as COVID-19 pay-fors have already been spent. Sen. Roy Blunt (R-Mo.), one of the Republicans working to negotiate an agreement, also stated that the overall size of the package may change as the total need has increased over the past two months. The deal has been stalled amidst a disagreement over the administration’s decision to end the Title 42 immigration policy.

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## Senate *FDA Safety and Landmark Advancements Act* (FDASLA) Introduced

Bipartisan leadership of the Senate Health, Education, Labor, and Pensions (HELP) Committee introduced [legislation](#) last week to reauthorize the Food and Drug Administration's (FDA) medical product user fee programs for another five years. The introduced bill contains several additions to the discussion draft released earlier this month, including changes to the accelerated approval process that would give the FDA the authority to remove from the market any products that obtained accelerated approval but fail to show a clinical benefit. The FDA would be allowed to require that post-market studies begin before approval is granted. The Senate's bill also adds a proposal to allow the FDA to require that opioids are dispensed to patients with safe, in-home disposal systems, based on [S. 2628](#). HELP Committee Ranking Member Richard Burr (R-N.C.) stated that the current infant formula shortages and the agency's response to the crisis may slow the reauthorization of the user fee programs. He said he planned to consider "whether now is the right time to move forward on our user fee negotiations...It may be that finding all the answers to this question is increasingly more important than expediting something that really doesn't have a finality until the end of this year." The HELP Committee is currently targeting June 8 for the markup of the must-pass bill. Congress must act on the legislation before the current user fee agreements expire on September 30. The House Energy and Commerce Committee reported out its user fee package on May 18.

## Burn Pitt Bill to Get Early June Vote

Senate Majority Leader Chuck Schumer (D-N.Y.) stated that he will bring legislation to support veterans who have been exposed to toxic substances during military deployments to the floor in early June. The expansive bipartisan agreement is based on the *Sergeant First Class Heath Robinson Honoring Our Promise to Address Comprehensive Toxics (PACT) Act* ([H.R. 3967](#)), introduced by House Veterans Affairs Committee Chair Mark Takano (D-Calif.). 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.

## Finance Members Release Bipartisan Telemental Health Draft

A bipartisan group of Senate Finance Committee members has released a discussion [draft](#) detailing their proposal to expand telehealth services for Medicare beneficiaries as a part of the panel's forthcoming mental health care package. The measure would remove Medicare's requirement for in-person visits before telemental health services, direct the Centers for Medicare and Medicaid Services to encourage more virtual and telephonic mental health visits, and promote telehealth cost transparency and new mental health programs in CHIP. The draft was issued by Chair Ron Wyden (D-Ore.), Ranking Member Mike Crapo (R-Idaho), Sen. Ben Cardin (D-Md.), and Sen. John Thune (R-S.D.).

## Pharmacist Lawmakers Request PBM Probe

Reps. Buddy Carter (R-Ga.) and Diana Harshbarger (R-Tenn.) have sent a [letter](#) to the Federal Trade Commission (FTC) calling for an investigation into business practices of pharmacy benefit managers (PBMs) that increase the out-of-pocket cost of prescription medications for patients. Both lawmakers worked as pharmacists before being elected to Congress. They argue that an investigation into PBMs is necessary "to obtain an understanding of conflicts of interest, anti-competitive conduct, and marketplace distortions that are causing prescription drug prices to increase continuously." The legislators sent the letter in response to a solicitation for comments by the FTC on this topic.

## Lawmakers Ask Leadership to Extend Expanded ACA Subsidies

A group of more than two dozen Democrats led by Rep. Lauren Underwood (D-Ill.) is [asking](#) congressional leadership to use the reconciliation process to pass legislation that would permanently extend the expanded Affordable Care Act subsidies used to offset the cost of insurance plans. The subsidies lowered premium costs and resulted in 2.5 million new enrollees following their creation in the American Rescue Plan. Thirteen million Americans would see the price of their premiums spike if the subsidies are not extended before the new year. The lawmakers also call for the use of reconciliation to expand Medicaid coverage in states that have not yet done so.

## Oversight Panel Investigates Birth Control Coverage

The House Committee on Oversight and Reform sent [letters](#) to nine of the nation's largest pharmacy benefit managers (PBMs) and insurers to confirm their compliance with the Affordable Care Act's requirement that they provide birth control at no cost to the patient. According to Chair Carolyn Maloney (D-N.Y.), "information obtained by the committee suggests that plans and issuers may not be fully complying with the ACA's requirements, potentially depriving enrollees of access to critically important reproductive health care." She requests a response from companies by June 9.

## More Breakthrough COVID-19 Cases on Capitol Hill

Sen. Jeff Merkley (D-Ore.) tested positive for COVID-19 in another breakthrough case of the virus amongst lawmakers on Capitol Hill. Merkley was experiencing mild symptoms, which he attributed to being fully vaccinated and boosted. On the House side, Rep. Al Green (D-Texas) also announced a positive test last week.

