Holland & Knight

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A weekly dose of healthcare policy news

Legislative Updates

Congress this Week

The House and Senate are currently in recess for the week approaching Veterans Day.

After several months' delay, the House passed the bipartisan infrastructure bill by a vote of 228-206 on Friday in a nail-biting turn of events that lasted late into the evening and eventually included the support of 13 Republicans. The bill now awaits President Biden's signature. Much of the $1.1 trillion infrastructure deal includes traditional infrastructure elements, such as roads and bridges. However, the legislation does include a $65 billion investment to expand broadband capabilities, which should help to boost access to telehealth services, especially in rural areas.

The bill had initially been held up by House progressives who wanted to vote on the legislation in tandem with the separate $1.75 trillion Build Back Better social spending legislation. Still, House Speaker Nancy Pelosi finally convinced them to allow the infrastructure bill to advance after securing tentative support from House moderates pending an economic score from the nonpartisan Congressional Budget Office.

After months of back and forth, the latest version of the sweeping legislation includes a more moderate version of Democrats' drug pricing proposal that would allow Medicare to negotiate prices for up to 10 drugs in 2025 and as many as 20 drugs by 2028, plus insulin, but only drugs and biologics that have passed their exclusivity periods and already face competition. The bill also includes a rebate for drugs whose price rises faster than inflation and a cap on out-of-pocket costs for Medicare Part D drugs starting in 2024. The latest version included several last-minute changes, including expanding Medicare hearing benefits by a year (to 2023) and increasing funding for National Health Service Corps and Nurse Corps scholarships. Funding was also set aside for nursing and medical schools in underserved areas.

The CBO announced that it would release estimates for the various sections as they are completed, some of which may come as early as this week, but it may not be completely done before Democrats' target date of Nov. 15. The Committee for a Responsible Federal Budget released its analysis yesterday, concluding that "the latest version of the bill includes roughly $2.4 trillion of spending increases and tax cuts through 2031 along with $2.2 trillion of offsets. The result is a roughly $200 billion deficit increase over ten years." A copy of that analysis is available here. Democratic leadership aims to pass the package in both chambers by Thanksgiving, a tall feat especially considering neither Sen. Joe Manchin nor Krysten Sinema has guaranteed their support.

Still hanging in the balance, the debt ceiling, which is set to expire Dec. 3, the exact date current government funding is scheduled to run out. Recent discussions between House and Senate appropriators for the fiscal year 2022 appropriations have reignited perennial battles over military spending levels, immigration, climate change, and Title X funding. Hanging in the balance are billions of dollars worth of congressional earmarks. While most suspect a series of short-term continuing resolutions to extend the Dec. 3 deadline closer to the end of the year, rumors are swirling of a potential longer-term continuing resolution (C.R.) into February, which could put F.Y. 2022 earmarks in jeopardy.

In separate news, the House Energy and Commerce Subcommittee on Health advanced nine bills to the full committee for markup last week.

More than 150 Members of Congress Urge Biden Administration to Rethink Surprise Billing Rule

In a bipartisan letter led by Reps. Suozzi, Wenstrup, Ruiz, and Bucshon, more than 150 members of Congress urged the Biden administration to reconsider its interpretation of the No Surprises Act in its Sept. 30 interim final rule which directs entities to assume that the median in-network rate is the appropriate payment amount and select the offer closest unless credible information is submitted by either party can clearly demonstrates that it is "materially different." The letter urges the administration to instead equally weigh all of the factors listed in the original legislation. The letter contrasts an earlier statement from Energy and Commerce Committee Chairman Frank Pallone and Senate HELP Committee Chair Patty Murray supporting the regulation, saying it implements the No Surprises Act "as we intended." The rule is an interim final rule, and most of the provisions become effective Jan. 1, 2022.

Administrative/Regulatory Updates

CMS Issues Vaccine Rule for Healthcare Facilities, Federal Court Blocks OSHA Mandate

On Nov. 4, CMS issued an interim final rule with comment (IFC) that mandates staff at most healthcare facilities be fully vaccinated against COVID-19. Under the emergency regulation, facilities must establish a policy ensuring that by Dec. 5 all eligible staff has received at least one dose of a COVID-19 vaccine and are fully vaccinated by Jan. 4, 2022. The rule applies to all staff at applicable facilities regardless of clinical responsibility but does exclude certain staff that operate outside of the facility setting and do not have direct contact with patients or on-site staff. See our analysis here.

