



H&K Health Dose January 11, 2022

A weekly dose of healthcare policy news

Legislative Updates

What's on the agenda for the first months of 2022?

Members of Congress returned to Washington this week for the second session of the 117th Congress, facing a busy agenda in a legislative year abbreviated by the approaching 2022 midterm elections. The *Build Back Better Act* (BBBA) remains stalled as Sen. Manchin (D-W.V.) does not appear to be reconsidering his opposition on the tax and spending reconciliation package. Without his support, Democrats do not have the votes to pass the legislation in the Senate. Despite this opposition, Majority Leader Schumer (D-NY) has repeatedly stated that BBBA will come to the Senate floor, but it is not clear when or in what form.

Meanwhile, Congress has until February 18 to authorize appropriations bills for fiscal year (FY) 2022, pass another continuing resolution (CR), or face a government shutdown. Democrats and Republicans have been at a standoff over conflicting policy and funding priorities since the new fiscal year began on Oct. 1, 2021. Democrats would like to secure significant increases for domestic priorities, but Republicans insist on equal treatment for defense funding and no changes in certain longstanding policy riders (such as the Hyde Amendment). Ultimately, both sides have reasons to cooperate on resolving the appropriations standoff, hopefully in February. If so, significant funding increases for many healthcare programs – such as the National Institutes of Health (NIH), substance abuse programs, and public health and workforce investments – can be expected.

The other funding bill that may materialize is an FY 2022 emergency supplemental funding bill that would likely include additional pandemic response funds and natural disaster relief funding. The measure to fund the federal government beyond the expiration of the CR on Feb. 18 could serve as a vehicle for these additional resources. However, several Senators are pushing for a standalone measure to provide additional funding for restaurants, gyms, and other businesses impacted by the pandemic.

Looking ahead, the Biden Administration is scheduled to release its FY 2023 Presidential budget proposal, though there is some uncertainty around timing. Congressional staff indicated the release might be in March following the President's State of the Union address to Congress on March 1, 2022 (which is historically late).

In the Senate, the long-awaited votes on election and voting rights reforms are expected, even though the legislation likely will not advance. Senators Manchin and Sinema (D-AZ) are still opposed to changing Senate rules so the voting rights legislation could pass, but Majority Leader Schumer is determined to press on. The House of Representatives has already passed three separate voting rights bills: the *For the People Act* (H.R. 1), the *John R. Lewis Voting Rights Advancement Act* (H.R. 4), and the *Protecting Our Democracy Act* (H.R. 5314). One of the bills Schumer hopes to get through the Senate is the *Freedom to Vote Act* (S. 2747), a slimmed-down version of the *For the People Act* (H.R. 1). The bill would enact policies establishing automatic voter registration, protecting against election subversion, and preventing partisan gerrymandering, among other things.

Please see our [recent alert](#) for more on what to expect in 2022 and the top ten health policy issues to watch.



Quick Legislative Takes:

- The Senate Health, Education, Labor, and Pensions (HELP) Committee plans to vote on Dr. Califf's FDA Commissioner nomination tomorrow, January 12. For more information, click [here](#).
- Reps. Suzan DelBene (D-WA) and Larry Bucshon, MD (R-IN), co-chairs of the Congressional Kidney Caucus, led a [letter](#) requesting that the Biden administration invest \$25 million in the KidneyX initiative. KidneyX is a public-private partnership between the Department of Health and Human Services (HHS) and the American Society of Nephrology that aims to accelerate research into chronic kidney disease and improve kidney care.
- Significant provisions of the *No Surprises Act* took effect January 1, 2022. The Centers for Medicare and Medicaid Services (CMS) posted additional [guidance](#) expounding on, among other things, the Independent Dispute Resolution (IDR) processes. More information regarding the protections provided under the new law can be found on the HHS [website](#).
- The Congressional Research Service [released](#) a report on the FDA regulation of over-the-counter (OTC) drugs.
- Over the weekend, Sen. John Thune (R-S.D.) announced that he would run for reelection. Sen. Ron Johnson (R-Wisc.) also announced his plan to run for a third term. At the same time, Rep. Bobby Rush (D-Ill.) announced that he would not seek reelection.

Administrative/Regulatory Updates

Administration Requires Insurance Companies and Group Health Plans to Cover the Cost of At-Home COVID-19 Tests

Yesterday, the Departments of Labor and Treasury released [guidance](#) that will significantly expand the scope of required coverage of at-home COVID testing without participant cost-sharing and without a physician order. Starting, Jan. 15, insurance companies must cover the cost of at-home testing, meaning most consumers with private health coverage can buy a test and either get the cost covered upfront or get reimbursed later by submitting a claim to their plan.

Under existing guidance (see [FAQ Part 43, Q/A-4](#)), at-home COVID tests must be covered without participant cost-sharing, but only when ordered by an attending health care provider who has determined the test is medically appropriate based on currently accepted standards of medical practice.