## Becerra Taps ARPA-H Second in Command

U.S. Department of Health and Human Services (HHS) Secretary Xavier Becerra [announced](#) the formal establishment of the Advanced Research Project Agency for Health (ARPA-H) as an independent entity within the National Institutes of Health last week. Adam H. Russell, D.Phil., was appointed acting deputy director. Dr. Russell is the Chief Scientist at the University of Maryland's Applied Research Laboratory for Intelligence and Security. He spent more than a decade as a Program Manager, first at the Intelligence Advanced Research Projects Activity (IARPA) and then at the Defense Advanced Research Projects Agency (DARPA). Dr. Russell will begin his new role in June. As ARPA-H's second in command, he will be responsible for building the administrative structure of the agency and overseeing the hiring of initial operational staff to ensure the agency is stood up as effectively and efficiently as possible. An ARPA-H director will be appointed by President Joe Biden at a future date. The Director will be responsible for the administration and operation of ARPA-H and will report to the HHS Secretary.

## AHA Asks CMS to Hold MA Plans Accountable for Utilization Management Practices

The American Hospital Association (AHA) has sent a [letter](#) to the Centers for Medicare and Medicaid Services (CMS) asking the agency for a meeting to discuss ways to hold Medicare Advantage (MA) plans accountable for utilization management and prior authorization policies that they argue inappropriately and illegally restrict beneficiary access to care. AHA points to the disparity in the use of prior authorization in MA compared to traditional fee-for-service Medicare, resulting in equity issues between beneficiaries in the different parts of the program. They ask CMS to align medical necessity and coverage criteria in MA with traditional Medicare regulations. AHA also asks CMS to reform the prior authorization process itself to make it less burdensome on providers, encouraging the agency to work with Congress on legislative proposals like the [Improving Seniors' Timely Access to Care Act](#). AHA recommends that CMS collect and make public data on coverage denials, appeals, and grievances while setting up a provider complaint process. They suggest appropriate enforcement action and penalties to help ensure compliance by MA plans. The letter also notes that plans should be prohibited from submitting beneficiary diagnoses for the purposes of risk adjustment when no care has been provided for the diagnoses or when care was denied.

## Upcoming Congressional Hearings and Markups

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

## Recently Introduced Health Legislation

S.Res.648 — A resolution designating May 2022 as “National Brain Tumor Awareness Month”; Sponsor: Sen. Daines, Steve [R-MT]; Submitted in the Senate, considered, and agreed to without amendment and with a preamble by Unanimous Consent.

S.4289 — A bill to prohibit an employer from terminating the coverage of an employee under a group health plan while the employer is engaged in a lock-out, and for other purposes; Sponsor: Sen. Brown, Sherrod [D-OH]; Committees: Senate - Health, Education, Labor, and Pensions

S.4293 — A bill to prevent unfair and deceptive acts or practices and the dissemination of false information related to pharmacy benefit management services for prescription drugs, and for other purposes; Sponsor: Sen. Cantwell, Maria [D-WA]; Committees: Senate - Commerce, Science, and Transportation

H.R.7864 — To authorize assistance to train and retain obstetrician-gynecologists and sub-specialists in urogynecology and to help improve the quality of care to meet the health care needs of women in least developed countries, and for other purposes; Sponsor: Rep. DeLauro, Rosa L. [D-CT-3]; Committees: House - Foreign Affairs

H.R.7869 — To authorize assistance to aid in the prevention and treatment of obstetric fistula in foreign countries, and for other purposes; Sponsor: Rep. Maloney, Carolyn B. [D-NY-12]; Committees: House - Foreign Affairs

H.R.7876 — To amend title XVIII of the Social Security Act to protect access to telehealth services under the Medicare program; Sponsor: Rep. Smith, Adrian [R-NE-3]; Committees: House - Ways and Means; Energy and Commerce

H.R.7878 — To amend title XVIII of the Social Security Act to expand the ability of renal dialysis facilities to serve as originating sites for telehealth services under the Medicare program; Sponsor: Rep. Wenstrup, Brad R. [R-OH-2]; Committees: House - Energy and Commerce; Ways and Means

S.4312 — A bill to amend the Internal Revenue Code of 1986 to repeal the direct payment requirement on the exclusion from gross income of distributions from governmental plans for health and long-term care insurance. Sponsor: Sen. Brown, Sherrod [D-OH]; Committees: Senate - Finance

S.4307 — A bill to amend title XVIII of the Social Security Act to expand the ability of renal dialysis facilities to serve as originating sites for telehealth services under the Medicare program. Sponsor: Sen. Warner, Mark R. [D-VA]; Committees: Senate - Finance

S.4306 — A bill to support behavioral health integration into primary care practices, and for other purposes. Sponsor: Sen. Smith, Tina [D-MN]; Committees: Senate - Health, Education, Labor, and Pensions

