



## H&K Health Dose November 2, 2021 A weekly dose of healthcare policy news

### Legislative Updates

#### **Congress this Week**

After releasing updated [draft text](#) last week, the House and Senate continue to iron out the final details of President Biden's social spending plan in hopes of convincing key holdouts and securing enough Democratic votes to pass the House and 50-50 Senate. The now \$1.75 trillion package, about half of the original \$3.5 trillion price tag, is likely to see House floor action this week with votes currently expected Thursday.

The latest package includes \$150 billion for home- and community-based care services, three additional years of enhanced ACA premium tax credits, \$30 billion for state reinsurance programs, access to \$0 premium exchange plans for Medicaid eligible in non-expansion states, \$3.37 billion for graduate medical education funding, and “targeted investments” in maternal health, pandemic preparedness, public health and research infrastructure, and domestic supply chain. The bill would also permanently fund the Children’s Health Insurance Program and includes Medicaid extenders. Notably, the draft text also includes a provision that would limit the number of rare disease drugs that can qualify for tax credits under the Orphan Drug Act to first-approved uses only. Experts worry the move could incentivize development of treatments for rare diseases and disproportionately impact minority populations.

Notable provisions left out of the bill include paid family leave, Hill Burton (i.e. hospital infrastructure funding), and Biden’s signature new agency to accelerate cancer and disease research. Still outstanding is prescription drug pricing reform. Democrats issued a new proposal today that would allow the Secretary of HHS to select 10 drugs for price negotiation that are outside their initial exclusivity periods (a significantly scaled back version of their earlier Medicare drug price negotiation proposal), create automatic rebates for drugs whose prices rise faster than inflation, and set annual out-of-pocket patient spending limits for Medicare Part D plans. Some progressives are hesitant to include because they say such a significantly scaled back plan would do little to move the needle on prices and may remove any onus to address the issue in the future. Also reportedly still on the table: Medicare vision and dental coverage, which were left out of the latest version (though hearing coverage made it in). Negotiations are still considered highly fluid.

When and if the package clears the House, it would head to the Senate where it could face additional changes. Sen. Kyrsten Sinema tweeted that significant progress had been made but did not commit to voting for it. Sen. Joe Manchin delivered a major blow yesterday when he refused to endorse the latest version, instead expressing continued heartburn over financial viability. Moderates are now requesting that the Congressional Budget Office score the bill, a potentially two-week process. If any changes are made in the Senate, it would have to re-pass the House. Crucially, the debt ceiling is not currently included despite Republicans vowing they will not vote to raise it come December. Also caught up in this discussion is the separate bipartisan infrastructure proposal, which has already passed the Senate but is behind held up by progressives in the House until they have assurance their social spending bill will pass.

For now- all attention remains on whether the House will vote on the social spending reconciliation package this week.

Meanwhile, appropriations for Fiscal Year 2022 hang in the balance. This morning, top House and Senate appropriators met to discuss top-line funding figures. Republicans publicly [dismissed](#) previously released Democratic [House](#) and [Senate](#) appropriations bills and say they’re skeptical a deal can happen before the Dec. 3 shutdown deadline. In addition to Republicans wanting to bring defense and non-defense spending to parity despite a current 8% difference, several controversial policy issues threaten to slow negotiations, including abortion, border security, and climate change.

In other news, the Senate confirmed former WV health official Dr. Rahul Gupta to serve as director of the Office of National Drug Control Policy. He will be responsible for managing a cross-agency effort to combat the opioid crisis.



## Administrative/Regulatory Updates

### **2022 Medicare Payment Rules Released**

Today, CMS [released](#) a slew of 2022 Medicare payment rules including the Medicare Physician Fee Schedule for Part B services, the Outpatient Prospective Payment System (OPPS) and Ambulatory Surgical Center (ASC) rule, and the Home Health Prospective Payment System Rate rule. On Friday, CMS released the [ESRD Payment rule](#). All impact Medicare services starting Jan. 1, 2022.

Notable takeaways include, CMS not finalizing its proposal to bundle critical care visits with procedure codes that have a global surgical period and a decision to phase in clinical labor rate pricing updates over four years. The Agency also finalized several telehealth policies, increased hospital price transparency civil monetary penalties, formally delayed the penalty phase of the Appropriate Use Criteria Program, and made changes to several federal quality reporting programs and value-based payment models. Please see the attached Holland & Knight memorandum for additional information.

### **HHS Formally Proposes to Repeal Trump-Era SUNSET Rule**

In an expected move, after initially delaying its effective date, HHS has formally [proposed](#) to repeal the SUNSET rule, a hangover from the Trump administration that would have required re-approval of every HHS federal regulation every ten years. [Comments](#) are due Dec. 28.

