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A weekly dose of healthcare policy news

Coronavirus One Year Later

This week likely marks your one-year anniversary of working from home. I hear the traditional one-year anniversary present for the occasion is toilet paper (ba-dum ching). While looking back at March 2020 feels like looking at a time capsule; there is hope on the horizon. We've seen promising new data about vaccine efficacy; we've seen more viral variants take hold; the pace of vaccines is accelerating, and just last week, we saw a third vaccine receive FDA authorization for use in the United States.

President Biden also noted that there would be enough vaccines for all adult Americans by the end of May, two months earlier than expected. To date, 78.6 million vaccines have already been administered in the United States–at a rate of 1.94 million doses per day. This timeline does not include a potential new vaccine by AstraZeneca, which says it is "on track" to eventually deliver a total of 300 million doses to the U.S. However, it has not yet applied to the FDA and hasn't said when it would. Baxter International and Moderna separately announced Monday that they have entered into an agreement in which Baxter will fill and package 60-90 million U.S. doses this year. Despite the positive progress on the vaccine fulfillment front- there are outstanding logistical concerns with the vaccine rollout, including a sufficient medical distribution chain, access for disadvantaged patient populations, and educating Americans who are hesitant or unwilling to get the vaccine.

A new "Vaccine Community Connectors" pilot will aim to get 2 million vulnerable seniors COVID-19 vaccines by addressing three common barriers: questions about the vaccine, scheduling, and transportation. Participating insurers will make outbound calls to unvaccinated seniors who live in areas of high social vulnerability. Outreach will be tailored to each community and will include discussions about vaccine safety and efficacy, assisting with vaccine registration and appointment scheduling, arranging transportation, and follow-up for second doses.

For those fortunate enough to already be fully vaccinated, CDC issued interim guidance**.** The guidance notes fully vaccinated people can gather without masks in small groups indoors with other fully vaccinated people. The CDC's panel of vaccine advisers separately debated last week whether only a single dose of the two-dose COVID-19 vaccines is needed for people who have already been infected.

Senate Passes COVID-19 Relief Package, Heads Back to the House

The Senate passed the American Rescue Plan Act over the weekend following a marathon "vote-a-rama." The legislation advanced along party lines 50-49. Vice President Kamala Harris was not required to cast the tie-breaking vote because Sen. Dan Sullivan (R-Alaska) had returned home for his late father-in-law's funeral. The COVID relief bill now heads back to the House of Representatives. The House will consider the Senate's amended version of the bill today or Wednesday. Democrats aim to send the measure to the President's desk ahead of the March 14 expiration of supplemental unemployment benefits.

There are a few healthcare changes in the final enrolled Senate-passed reconciliation bill compared to the House bill passed a week ago. The legislation now includes an additional $8.5 billion in Provider Relief Fund look-a-like funding for rural providers – this falls short of the request for $35 billion to be added to the Provider Relief Fund. As we best estimate, that is roughly $20 billion left in the $178 billion fund created by the Coronavirus Aid, Relief, and Economic Security (CARES) Act. Through this fund, virtually all health care providers have now qualified for a general grant that amounted to at least 2% of their previous annual patient revenue.

Another major priority was also not included: extending a moratorium on the 2% Medicare payment cut created under sequestration. Congress paused the sequester cuts at the onset of the pandemic. However, that moratorium ends on March 31.

The Senate bill also includes a 10% Federal Medical Assistance Percentage (FMAP) bump for home and community-based (HCBS) services, increasing from a 7.35% increase in the House-passed bill. The Senate bill also provides a 100% subsidy for COBRA premiums -- a boost from an 85% subsidy included in the House-passed version. The bill also eliminates the Medicaid cap on the total rebate amount starting January 1, 2024, instead of 2023 in the House bill. The removal of the rebate cap, which kicks in at 100% of a drug's average manufacturing price, will lead to higher rebates for Medicaid drugs.

Once the relief bill is signed into law, President Biden will focus on the "Build Back Better" recovery plan – an infrastructure recovery package that makes significant investments in rebuilding U.S. infrastructure.

Administration Personnel Update

Health and Human Services Secretary nominee Xavier Beccera advanced out of the Finance committee on a tied, party-line vote. Every Democrat on the Committee voted in favor of Becerra's nomination. No GOP member broke ranks on the vote. With the Committee roster evenly divided, Chairman Ron Wyden (D-OR) must notify the Secretary of the Senate of a tie vote, after which Senate Majority Leader Chuck Schumer (D-NY) will move to discharge the nomination from the Committee, bringing it to the Senate floor. This will require one additional procedural vote in the full Senate, allowing for four hours of debate, and will require a majority vote by the Senate before proceeding for a final vote on the floor. Though likely to be a close vote, he is expected to be confirmed.