The CMS IFC is intended to be "complementary" to an OSHA emergency rule also issued on Nov. 4, 2021, that applies to employers of 100 or more workers. Holland & Knight has provided an analysis of the OSHA large employer rule. Of note, the OSHA rule faces legal challenges and has been temporarily stayed by the U.S. Court of Appeals for the Fifth Circuit. The Biden administration told the Court that the federal government had the power to require large employers to mandate COVID-19 vaccines or require testing and is pushing to lift the temporary block. A White House spokesperson advised employers to move forward with the vaccine mandate despite the legal challenges it is currently facing.

The CMS requirements could apply even if a court enjoins the OSHA rules. CMS expects facilities certified by the agency to comply with the IFC, citing its authority to regulate healthcare facilities under Sections 1102 and 1871 of the Social Security Act. It remains to be seen whether the CMS rule will also be challenged. Facilities with questions regarding "moving forward" with becoming compliant or regarding implementing the requirements should consult Holland & Knight's Healthcare & Life Sciences Policy Team with any questions.

MedPAC Examines Site-Neutral Payment (again)

The Medicare Payment Advisory Commission (MedPAC) examined site-neutral payment during its latest public meeting on Nov. 8-9, among other issues. The commission examined expanding site-neutral payment policies and aligning payment across sites of care. While the federal government has implemented some site-neutral payments, many were grandfathered in and weren't affected by the reforms. MedPAC also contends that such policies would help address concerns with healthcare consolidation.

In the Courts

More Fuel Added to 340B Contract Pharmacy Fire

The battle over 340B contract pharmacies continues to wage on as two more rulings were handed down on Friday. Notably, parts of both were inconsistent with each other and rulings in prior cases.

In the first brought by Novartis and United Therapeutics, the U.S. District Court for D.C. held that the plaintiffs' policies to limit 340B discounts to contract pharmacies do not violate Section 340B as asserted by HRSA and set aside the violation letters sent to the plaintiffs in May saying they were based "upon an erroneous reading of Section 340B." While the Court acknowledged that the plaintiffs raised legitimate concerns about the potential for fraud within the 340B program, it also validated HRSA's concerns about the degree to which the manufacturers' conditions have made it difficult for covered entities to obtain covered drugs at discounted prices. The Court called its review "narrow" and stated that any future enforcement action must rest on a new statutory provision, legislative rule, or well-developed legal theory that Section 340B specifically precludes the conditions at issue in the case.

In the second ruling responding to lawsuits filed by Sanofi-Aventis and Novo Nordisk, the District of New Jersey ruled that the 340B statute permits contract pharmacy arrangements, that the plaintiffs' contract pharmacy policies violate the 340B statute and they "may not attach strings to 340B offers;" that the plaintiffs' policies constitute an "overcharge;" and that the HRSA letters do not violate the constitution. At the same time, the Court partially vacated the HRSA letters and remanded them to HRSA for further consideration and vacated HHS' determination that plaintiffs owe credits or refunds to covered entities and face civil monetary penalties. While the Court held that HHS has the statutory authority to require shipment to at least one contract pharmacy per covered entity and that plaintiffs may not unilaterally create and establish policies wherein they dictate how many contract pharmacies a covered entity may designate to receive delivery of covered drugs, it did not ultimately decide whether the 340B statute permits covered entities to use multiple or unlimited contract pharmacies saying those concerns must be resolved through rulemaking, further negotiations with HHS, or by Congress.

COVID Update

Following the CDC's approval and recommendation of a lower dose of Pfizer's COVID vaccine in children aged 5-11, the Biden administration said the pediatric vaccination program is set to be 'at full strength' next week and is encouraging local school districts to host vaccination clinics. Meanwhile, Pfizer is expected to seek FDA authorization for booster doses for anyone 18 and older, which insiders say is likely to be approved.

Federal restrictions were lifted on air travel from more than 30 countries, including Mexico, Canada, and most of Europe, for the first time since the start of the pandemic. Travelers must be vaccinated and show proof of a negative COVID-19 test. This occurs just as Europe is deciding how to confront a new wave of cases. The U.K. is considering a return to lockdown and Germany's infection rate is now at its highest since the start of the pandemic.

Regeneron Pharmaceuticals reported positive results of its COVID antibody cocktail offering long-term protection to patients in a late-stage trial. A single dose appears to curb the risk of illness by about 82%. Pfizer also announced its antiviral pill reduced COVID hospitalizations and deaths substantially. An FDA advisory committee meets to discuss authorizing Merck's antiviral pill on Nov. 30. The U.S. government has already purchased over 3 million doses and can purchase up to 2 million more under an existing agreement.