



H&K Health Dose– February 23, 2021

A weekly dose of healthcare policy news

Confirmations/Appointments/Staff Annoucments

- **Back to the drawing board for OMB-** President Biden’s pick to lead the Office of Management and Budget (OMB) Neera Tanden is having a bad week. Several Republican Senators and notably one Democratic Senator (Joe Manchin of West Virginia) announcing they will oppose her nomination. With a 50/50 split in the Senate, her chances are not looking good. The panel is slated to vote Wednesday.
- **New HHS Secretary in town-** After a tense round of hearings this week, it is expected that California Attorney General and former congressman Xavier Becerra will be confirmed to lead the Department of Health and Human Services (HHS).
- **ACA veterans tapped to lead CMS, CMMI-** After weeks of speculation, President Biden formally [tapped](#) Chiquita Brooks-LaSure to lead the Centers for Medicare & Medicaid Services (CMS) and intends to name Liz Fowler to lead the CMS Innovation Center. Both are no strangers to the health policy world and were key architects behind drafting and implementing the Affordable Care Act, Brooks-LaSure as a staffer on the House Ways and Means Committee, and Fowler at Finance under Chairman Max Baucus. Both also previously served in roles at CMS. If confirmed, Brooks-LaSure will be the first Black woman to lead CMS. Of note, Brooks-LaSure has shown support for increasing exchange subsidies and incentivizing remaining states to expand Medicaid—two proposals included in the House’s Covid-19 relief package. Note the CMMI position does not require the Senate’s approval.
- Former Senate Finance Committee staffer Arielle Woronoff will serve as CMS’s Director of the Office of Legislation.

Budget/Spending

- **COVID relief package-** House Democrats plan to pass the \$1.9 trillion American Rescue Plan Act of 2021 this week- though it could spill into the weekend. Once the House passes the bill, it goes to the Senate. While relatively few changes are expected, the package is about \$30 billion over the limit to pass via reconciliation, according to a Congressional Budget Office [estimate](#) released Saturday, which means changes are needed before a final vote. A few senators are also eyeing additional provider relief funds and extending the Medicare sequester relief, neither of which are included in the House version, which would add to the bill’s price tag. If senators make any changes to the bill, House members will need to vote again. Both sides are rushing to get the package signed into law before March 14, when unemployment benefits expire.



- **Provider Relief Fund Update-** While estimates vary, it appears that there is presently somewhere around \$27-40 billion in uncommitted funds in the Provider Relief Fund. Note HRSA still is making payments to those providers that applied for Phase III General Distribution funds. The [most recent report](#) from the agency states \$10.9 billion in payments have been made, with \$13.6 billion yet to be distributed to providers. The Biden Administration has indicated that they are pausing PRF funds as they want to account for those who have received funds to date and what more may be needed. For this reason, they did not request additional PRF funds at this time. However, as noted above, stakeholders and several Senators continue to push for additional PRF funding in the rescue plan. So, while we do not expect significant material changes, there is a small chance these Medicare policies could still make their way into the final reconciliation package.
- **Blast from the past - earmark revival-** Democrats are proposing to lift the moratorium on earmarks, and Democrat leaders are crafting an overhauled version of the tool. It is likely, if advanced, that the eligibility for earmarks will be limited to state and local governments and nonprofits that carry out quasi-government functions, and there will be limits on how much of each spending bill can be allocated towards earmarks. More information will be released shortly, and there is a chance given the opposition that earmarks do not advance. If they do move forward for healthcare stakeholders, this presents a significant change and opportunity.

Vaccine Production/Rollout

- **Vaccine production ramping up-** [Testifying](#) before the House Energy and Commerce Committee Tuesday, Pfizer and Moderna told lawmakers after a slow start, they can produce 140 million additional doses, for a total of 220 million doses, by March 31. The drugmakers stated that they had solved several manufacturing challenges. The two remain the only companies with authorized vaccines so far. Biden administration officials have expressed skepticism about the new target and estimate closer to 200 million. The single-shot Johnson & Johnson vaccine is expected to be authorized for emergency use as soon as this weekend. While only a few million doses will be immediately available, the company promised in their testimony they will deliver 20 million by the end of March. Federal regulators approved Pfizer's request to store COVID-19 vaccine at standard freezer temperatures instead of ultra-cold conditions.
- **Booster shots receive a boost from the FDA-** In [guidance](#) released Monday, the U.S. Food and Drug Administration (FDA) announced that companies with authorized COVID-19 vaccines could build on existing applications and clinical trials to create booster shots, clearing certain regulatory hurdles in an attempt to speed the response to emerging virus variants.

Title X

- The U.S. Supreme Court announced Monday that it would resolve a circuit split over a Trump administration rule prohibiting federally funded family planning providers from discussing or



referring clients for abortion services, commonly known as the “gag rule.” Existing federal law bans using any federal taxpayer money for abortions.

Pharmacy Benefit Manager (PBM) Rebate Rule Delayed

- HHS has officially delayed for one year a rule that creates a new safe harbor protecting discounts reflected at the point of sale and given to consumers and creates new safe harbor protection for fixed-fee services arrangements between manufacturers and PBMs. The new rebate rule requirements were set to begin on January 1, 2022 - the beginning of the next plan year. However, they will now be pushed back to January 1, 2023. The rule, which insurers and PBMs have opposed, was among several regulations issued during the last stretch of the Trump administration that has been delayed or halted by the Biden administration.

Rolling Back Medicaid Work Requirements

- Last week, CMS sent letters to 10 states that have implemented or sought to enforce Medicaid work requirements, saying the agency does not believe work requirements promote Medicaid objectives. The letters say that CMS is considering whether to withdraw the authorities allowing states to implement work requirements. CMS is giving states 30 days to submit the information that would support leaving the programs in place.