



Health Policy Briefing

April 18, 2022

HHS Extends PHE Declaration

U.S. Department of Health and Human Secretary Xavier Becerra has extended the COVID-19 public health emergency (PHE) declaration for another 90 days. The nation is currently grappling with rising cases of the Omicron subvariant BA.2. The PHE renewal will allow policies like expanded telehealth flexibilities and Medicaid coverage protections instituted in response to the pandemic to continue through at least July. The administration has pledged to provide at least 60 days notice before terminating the PHE. The U.S. is still averaging 30,000 new COVID-19 cases each day, but hospitalizations and death rates are on the decline, averaging approximately 1,400 and 500 per day respectively. Roughly 82% of eligible Americans have received at least one COVID-19 shot.

FDA Issues EUA for COVID-19 Breath Test

On Thursday, the Food and Drug Administration (FDA) issued an emergency use authorization (EUA) for the InspectIR COVID-19 Breathalyzer. The rapid diagnostic detects COVID-19 using breath from individuals aged 18 years and older. It may be used on individuals regardless of whether they are experiencing symptoms. Testing is “limited to use by a qualified, trained operator under the supervision of a healthcare provider licensed or authorized by state law to prescribe tests in an environment where the patient specimen is both collected and analyzed.”

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Lawmakers Push OTC Status for Naloxone

A group of 30 lawmakers in the Senate and House of Representatives are [pushing](#) Pfizer, Teva Pharmaceuticals, Hikma, Emergent BioSolutions, Amphastar Pharmaceuticals, and Adamis Pharmaceuticals to apply for over-the-counter (OTC) status for their respective naloxone products. Their letters to the companies argue that the OTC status of the opioid overdose reversal drug will reduce the stigma around addiction and drug-related death. “The COVID-19 pandemic has dramatically exacerbated the opioid and substance use disorder epidemic in this country, with reported overdoses and deaths spiking to historic levels,” the letter states. “It has never been more important to adopt opioid overdose prevention and reversal strategies on a wide scale. This includes steps to increase access to affordable naloxone, which is a proven, effective tool to reduce medical emergencies, drug overdoses, and deaths.” The lawmakers assert that the Food and Drug Administration “strongly supports” OTC naloxone, but that it is the company’s responsibility to submit the required paperwork.

Timeline for Marijuana Bill Slips to Summer

Senate Majority Leader Chuck Schumer (D-N.Y.), Senate Finance Committee Chair Ron Wyden (D-Ore.), and Sen. Cory Booker (D-N.J.) have confirmed that legislation to establish a federal standard for cannabis legalization and regulation is on track to be introduced before the August recess. The lawmakers had previously announced plans to file a bill sometime this month. The House of Representatives passed H.R. 3617, the *Marijuana Opportunity Reinvestment and Expungement (MORE) Act*, to remove marijuana from the federal controlled substances list, earlier this month by a vote of 220-204.

More Breakthrough Cases on Capitol Hill

Six more lawmakers have tested positive for COVID-19 in the ongoing series of breakthrough cases of the virus on Capitol Hill. Reps. Raja Krishnamoorthi (D-Ill.), Earl Blumenauer (D-Ore.), Frank Pallone Jr. (D-N.J.), Lisa Blunt Rochester (D-Del.), Elaine Luria (D-Va.), and Rashida Tlaib (D-Mich.) have all announced positive COVID-19 test results in recent days. Each member of Congress was fully vaccinated and boosted.

Lisa Barclay to Service as COVID Response Coordinator Deputy

The White House has announced the appointment of Lisa Barclay to assume the role of deputy COVID-19 response coordinator. Barclay currently serves as a top lawyer at the U.S. Department of Health and Human Services covering Food and Drug Administration and COVID-19 issues. In her new position, she will work under Ashish Jha, MD, MPH, who recently started as the White House’s COVID-19 response coordinator. Jha and Barclay replace Jeff Zients and Natalie Quillian, respectively.