The Biden administration announced last week that it had withdrawn the nomination of Neera Tanden to serve as director of the Office of Management and Budget (OMB). Shalanda Young, the nominee for OMB deputy director, is now under consideration for the position.

While Janet Woodcock previously appeared to be a frontrunner for the FDA Commissioner, new reports indicate that the administration has started to vet other candidates for the job. Woodcock has been at the FDA since 1986. She has faced criticism for her role in the approval of painkillers that led to the opioid epidemic.

Finally, HHS recently announced additional Biden-Harris administration staff appointments here.

4 of 9 Trump-Era ACA Marketplace Changes Vacated by Federal Court

The U.S. District Court of Maryland found HHS "acted improperly" and against the spirit of the law when it adopted provisions that eliminated federal review of network adequacy, did away with standardized options, imposed income verification requirements, and reduced medical loss ratio rebates (i.e., change how much insurers must repay customers if the amount spent on administrative costs versus actual health costs exceeds 20%). The court ruled that the agency acted appropriately and in compliance with the law with respect to five provisions that eliminated direct notices to taxpayers at risk of losing premium tax credits, did away with federal oversight of insurance, revised standards for exchange "navigators," changed aspects of the small business exchange program and limited review of insurance rate increases.

OIG Report Suspects Upcoding; Recommends Targeted Reviews

The OIG report found that hospitals are increasingly billing Medicare for inpatient stays at the highest, most expensive severity level despite many of these stays having only one qualifying diagnosis for payment at the highest severity level and others lasting only a relatively short amount of time. From FY 2014 to 2019, the number of claims submitted for inpatient stays at the highest severity level increased by 20%, while the average length of stay for high-severity cases decreased, suggesting sicker beneficiaries was not the cause. The report recommends HHS perform targeted reviews of MS-DRGs and stays that are vulnerable to upcoding, as well as the hospitals that frequently bill for them.

FDA Grants Emergency Use Authorization for 2nd Non-Rx, At-Home COVID-19 Test

By this summer, the test's manufacturer Cue Health said it expects to manufacture more than 100,000 over-the-counter test kits per day. The test is the first at-home molecular test (the only other over-the-counter, at-home test approved so far is a nasal swab test) and works by analyzing a self-taken swab for nucleic acid from the virus. Results are available via Cue's mobile health app in approximately 20 minutes. The test correctly identified positive results for 96% of symptomatic patients and 100% of asymptomatic patients. Users must create a profile that requires certain "personal information" to be reported to public health authorities to help monitor the spread of COVID-19. Though not required, the company says the test is HIPAA compliant. The FDA says it will continue to prioritize at-home tests to expand testing access.

COVID Tracing Prompts Patient Data Privacy Concerns

Health policy experts say they need more complete data to track where vaccinations are occurring and which communities are lagging. Last week, the AMA, ANA, and APhA urged providers to ramp up efforts to collect race and ethnicity data in the interest of equitably allocating resources. But sharing private information has encountered pushback, including concerns that data will be used for deportation purposes or will be breached. Several states directly negotiated compromises with the CDC. California will limit data sharing to non-identifiable information, and New York "will not send individual data identifying a person in a way that could be used to document citizenship."

GAO Report Identifies Halt of FDA Surveillance of Drugs Due to the Pandemic

Since March 2020, the FDA has paused foreign and domestic inspections due to the COVID-19 pandemic, conducting only those deemed "mission-critical." In the meantime, the FDA has used alternative inspection tools to maintain some oversight, including relying on inspections conducted by foreign regulators, requesting and reviewing records and other information, and sampling and testing drugs. In total, the FDA was unable to carry out more than 1,000 planned inspections in fiscal 2020 and will likely face a backlog of inspections in future years. The report recommends the FDA address staffing and other issues and leverage alternative inspection tools.

CMS Plans to Align Quality Measures Across Programs, Payers

CMS is crafting an action plan to better align quality measures across the agency, federal programs, and private payers, says Michelle Block Schreiber, CMS Director for Quality Measurement & Value-Based Incentives. Other priorities include making all quality measures digital by 2025, adding more patient-reported measures, placing a greater focus on health equity and public health measures, and understanding measures to accommodate unique patient populations with different needs.