S.4303 — A bill to provide for a period of exclusivity for first interchangeable biological products. Sponsor: Sen. Kaine, Tim [D-VA]; Committees: Senate - Health, Education, Labor, and Pensions

S.4302 — A bill to amend the Federal Food, Drug, and Cosmetic Act to require prompt reports of marketing status by holders of approved applications for biological products, and for other purposes. Sponsor: Sen. Kaine, Tim [D-VA]; Committees: Senate - Health, Education, Labor, and Pensions

S.4301 — A bill to reauthorize and improve the block grants for prevention and treatment of substance abuse. Sponsor: Sen. Hassan, Margaret Wood [D-NH]; Committees: Senate - Health, Education, Labor, and Pensions

S.Res.656 — A resolution designating May 2022 as “Older Americans Month”; Sponsor: Sen. Kelly, Mark [D-AZ]; Latest Action: Submitted in the Senate, considered, and agreed to without amendment and with a preamble by Unanimous Consent.

S.Res.657 — A resolution designating May 16, 2022, as “Older Americans Mental Health Awareness Day” to raise awareness of the mental health needs of older adults; Sponsor: Sen. Casey, Robert P. [D-PA]; Latest Action: Submitted in the Senate, considered, and agreed to without amendment and with a preamble by Unanimous Consent.

S.4316 — A bill to direct the Secretary of Health and Human Services to update and clarify its rule on substances generally recognized as safe and to establish within the Center for Food Safety and Applied Nutrition of the Food and Drug Administration the Office of Food Chemical Safety Reassessment, and for other purposes; Sponsor: Sen. Markey, Edward J. [D-MA]; Committees: Senate - Health, Education, Labor, and Pensions

S.4323 — A bill to amend the Indian Health Care Improvement Act to establish an urban Indian organization confer policy for the Department of Health and Human Services; Sponsor: Sen. Smith, Tina [D-MN]; Committees: Senate - Indian Affairs

S.4330 — A bill to amend the Public Health Service Act to authorize a loan repayment program to encourage specialty medicine physicians to serve in rural communities experiencing a shortage of specialty medicine physicians, and for other purposes; Sponsor: Sen. Rosen, Jacky [D-NV]; Committees: Senate - Health, Education, Labor, and Pensions

S.4332 — A bill to amend the Public Health Service Act to direct the Secretary of Health and Human Services, acting through the Director of the Centers for Disease Control and Prevention, to support research and programmatic efforts that will build on previous research on the effects of adverse childhood experiences; Sponsor: Sen. King, Angus S. [I-ME]; Committees: Senate - Health, Education, Labor, and Pensions

S.4333 — A bill to deem certain products regulated by the Food and Drug Administration as drugs; Sponsor: Sen. Smith, Tina [D-MN]; Committees: Senate - Health, Education, Labor, and Pensions

S.4336 — A bill to require the Secretary of Health and Human Services, in consultation with the Director of the Cybersecurity and Infrastructure Security Agency, to annually review and as appropriate update guidance for industry and Food and Drug Administration staff on medical device cybersecurity, and for other purposes; Sponsor: Sen. Rosen, Jacky [D-NV]; Committees: Senate - Health, Education, Labor, and Pensions

S.4338 — A bill to provide for increased transparency in generic drug applications; Sponsor: Sen. Hassan, Margaret Wood [D-NH]; Committees: Senate - Health, Education, Labor, and Pensions

S.4340 — A bill to allow the Secretary of Health and Human Services to deny approval of a new drug application for an opioid analgesic drug on the basis of such drug not being clinically superior to other commercially available drugs; Sponsor: Sen. Manchin, Joe [D-WV]; Committees: Senate - Health, Education, Labor, and Pensions

S.4341 — A bill to require the Government Accountability Office to issue a report on nonprofit pharmaceutical organizations; Sponsor: Sen. Rosen, Jacky [D-NV]; Committees: Senate - Health, Education, Labor, and Pensions

S.4343 — A bill to require any convention, agreement, or other international instrument on pandemic prevention, preparedness, and response reached by the World Health Assembly to be subject to Senate ratification; Sponsor: Sen. Johnson, Ron [R-WI]; Committees: Senate - Foreign Relations

S.4347 — A bill to require group health plans and group or individual health insurance coverage to provide coverage for over-the-counter contraceptives; Sponsor: Sen. Murray, Patty [D-WA]; Committees: Senate - Health, Education, Labor, and Pensions

S.4348 — A bill to amend the Federal Food, Drug, and Cosmetic Act to revise and extend the user-fee programs for prescription drugs, medical devices, generic drugs, and biosimilar biological products, and for other purposes; Sponsor: Sen. Murray, Patty [D-WA]; Committees: Senate - Health, Education, Labor, and Pensions