



H&K Health Dose October 26, 2021

A weekly dose of healthcare policy news

Legislative Updates

Congress this Week:

This week, the House and Senate are both in session and continuing to work feverishly on a reconciliation plan that stands a chance of passing the House and 50-50 Senate. As leadership attempts to bring the originally \$3.5 trillion plan down to the \$1.5-\$1.75 range, certain provisions are in jeopardy of being cut or significantly scaled back. The federal program originally envisioned to cover Medicaid-eligible individuals in non-expansion states may change into a few years of subsidized marketplace plans. Paid leave will reportedly be slashed from 12 weeks to four and ACA subsidies are likely to be extended on a temporary basis as well. Senator Bernie Sanders' signature Medicare coverage expansion to dental, vision, and hearing screening is also on the chopping block, particularly dental, which is by far the most expensive of the three and has drawn significant scrutiny including from the dental community. A cheaper \$800 voucher alternative was met with scrutiny from several patient advocacy groups.

In addition, issues remain on how to fund the package after opposition from moderates on several major tax provisions including raising corporate tax rates. One potential compromise being discussed, proposed by Senate Finance Committee Chair Ron Wyden, would create a tax on the nation's billionaires, a policy that lynchpin vote Sen. Manchin (D-WV) supports. Democrat's signature plan for Medicare drug negotiation could also be significantly scaled back by limiting to medicines that already face competition, as opposed to typically more expensive drugs that are new to the market. The proposal could cut estimated savings by as much as 60% but may help to pick up key moderate votes including Kyrsten Sinema. A proposal to tie the Medicare rebate calculation to commercial rates, which Senate Finance Committee Chair Ron Wyden is saying is in the package, could salvage some of the scope and therefore savings.

Democrats are under pressure to come to an agreement on the reconciliation and separate infrastructure package before President Biden departs for the UN Climate Change Conference later this week and funding for surface transportation programs expires Oct. 31. While House Speaker Nancy Pelosi said Friday is "more than 90% is agreed to and written" others are saying talks over the remaining points of contention could stretch into next week.

This morning, the Senate Finance Committee held a [hearing](#) on several nominations including Samuel Bagenstos to be HHS general counsel.

Administrative/Regulatory Updates

CMMI Takes Hard Look at Lessons Learned as It Sets Strategy for Next Decade

In a new [white paper](#), CMS takes stock of its Innovation Center's performance over the last decade stating "over the last ten years, only six out of more than 50 models launched generated statistically significant savings to Medicare and four of these met the requirements to be expanded in duration and scope." The agency aims to take policy and operational lessons learned from past models and apply them to future models. Among its future goals, CMS intends to streamline model offerings, focus on mandatory, multi-payer, and total cost of care models, support providers in taking on financial risk, improve the accuracy of benchmarking and risk adjustment, and ensure health equity is embedded in every model.

MA Plans Continue to Draw Scrutiny

A Senior CMS official threw more fuel on the fire when it comes to scrutiny Medicare Advantage plans are facing over possible "up-coding" saying at an event last week that CMS is "very concerned with the overall trend lines for code growth in the MA program versus the overall fee-for-service program." OIG and MedPAC have both previously drawn



attention to the issue. The official added that CMS is “looking at the same data as the oversight community and [is] thinking carefully about how [to] respond.” According to a MedPAC report, in 2021, total Medicare payments to MA plans were at about 104% of traditional Medicare. A new Commonwealth Fund [report](#) found that after controlling for special needs plans, MA beneficiaries had similar health outcomes to traditional FFS Medicare beneficiaries despite MA plans being more expensive.

Over-the-Counter Hearing Aid Rule Could Rapidly Expand Access; Lower Costs

The FDA announced a new rule that intends to expand access and drastically reduce the cost of hearing aids by making them available over-the-counter without requiring a medical exam. The agency also released new accompanying draft guidance. Both can be found in the FDA’s [press release](#).

Healthcare.gov Opens for 2022 Enrollment Season with Unprecedented Offerings and Low Premiums

CMS opened healthcare.gov for consumers to begin browsing ahead of the 2022 open enrollment period, which will run from Nov. 1 - Jan. 15. According to the [announcement](#), consumers will have access to an average of 6-7 issuers and 107 plans, the most ever, and will have considerably lower premiums due to enhanced tax credits under the American Rescue Plan. The Biden Administration will also invest over \$90 million in care navigators to assist with enrollment.

Private Sector Moves

Two new PBMs Aiming for Industry Disruption Launch in Same Week

Mark Cuban’s generic drug company will launch its own pharmacy benefit management (PBM) company. It will start bidding for clients next year, intends to be operational by 2023, and aims to enhance transparency and pass more savings onto consumers. The same week, The Purchaser Business Group on Health, coalition of 40 large private and public employers also announced the launch of its own PBM company called EmsanaRx.

COVID Update

Half of the world’s population has received at least one dose of a COVID vaccine, though it varies heavily by nation. As international pressure mounts, Moderna announced it would make up to 110 million doses of its vaccine available to the African Union. The company also plans to build a vaccine factory on the continent. According to new CDC data, COVID cases in the U.S. have declined over the last 5 weeks and are projected to decline 20% on average over the next 3 weeks.

Following FDA authorization last week, a CDC panel approved the use of booster shots of the Moderna and J&J vaccines and authorized (but did not go as far as to recommend) patients “mixing and matching” different brands of vaccines based on recommendations from their medical provider.

A key FDA advisory panel deliberated today on whether to recommend the Pfizer vaccine for 5 to 11-year-olds, which could lead to approval by the end of next week. Moderna released promising results of a late stage trial which could set the stage for the company to request FDA clearance in children ages 6-12 in the near future.

The NIH will invest \$70 million to help speed development and authorization of cheap rapid results home COVID tests.

The Biden administration released [updated guidance](#) for vaccine requirements set to take effect Nov. 22 and Dec. 8 for federal workers and contractors respectively as well as [new travel rules](#) for foreigners entering the U.S. starting Nov. 8.