



H&K Health Dose August 3, 2021

A weekly dose of healthcare policy news

Legislative Updates

Congress this Week

The Senate released its \$550 billion bipartisan infrastructure [bill](#) late Sunday. The bill largely excludes healthcare provisions, but would provide \$65 billion to expand broadband access, which will have implications for access to telehealth services. The bill also includes several healthcare related pay-fors, including \$49 billion from delaying the Trump-era Medicare Part D rebate rule, \$8.7 billion from an extension of the Medicare sequester, and nearly \$3 billion in savings from reducing Medicare spending on discarded medications from single-use vials. The Senate is scheduled to be on recess next week, but Senate Majority Leader Chuck Schumer (D-N.Y.) said he hopes to take action on the bipartisan infrastructure bill and a \$3.5 trillion reconciliation package before leaving that could delay those plans.

In addition, Senate Appropriations Subcommittees are marking up three spending bills this week including FDA funding. These actions will set up these bills for consideration by the full Appropriations Committee, likely at the end of August. The remaining appropriations bills are still being crafted by the various subcommittees for consideration in the fall.

House members passed nine of their 12 appropriations bills before leaving for August recess this week and will attend to the rest when they return in September.

The legal debt limit was re-imposed Sunday. The Treasury Department will now begin taking what it refers to as “extraordinary measures” to prevent the U.S. from defaulting on its debt, which should avert a default until October or possibly November, though the exact timing is uncertain. Treasury Secretary Janet Yellen [urged](#) congressional leaders last week to take action.

Administrative/Regulatory Updates

Final IPPS Rule Released

On August 2, CMS released the FY 2022 Medicare Hospital Inpatient Prospective Payment System (IPPS) [final rule](#). The general effective date of the policies is Oct. 1, 2021. CMS released an accompanying [press release](#) and [fact sheet](#).

The general increase in operating payment rates for hospitals that successfully participate in the Hospital Inpatient Quality Reporting (IQR) Program and are meaningful EHR users is approximately 2.5%, reflecting the projected hospital market basket update of 2.7% with a -0.7% productivity adjustment and +0.5% statutorily mandated adjustment. Due to the pandemic, CMS will use pre-COVID data to set market baskets and utilization rates for FY 2022.

Among other provisions, CMS will:

- Repeal the requirement for hospitals to report their median charges negotiated with each MA payer.
- Extend add-on payments for new technologies and COVID-19 treatments.
- Require state Medicaid agencies to allow valid enrollments from all Medicare providers and suppliers serving dual eligibles – even if out of state – for purposes of processing Medicare cost sharing claims.
- Allow Medicare Shared Savings Program Accountable Care Organizations to continue at current risk levels for an extra year (before reverting to original risk levels they would have otherwise reached).

CMS notably did not finalize several provisions, including those pertaining to graduate medical education and indirect medical education, as well as scaling back Medicare’s share of organ acquisition costs. The agency cites the number of comments received on these proposals and says it will address both in future rulemaking.



Biosimilars' Very Big Week

The Food and Drug Administration [declared](#) biosimilar insulin product Semglee is interchangeable with brand-name Lantus, marking the first time that the agency has permitted pharmacists to substitute a biosimilar in lieu of a more expensive name-brand medication without requiring expressed permission from the prescribing provider.

Meanwhile, health insurers have been increasingly cracking down on members' use of high-cost biologic drugs. Aetna, UnitedHealth, and Cigna have each unveiled policies that either force patients to switch to biosimilars or restrict dosage.

COVID Update

New evidence suggests vaccinated people can carry and spread the Delta variant to the same extent unvaccinated people can. Florida just reported its highest single day number of new cases since the pandemic started. The spread of the Delta variant has prompted the CDC updated its guidance to recommend measures such as mask wearing indoors in public places regardless of vaccination status and whether it is a high transmission area. Experts are also calling for ramped-up testing to prevent infected, vaccinated people from spreading the illness unknowingly.

Federal employees are now required to get vaccinated or subject to weekly testing, social distancing, and mask wearing. Private companies are increasingly moving toward vaccine mandates as well.

U.S. drug regulators say they are taking an "all-hands-on-deck approach" to reviewing Pfizer and BioNTech's shot for full approval and will do so as soon as possible, potentially within weeks.