



Health Policy Briefing

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Administration Previews Booster Shot Recommendations

President Joe Biden announced last week that the U.S. will likely advise most Americans to get a coronavirus vaccine booster shot. The mRNA booster should be administered eight months after an individual received their second dose of either the Moderna or Pfizer vaccine; boosters will be made available as early as mid-September. Regulators are still awaiting the results of Johnson & Johnson’s clinical trial examining a two-dose regimen. The results are expected to be released later this month, though officials stated that they anticipate that booster shots will be needed for people who received the J&J vaccine as well. A [statement](#) from top individuals at the U.S. Department of Health and Human Services (HHS) asserts that the “COVID-19 vaccines authorized in the United States continue to be remarkably effective in reducing risk of severe disease, hospitalization, and death, even against the widely circulating Delta variant. Recognizing that many vaccines are associated with a reduction in protection over time, and acknowledging that additional vaccine doses could be needed to provide long lasting protection...we conclude that a booster shot will be needed to maximize vaccine-induced protection and prolong its durability.” Administration of booster shots will likely follow in the same tiered eligibility system used when vaccinations first began in late 2020, with nursing home residents, health care workers, and older people being first in line. The administration is expected to recommend that people receive a booster from the same manufacturer of their initial vaccine. The announcement comes amidst the surge of the Delta variant and concerns that Delta is able to evade the vaccine and that vaccine effectiveness has waned over time. The booster shot policy is dependent upon authorization of the additional shots by the Food and Drug Administration (FDA). The agency recently authorized third doses of both Pfizer and Moderna vaccines for certain populations with weakened immune systems. The nation’s top public health officials have also continued to emphasize “the ongoing urgency of vaccinating the unvaccinated in the U.S. and around the world,” following criticism from the World Health Organization (WHO) toward nations who are moving to administer booster shots despite shortages of the vaccine globally.

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Pfizer COVID-19 Vaccine Expected to Receive Full Approval Soon

Reportedly, the Food and Drug Administration (FDA) is expected to grant full approval of Pfizer's COVID-19 vaccine as early as this week. To date, the vaccine has been available under emergency use authorization.

WH to Tie Receipt of Federal Funds to Vaccination for Staff at Nursing Homes

President Biden announced that nursing homes currently participating in the Medicare and Medicaid programs will be required to vaccinate their staff against COVID-19 to continue receiving federal funds. In response, the American Health Care Association and National Center for Assisted Living [wrote](#) HHS Secretary Becerra and CMS Administrator Brooks-LaSure outlining concerns related to workforce shortages, access to quality care, and the disproportionate impact on women of color. The letter provides suggestions including a vaccine mandate for all health care workers in federally funded certified settings, education to address vaccine hesitancy, federally funded testing for unvaccinated staff, \$3 billion from the Provider Relief Fund to recruit/replace and test staff, reopening the Provider Relief Fund, and allowing providers to ask visitors about their vaccination and test results.

Sources Say Woodcock No Longer Under Consideration to Lead FDA

The White House has ruled out Janet Woodcock as a potential nominee to serve as Commissioner of Food and Drugs, according to anonymous sources inside the administration. Woodcock, the Food and Drug Administration's (FDA) acting commissioner, has been with the agency in various capacities for 35 years, most recently serving as the Director of the Center for Drug Evaluation and Research (CDER). She is eligible to remain acting commissioner until November 15, unless President Joe Biden nominates another candidate for the job. In this case, she could remain at her post throughout the nominee's Senate confirmation process. Woodcock has faced criticism from lawmakers, including Democratic Sen. Joe Manchin (D-W.Va.), for her role in the approval of certain pain medications that contributed to the opioid epidemic and more recently for the accelerated approval of the Alzheimer's treatment Aduhelm.

WH Delays Surprise Billing Law's Reporting Requirements

The Biden administration has decided to delay enforcement of the *No Surprises Act's* price reporting requirements until July 1, 2022 pending further rulemaking, according to a [frequently asked questions](#) document published by the Departments of Labor, Health and Human Services, and Treasury. The law, which takes effect January 1, 2022, requires health plans to publicly disclose prescription drug prices in a machine-readable format. The agencies stated that the delay is the result of concerns from stakeholders that some of the law's requirements may be duplicative. The FAQ also explains that the administration will not be issuing regulations for several other aspects of the *No Surprises Act*, including the law's advanced explanation of benefits requirement and its prohibition on gag clauses.

