



H&K Health Dose: August 9, 2022

A weekly dose of healthcare policy news

Legislative Updates

Senate Moves Forward with Reconciliation

The Senate on Aug. 7, 2022, passed the [Inflation Reduction Act](#) (IRA) after an hours-long vote-a-rama (a marathon series of back-to-back amendment votes with no time limit), sending the measure to the House for a final vote this Friday, Aug. 12. (See Holland & Knight's detailed summary, "[The Inflation Reduction Act: Summary of the Budget Reconciliation Act](#)," Aug. 8, 2022.)

Democratic leadership reached a breakthrough after Senate Majority Leader Chuck Schumer (D-N.Y.) offered a series of tweaks to tax and climate policies within the underlying bill to address some concerns from Sen. Kyrsten Sinema (D-Ariz.), who was the last remaining holdout. The Senate Parliamentarian review resulted in a few changes to the drug pricing provisions included in the initial July draft bill. The draft bill applied an inflation rebate for manufacturers when the price of a drug outpaces inflation in both Medicare and private insurance; however, the Senate Parliamentarian struck private insurance from the final bill. The rebates remain in effect for prices charged within the Medicare program.

Additionally, Senate Democrats added language to the IRA to cap the amount that consumers pay for insulin when insured by either Medicare or commercial insurance. This language was not included in the Senate Parliamentarian's review. Sen. Lindsey Graham (R-S.C.) called a Point of Order to challenge language that would have capped consumer costs on insulin for the commercial insurance market, arguing that it ran afoul of rules for budget reconciliation. Sen. Patty Murray (D-Wash.) moved to waive that Point of Order, a motion that requires 60 votes. (Notably, the Senate voted 57-43; falling short of the required 60 votes needed for passage). Therefore, the final text did not include language regarding caps under commercial insurance. A \$35 insulin cap for Medicare beneficiaries, however, remains in the package. Specifically, cost-sharing for Part D plans will be capped at \$35 for approved insulin products starting in the plan year 2023 through 2025, after which it will be the lesser of \$35; 25 percent of the established maximum fair price; or 25 percent of the negotiated price. There will be temporary subsidies for January-March 2023 for any cost-sharing over this amount and special limitations for insulin furnished under durable medical equipment.

The House is expected to vote on the IRA on Friday, and it appears highly likely it will pass. The vote will mark the end of this work period, with the Senate on recess until Sept. 6, and the House will return on Sept. 13.

Senate Passes Veteran Burn Pit Legislation

The Senate passed the PACT Act ([S. 3373](#)) in an 86-11 vote on Aug. 2, 2022. The bill would expand health benefits for veterans exposed to toxic burn pits and substances while on active duty. The Senate approved the legislation in June, but another vote was needed to address a technical fix but was then delayed by Senate Republicans because of a disagreement over the technical issue related to mandatory entitlement spending. The legislation will now be sent to President Joe Biden to be signed into law.



Regulatory Updates

Monkeypox Officially Declared Public Health Emergency as Administration Looks to Shore Up Response

The number of Americans who have been infected with monkeypox passed the 7,500 mark, prompting the Biden Administration to declare monkeypox as a Public Health Emergency (PHE). With that comes important implications for data sharing, including requiring all jurisdictions to share data with the Centers for Disease Control and Prevention (CDC) related to vaccine administration, and providing authorities to the Centers for Medicare & Medicaid Services (CMS) to collect testing and hospitalization data. The administration is also gearing up to test the effectiveness of "dose sparing," which would stretch the current vaccine supply by using around one-fifth the dosage level per shot. Moderna also announced that they have initiated research into creating a monkeypox vaccine with mRNA technology. The administration is reportedly in conversations with Capitol Hill about potential emergency funding, but with Congress in August recess, talks are on hold for the next few weeks.

Biden Administration Moves to Defend Abortion Access Post-Dobbs

In the first post-Dobbs lawsuit, the U.S. Department of Justice sued the state of Idaho for its near-total abortion ban that would go into effect on Aug. 25, 2022, stating that it violates the Emergency Medical Treatment and Labor Act (EMTALA) by infringing on clinicians' ability to provide the necessary care in emergencies. President Joe Biden also [issued](#) his second abortion-related executive order, which, among other provisions, directs the Secretary of U.S. Department of Health and Human Services to consider using Medicaid funds to cover the cost of travel for patients seeking abortion services out of state.

COVID-19 PHE Expected to Extend Beyond Midterms; HHS Creates Office Dedicated to Studying Long COVID

According to multiple sources, the Biden Administration is also expected to extend the COVID-19 PHE beyond midterms, possibly into early 2023, depending on prospects of a fall and/or winter surge. HHS' Assistant Secretary for Health, Dr. Rachel Levine, will oversee the new Office of Long COVID Research and Practice, which will be tasked with carrying out the recommendations included in two new HHS reports on long-COVID and advancing treatments.