The new guidance (beginning Jan. 15) affirms that the limit of eight tests is per beneficiary. The limit is only for the tests that a provider does not order -- so a consumer with a provider order is eligible for additional tests without cost-sharing. When plans and insurers make tests available for upfront coverage through preferred pharmacies or retailers, they are still required to reimburse tests purchased by consumers outside of that network, at a rate of up to \$12 per individual test (or the cost of the test, if less than \$12).

The guidance also creates a safe harbor for plans that move forward with a so-called "direct coverage" process. For purposes of this safe harbor, direct coverage of over the counter (OTC) COVID-19 tests means that a participant, beneficiary, or enrollee is not required to seek reimbursement post-purchase; instead, the plan or issuer must make the systems and technology changes necessary to process the plan's or issuer's payment to the preferred pharmacy or retailer directly with no upfront out-of-pocket expenditure by the participant, beneficiary, or enrollee. Under this safe harbor, plans or issuers may not impose any prior authorization or other medical management requirements on



participants, beneficiaries, or enrollees that obtain applicable OTC COVID-19 tests via such a direct coverage program or otherwise.

CMS Rescinds the Most Favored Nation (MFN) Rule

In late December, CMS posted a final rule rescinding the November 2020 Most Favored Nations (MFN) Model Interim Final Rule (IFR). The MFN rule would have created a mandatory, seven-year payment model for the 50 highest-cost drugs and biologics in Medicare Part B to replace the current reimbursement formula for these drugs. Instead of adding a 6 percent administration fee to the drug's average sale price (ASP), the new reimbursement system would have been based on international pricing information from 22 different countries.

CMS Releases the 2023 Medicare Advantage/Part D Rule

CMS [issued](#) a proposed rule for the contract year 2023 policy and technical changes to Medicare Advantage (MA) and the Medicare prescription drug benefit (Part D). Most notably, CMS is proposing to require Part D plans to apply all price concessions they receive from network pharmacies at the point of sale so that the beneficiary can also share in the savings. Specifically, CMS proposed redefining the negotiated price as the baseline, or lowest possible, payment to a pharmacy, effective January 1, 2023.

Public Health Emergency (PHE) Extension

The current PHE [declaration](#) from HHS is set to expire January 16. By law, the federal PHE cannot be extended for more than 90 days at a time. It is expected that an additional 90-day renewal will be announced soon, through April, but no news yet. The PHE affords several flexibilities, which would expire when the PHE does.

HRSA to Allocate \$48 Million in Community-Based Health Organizations in Rural and Tribal Communities

On Dec. 23, the Health Resources and Services Administration's (HRSA) Federal Office of Rural Health Policy [announced](#) the availability of nearly \$48 million in funding. The funding will be directed to community-based organizations expanding rural and tribal public health capacity through job development and training. Grant applications are due on March 18, 2022.

CMS Unveils New Medicaid Program for Mental Health and Substance Use Care

On December 28, the CMS [announced](#) a new Medicaid option for supporting community-based mobile crisis-intervention services. Authorized under the *American Rescue Plan*, CMS will work with states to build mobile community-based crisis intervention services to provide individuals with behavioral health specialists 24 hours a day, 365 days a year.

FDA Delays Some On-site Facility Inspections Due to Omicron Variant

On Dec. 29, the Food and Drug Administration (FDA) decided to postpone some on-site inspections amid the Omicron variant surge of the COVID-19 virus. The FDA will temporarily suspend non-critical on-site facility inspections to focus on in-person mission-critical work and will monitor non-critical facilities using remote tools through Jan. 19.



FDA Issues EUA for COVID-19 Oral Antiviral Treatment

On Dec. 22, the FDA issued its first emergency use authorization (EUA) for oral antiviral treatment of COVID-19. Pfizer's Paxlovid is authorized to treat mild-to-moderate COVID-19 in adults and adolescents above 12 years of age who are at high risk for progression to severe COVID-19.

ONC Issues Data Standard for Patient Addresses

On January 7, the Office of the National Coordinator (ONC) for Health Information Technology released [the final version of Project US@](#), a technical specification for representing patient addresses to improve patient matching. The effort came after studies, such as the 2019 study [conducted](#) by researchers at Bloomington-based Indiana University, concluded that using the U.S. Postal Service's address format can improve patient matching by up to 3 percent. ONC has been working on Project US@ with standards development and health IT organizations since launching the effort in early 2021. ONC also released a "[companion guide](#)" with best practices and guidance for capturing and managing patient address data, which it developed with the American Health Information Management Association. The agency encourages providers, payers, public health organizations, state and federal agencies, and other healthcare stakeholders to implement the specification.

Judicial Updates

Supreme Court Weighs Vaccine Mandates

On January 7, the Supreme Court heard oral arguments for two cases challenging federal COVID-19 vaccination requirements issued by the Occupational Safety and Health Administration (OSHA) and CMS. The OSHA rule says that businesses with more than 100 employees must require their workers to either be vaccinated or wear masks and undergo weekly testing. The CMS rule requires that healthcare workers in facilities that receive federal Medicare or Medicaid funding be vaccinated, recognizing that they work with vulnerable patients. The Court fast-tracked the cases to expedite consideration of the vaccine mandates. For a more detailed analysis of the arguments to stay both mandates, please see H&K's most recent alert [here](#).