FTC Extends PBM Comment Deadline

The Federal Trade Commission (FTC) has extended its public comment period on the practices of pharmacy benefit managers (PBMs) until May 25. The agency is seeking information on PBM rebates and contracts and their impact on the cost of drugs for patients. The request for information was opened in February, following a Commission deadlock vote about whether the FTC should study the competitive impact of PBM practices.

ACIP to Meet This Week on COVID Boosters

The Centers for Disease Control and Prevention's (CDC) Advisory Committee on Immunization Practices (ACIP) will meet on April 20 to discuss COVID-19 booster recommendations. The meeting follows a discussion amongst the Food and Drug Administration's (FDA) Vaccines and Related Biological Products Advisory Committee that did not result in a formal recommendation on the administration of another round of booster shots, if necessary, this fall. Both the FDA and the CDC have already cleared a second booster dose of the Pfizer-BioNTech and Moderna vaccines for adults aged 50 and older and individuals aged 12 and older with weak immunity.

FDA Issues Draft Guidance on Clinical Trial Diversity

The Food and Drug Administration (FDA) [released](#) new draft guidance for the industry last week recommending that drug and medical device companies create formal plans for ensuring clinical trial diversity. The agency suggests that manufacturers send their plans, outlining specific goals for attracting and enrolling underrepresented groups and racial and ethnic minorities, to the FDA early in the clinical development process. According to the draft guidance, companies should also consider strategies for retaining diverse trial participants.

CMS Requests Feedback on Nursing Home Staffing Levels

The Centers for Medicare and Medicaid Services (CMS) is [asking](#) for public comments on requiring minimum staffing levels in nursing homes. The agency, which is also considering tying some payments to level of staff turnover, plans to issue rulemaking on the issue within a year. The move is a part of President Joe Biden's agenda to strengthen oversight of the nation's nursing home industry.

Recently Introduced Health Legislation

H.R.7487 — To amend the Internal Revenue Code of 1986 to clarify that individuals who have access to certain healthcare services through a worksite health clinic are eligible to make pre-tax contributions to a health savings account. Sponsor: Rep. Sewell, Terri A. [D-AL-7]; Committees: House - Ways and Means

H.R.7483 — To direct the Secretary of Health and Human Services to conduct a study on the direct and indirect costs of serious mental illness for nongovernmental entities, the Federal Government, and State, local, and Tribal governments, and for other purposes. Sponsor: Rep. Reschenthaler, Guy [R-PA-14]; Committees: House - Energy and Commerce

H.R.7482 — To authorize the Secretary of Health and Human Services to award grants to eligible entities for creating or enhancing capacity to treat patients with Long COVID through a multidisciplinary approach. Sponsor: Rep. Pressley, Ayanna [D-MA-7]; Committees: House - Energy and Commerce

H.R.7475 — To amend title XIX of the Social Security Act to provide coverage under the Medicaid program for services provided by doulas and midwives, and for other purposes. Sponsor: Rep. Moore, Gwen [D-WI-4]; Committees: House - Energy and Commerce

H.R.7474 — To amend the Public Health Service Act to increase the transparency of pharmaceutical research costs, and for other purposes. Sponsor: Rep. Maloney, Carolyn B. [D-NY-12]; Committees: House - Energy and Commerce; Financial Services

H.R.7473 — To prohibit pharmaceutical manufacturers from interfering with therapeutically equivalent or interchangeable substitution decisions by health care providers to limit competition from a generic drug or biosimilar biological product, and for other purposes. Sponsor: Rep. Maloney, Carolyn B. [D-NY-12]; Committees: House - Judiciary

H.R.7472 — To amend the Federal Food, Drug, and Cosmetic Act to grant eligible researchers access to eligible products at a discounted price for qualified research, and for other purposes. Sponsor: Rep. Maloney, Carolyn B. [D-NY-12]; Committees: House - Energy and Commerce

H.R.7458 — To establish a procedure for terminating the suspension of entries and imports from designated places related to the COVID-19 pandemic. Sponsor: Rep. Golden, Jared F. [D-ME-2]; Committees: House - Energy and Commerce

