



McDermottPlus Check-Up: June 25, 2021

McDermott+Consulting is pleased to provide the McDermottPlus Check-Up, your regular update on health care policy from Washington, DC.



This Week's Dose: An agreement on infrastructure emerges. Wyden releases drug pricing principles. Upton and DeGette introduce long-awaited 'Cures 2.0' draft legislation.

Congress

- + **Congressional Leaders Reached a Deal on Infrastructure.** After weeks of closed-door meetings and ongoing discussions with the White House, Speaker Nancy Pelosi and Senate Majority Leader Chuck Schumer told reporters Wednesday night that negotiators had come to an agreement on the terms of a \$1.2 trillion [framework](#) for a major infrastructure package. The package is comprised almost exclusively of physical infrastructure, like transportation, roads and broadband. However, a clear message from Democratic leaders accompanied this framework: physical infrastructure legislation must move contemporaneously with another reconciliation bill including more of the President's infrastructure priorities beyond traditional physical infrastructure. President Biden endorsed this strategy to ensure that the "human infrastructure" components of his American Families and Jobs plan—like childcare and an investment in home and community-based services—advance through Congress as well. In fact, the President went so far as to say he would not sign the bipartisan physical infrastructure legislation unless it is accompanied by companion human infrastructure legislation. The framework, as outlined, would be paid for through a combination of policies that also could impact healthcare, including: tax policies, targeted corporate user fees, redirecting unspent 2020 emergency relief funds, and extending mandatory sequester. The agreement is a significant step forward after reports of deteriorating negotiations, but the legislative path ahead remains tenuous. This two-pronged approach will be very difficult to achieve.
- + **Senate Finance Committee Chair Ron Wyden (D-OR) Released 'Principles for Lower Drug Prices.'** The [policy document](#) draws on familiar legislative proposals and echoes provisions of the Prescription Drug Pricing Reduction Act (PDPRA), which Wyden co-sponsored with then-Finance Chair, Senator Chuck Grassley (R-IA), last Congress. These policies include penalties for drug prices that outpace inflation and intellectual property reforms to enhance competitive pricing. Wyden's policies, however, depart from the PDPRA with the call to authorize Medicare to negotiate drug prices—a priority for Democrats on this issue. There is no legislative text accompanying these policies yet, but this could be a starting point for prescription drug reform for future legislation.
- + **Reps. Fred Upton (R-MI) and Diana DeGette (D-CO) Introduced Proposal for Cures 2.0.** The [discussion draft](#) outlined a set of policies to build on the 21st Century Cures Act, passed in 2016, and respond to needs that have emerged out of the COVID-19 pandemic. This legislation authorizes more than \$6.5 billion in funding for the Biden Administration's Advanced Research Projects Agency for Health (ARPA-H), which will aim to speed innovation in health research and breakthrough treatments. Other topline proposals include additional funding for studies around clinical trial diversity, long COVID and caregiver education and health literacy. There are also several U.S. Food and Drug Administration (FDA) modernization provisions that would allow for



innovative clinical trial designs and closer coordination with the Centers for Medicare and Medicaid Services (CMS) on coverage policy and access. Finally, the proposal seeks to remove barriers to telehealth access by making permanent some of the waivers exercised during the Public Health Emergency, including the elimination of restrictions on originating and geographic sites.

- + **Reps. DeGette and Bucshon (R-IN), Among Others, Introduced Updated VALID Act.** The Verifying Accurate Leading-edge IVCT Development (**VALID**) Act of 2021 has both Democrat and Republican support in the House and Senate. The new version of bill applies learnings from the COVID-19 pandemic, allowing labs to use their tests to diagnose patients upon providing validation data to the FDA. It also creates a new category of diagnostic and lab tests for in vitro clinical tests (IVCTs), over which the FDA would have approval authority, as well as a program to accelerate the development high-need diagnostic tests. Oversight of laboratory-developed tests (LDTs) came to the forefront in 2020, when the Trump Administration made a surprising policy change that allowed LDTs to be used without premarket review by the FDA. The VALID Act seeks to balance the needs of accelerating high-quality and accessible diagnostics with safety and oversight. The legislation would create a regulatory framework that includes advisory committees, annual reporting, quality and labeling requirements and adverse event reporting. It would also preserve CMS' jurisdiction over labs certified under the Clinical Laboratory Improvement Amendments (CLIA).

States and Courts

- + **U.S. Supreme Court Declined to Take Up Cost Sharing Reductions.** The case came out of the Court of Federal Claims, which ruled that plans that use the practice of raising premiums on “Silver Level” plans under the Affordable Care Act (ACA) were not entitled to cost-sharing reduction payments (CSRs) from the federal government. This issue extends back to a 2017 policy under the Trump Administration that stopped reimbursing the CSRs for silver-level plans provided to low-income individuals. This resulted in the practice of “silver loading” to offset the loss of federal CSR dollars, in which insurers were able to get larger premium tax credits by upping the premiums on other silver-tier plans. Despite the offset, a group of plans still sued the administration, saying the government owed them money. The Biden Administration has remained supportive of the lower court's decision. The case now heads back to the Court of Federal Claims where parties must sort out which premium tax credit increases were due to silver loading—if they do not reach a settlement with the government first.

Quick Hits

- + White House expects to **fall short** of 70% adult vaccination goal by July 4, but will meet it for adults over 27 years old.
- + Medicaid and CHIP enrollment has **increased** by nearly 14% since the beginning of the pandemic.
- + Senators Crapo (R-ID) and Burr (R-NC) **reintroduced** the Lower Costs, More Cures Act aimed at prescription drug pricing.
- + Senator Casey (R-PA) **released** the Better Care Better Jobs Act, which outlines proposals for home and community-based service planning program grants for investment in the direct care work force.



- + CMS withdrew Medicaid 1115 Waivers for work requirements in [Arizona](#) and [Indiana](#).
- + CMS has published 2021 Alternative Payment Model Incentive Payment details on the Quality Payment Program [website](#).

M+ Resources

- + On this week's [Breakroom podcast](#), we introduced our newest McDermottPlus team member, Debbie Curtis.
- + On June 29 at 12 p.m., join a group of leaders in value-based care for a virtual panel on "Alternative Payment Models: A Springboard for Achieving an Equitable Healthcare System." [Register here](#).

NEXT WEEK'S DIAGNOSIS: Congress will wind down heading into the Fourth of July Holiday weekend. There are currently no scheduled healthcare-related hearings. July 1 is the statutory deadline for the first surprise medical billing regulation, which will focus on payment methodology.



For more information, contact [Aaron Badida](#), [Mara McDermott](#), [Kristen O'Brien](#) and [Katie Waldo](#).

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