### **OIG Report Finds Most Turn to Established Provider Relationships for Telehealth Services**

An OIG [report](#) found that 84% of Medicare beneficiaries received all of their telehealth services from providers with whom they had an established relationship. Beneficiaries enrolled in traditional Medicare, as opposed to Medicare Advantage, were even more likely to seek care through an established provider. This trend was relatively consistent across service types, though it did dip significantly for home visits, which make up a small portion of Medicare telehealth services. In all, 26 million beneficiaries accessed health services via telehealth from March through December of 2020.

### **FTC Reinstates Prior Approval Policy**

The FTC [announced](#) it will restore its practice of requiring companies that previously pursued an anticompetitive merger to get prior approval for future transactions after ordering analysis chain DaVita to divest three dialysis clinics in Provo and limit future acquisitions across Utah after the company acquired University of Utah Health's dialysis clinics, which the FTC says created a monopoly in Provo.

### **FDA Releases; Seeks Feedback on International Guiding Principles for AI Development**

The FDA and its Canadian and UK counterparts issued joint [guiding principles](#) for developing medical devices that use artificial intelligence. The FDA is seeking feedback on the new joint guidelines (no deadline given).

### **HHS Unveils Overdose Prevention Strategy**

HHS unveiled a new [overdose prevention strategy](#) featuring four key priority areas of primary prevention, harm reduction, evidence-based treatment, and recovery support.



## In the Courts

### **Latest 340B Ruling Deals Drug Manufacturers a (Limited) Victory**

A federal judge [ruled](#) that HHS exceeded acted in an "arbitrary and capricious" manner when it issued an advisory opinion that Eli Lilly & Co. and other drug makers clearly violated the law by refusing 340B discounts to contract pharmacies. At the same time, the judge said that not permitting drug manufactures to impose "extra-statutory conditions" on covered entities' access to discounted medications is "not only permissible, but...best aligns with congressional intent." HHS already removed the guidance at the center of the lawsuit but has maintained that drug makers are still on the hook for civil monetary penalties, which several manufactures continue to push back on. This is one of a handful of active cases over contract pharmacy rates for 340B drugs.

### **Texas Medical Association Sues over No Surprises Act Rulemaking**

The Texas Medical Association sued the federal government and requested a federal court to halt a new regulation implementing provisions of the No Surprises Act, which are set to take effect Jan. 1. They maintain that the regulation unfairly favors health insurers over providers in determining payment rates as part of a dispute resolution process.

## Private Sector Moves

### **Hundreds of Organizations Make Appeal to Governors to Extend State Licensure Flexibilities for Telehealth Services**

More than 230 organizations signed onto a [letter](#) calling on state governors to extend state medical licensure flexibilities for telehealth at least until the public health emergency ends and to find permanent solutions, including participation in interstate compacts. The effort comes as several dozen states have allowed emergency declarations to lapse.

## COVID Update

Merck granted a royalty-free license for its COVID-19 antiviral pill to a UN-backed nonprofit in an effort to expand access in African and Asian countries where vaccines are scarce. More than 50 companies have already expressed interest.

Following FDA approval last week, the CDC [recommended](#) today that all children ages 5 through 11 get a lower-dose COVID-19 vaccine, clearing the way for shots to be administered as soon as tomorrow, though it may take a few days before it is widely available. Meanwhile, according to a Moderna [announcement](#), the FDA is delaying approval of its vaccine in adolescents to allow more time to evaluate whether the shot increases the risk of a rare cardiac side effect. The announcement indicates that this work may not be completed before January 2022.

President Biden's vaccine mandates are facing a slew of public opposition and lawsuits. [Ten states](#) have sued the administration over its impending Dec. 8 vaccine mandate for federal contractors. Florida filed a separate [lawsuit](#) over the same issue. 21 Republican state attorneys general also sent a [letter](#) to the President warning they think it "stands on shaky legal ground," is confusing, and could exacerbate supply-chain problems. Iowa Governor Kim Reynolds signed into law a bill that allows employees to seek medical and religious exemptions from COVID-19 vaccine mandates and guarantee those fired for refusing vaccines unemployment benefits. Meanwhile, companies anxiously await new OSHA regulations that will detail mandates for private businesses with 100 or more employees, which could trigger more lawsuits. According to the AHA, the number of hospitals mandating vaccines for workers has leveled off at around 42% since President Biden announced employee vaccine mandates for all facilities paid by Medicare and Medicaid.