H.R.7436 — To amend title 38, United States Code, to improve the quality assurance program of the Veterans Benefits Administration of the Department of Veterans Affairs. Sponsor: Rep. Cloud, Michael [R-TX-27]; Committees: House - Veterans' Affairs

H.R.7435 — To amend the Internal Revenue Code of 1986 to provide that coverage under Medicare is permissible for purposes of contributions to health savings accounts. Sponsor: Rep. Bera, Ami [D-CA-7]; Committees: House - Ways and Means

H.Res.1045 — Supporting the goals and ideals of “National Youth HIV/AIDS Awareness Day”. Sponsor: Rep. Lee, Barbara [D-CA-13]; Committees: House - Energy and Commerce

H.Res.1051 — Expressing support for the designation of the week of April 11 through April 17, 2022, as the fifth annual “Black Maternal Health Week” to bring national attention to the maternal health crisis in the United States and the importance of reducing maternal mortality and morbidity among Black women and birthing persons; Sponsor: Rep. Adams, Alma S. [D-NC-12]; Committees: House - Energy and Commerce; Financial Services; Transportation and Infrastructure; Education and Labor; Judiciary; Natural Resources; Agriculture; Veterans' Affairs

H.R.7497 — To provide for lower prices for drugs through drug price negotiation, and for other purposes; Sponsor: Rep. Slotkin, Elissa [D-MI-8]; Committees: House - Energy and Commerce; Ways and Means; Education and Labor

H.R.7500 — Fiscal Year 2022 Veterans Affairs Major Medical Facility Authorization Act; Sponsor: Rep. Allred, Colin Z. [D-TX-32]; Committees: House - Veterans' Affairs

H.R.7504 — To amend the Internal Revenue Code of 1986 to make a portion of research credit refundable for certain small businesses engaging in specified medical research; Sponsor: Rep. Buchanan, Vern [R-FL-16]; Committees: House - Ways and Means

H.R.7505 — To amend the Internal Revenue Code of 1986 to add a new medical research component to the credit for increasing research activities; Sponsor: Rep. Buchanan, Vern [R-FL-16]; Committees: House - Ways and Means

H.R.7506 — To amend the Public Health Service Act with respect to preventing end-stage kidney disease, and for other purposes; Sponsor: Rep. Butterfield, G. K. [D-NC-1]; Committees: House - Energy and Commerce; Ways and Means

H.R.7508 — Improving Specialty Care for Women Veterans Act; Sponsor: Rep. Crist, Charlie [D-FL-13]; Committees: House - Veterans' Affairs

H.R.7512 — To amend title XXVII of the Public Health Service Act, title I of the Employee Retirement Income Security Act of 1974, and the Internal Revenue Code of 1986 to limit enrollment in coverage for excepted benefits to individuals enrolled in a health plan providing minimum essential coverage; Sponsor: Rep. Hayes, Jahana [D-CT-5]; Committees: House - Energy and Commerce; Education and Labor; Ways and Means

H.R.7513 — To establish a Commission on the Federal Regulation of Cannabis to study a prompt and plausible pathway to the Federal regulation of cannabis, and for other purposes; Sponsor: Rep. Joyce, David P. [R-OH-14]; Committees: House - Energy and Commerce; Judiciary; Ways and Means; Agriculture; Financial Services

H.R.7515 — To amend the Internal Revenue Code of 1986 to provide an exception from the passive loss rules for investments in specified medical research small business pass-thru entities; Sponsor: Rep. Kelly, Mike [R-PA-16]; Committees: House - Ways and Means

H.R.7524 — To direct the Secretary of Veterans Affairs to seek to enter into an agreement with the National Academies of Sciences, Engineering, and Medicine to study the incidence and mortality of cancer among individuals who served in the Navy, Air Force, or Marine Corps as aircrew; Sponsor: Rep. Pfluger, August [R-TX-11]; Committees: House - Veterans' Affairs

H.R.7529 — To require direct-to-consumer advertisements for prescription drugs and biological products to include truthful and not misleading pricing information; Sponsor: Rep. Williams, Nikema [D-GA-5]; Committees: House - Energy and Commerce; Ways and Means