Three More Senators Experience Breakthrough COVID Cases

Three fully-vaccinated U.S. senators have tested positive for COVID-19 in the past week: Roger Wicker (R-Miss.), Angus King (I-Maine), and John Hickenlooper (D-Colo.). These cases bring the total number of known breakthrough cases amongst congressional lawmakers to six. The Senate is on recess until next month so the members' quarantine periods will not impact the chamber's business.

Recently Introduced Health Legislation

H.R.5036 — *To amend titles 36 and 38, United States Code, to direct the Secretary of Veterans Affairs to carry out actions for certain surviving family members of veterans deceased as the result of suicide, and for other purposes. Sponsor: Rep. Van Drew, Jefferson [R-NJ-2]; Committees: House - Veterans' Affairs; Judiciary*

H.R.5035 — *To authorize the Secretary of Health and Human Services to award grants to establish or expand programs to implement evidence-aligned practices in health care settings for the purpose of reducing the suicide rates of covered individuals, and for other purposes. Sponsor: Rep. Underwood, Lauren [D-IL-14]; Committees: House - Energy and Commerce; Education and Labor*

H.R.5030 — *To improve diversity in clinical trials and data collection for COVID-19 and future public health threats to address social determinants of health. Sponsor: Rep. Ruiz, Raul [D-CA-36]; Committees: House - Energy and Commerce; Ways and Means*

H.R.5029 — *To amend title 38, United States Code, to furnish Vet Center readjustment counseling and related mental health services to members of the families of members or veterans of the Armed Forces who died by suicide, and other purposes. Sponsor: Rep. Rouzer, David [R-NC-7]; Committees: House - Veterans' Affairs*

H.R.5026 — *To amend title 38, United States Code, to provide for a presumption of service connection for illnesses associated with service in the Armed Forces in the Panama Canal Zone, and for other purposes. Sponsor: Rep. Newman, Marie [D-IL-3]; Committees: House - Veterans' Affairs*

H.R.5021 — *To require States and local jurisdictions that institute vaccine passports to require voter identification in Federal elections. Sponsor: Rep. Mace, Nancy [R-SC-1]; Committees: House - House Administration*

H.R.5015 — *To amend title XIX of the Social Security Act to expand hospitals eligible for the Medicaid DSH payment adjustment. Sponsor: Rep. Higgins, Brian [D-NY-26]; Committees: House - Energy and Commerce*

H.R.5012 — *To amend title XVIII of the Social Security Act to provide for enhanced Medicare beneficiary information through access to annual Medicare notifications in multiple languages. Sponsor: Rep. Gomez, Jimmy [D-CA-34]; Committees: House - Ways and Means; Energy and Commerce*

H.R.5011 — *To provide for the establishment of Medicare part E public health plans, and for other purposes. Sponsor: Rep. Gomez, Jimmy [D-CA-34]; Committees: House - Energy and Commerce; Ways and Means; Education and Labor*

H.R.5009 — *To prohibit the District of Columbia Government from requiring individuals to present documentation certifying COVID-19 vaccination as a condition of entering any building, facility, or other venue in the District of Columbia. Sponsor: Rep. Fallon, Pat [R-TX-4]; Committees: House - Oversight and Reform*

H.R.5007 — *Protecting Vulnerable Patients Act; Sponsor: Rep. Beyer, Donald S., Jr. [D-VA-8]; Committees: House - Energy and Commerce; Ways and Means*

H.Res.587 — *Expressing the sense of the House of Representatives that Congress disapproves of Department of Defense leadership pursuing adverse actions toward members of the Armed Forces of the United States who choose not to receive a COVID-19 vaccine. Sponsor: Rep. Green, Mark E. [R-TN-7]; Committees: House - Armed Services*

H.Res.586 — *Expressing support for the United States Government to be a guaranteed buyer of vaccines and for the United States to develop a "Marshall Plan" for global vaccinations. Sponsor: Rep. Auchincloss, Jake [D-MA-4]; Committees: House - Foreign Affairs*

H.Res.590 — Recognizing that many Americans are not aware of the ways in which health care policy can affect every part of their lives and expressing support for the designation of the month of August as “National Health Care Awareness Month”; Sponsor: Rep. Maloney, Carolyn B. [D-NY-12]; Committees: House - Energy and Commerce

H.R.5040 — To amend titles XVIII and XIX of the Social Security Act to reduce cost-sharing, align income and resource eligibility tests, simplify enrollment, and provide for other program improvements for low-income Medicare beneficiaries; Sponsor: Rep. Blunt Rochester, Lisa [D-DE-At Large]; Committees: House - Energy and Commerce; Ways and Means