



UnityPoint Health Federal Update – July 2021

June 25, 2021 – July 23, 2021

July 23, 2021

Congress

Republicans Blocked Opening Debate on Infrastructure Bill. This procedural barrier came in response to Senate Majority Leader Chuck Schumer's attempt to force progress by scheduling a procedural vote to start debate (otherwise known as "invoking cloture") on the bipartisan physical infrastructure package agreed to by a group of 10 Democratic and Republican Senators at the end of June. This bill is distinct from the partisan Democrats-only version that the leader intends to advance through a reconciliation process. Republican leadership cited the lack of legislative text and a Congressional Budget Office score as primary reasons for blocking debate. However, many of the ten Republican Senators working on the bill signaled that they are likely to vote to begin debate next week, making passage possible before the looming August recess. The second partisan package also is starting to come together. Democrats envision a \$3.5 trillion "human" infrastructure package with climate, health and social service policies that Democrats intend to push through a second reconciliation. While Democrats will need only a simple majority to advance this bill – and not the 60 votes typically required to advance legislation in the Senate – the outcome is not guaranteed. Democrats have no margin for error in the Senate and hold only a slim 9 vote majority in the House. House Speaker Nancy Pelosi said this week that the House will not move the bipartisan physical infrastructure package until the Senate passes the second reconciliation, making it likely that the House will not move on any Senate-passed physical infrastructure package until fall.

House Committee on Energy and Commerce (E&C) Sends 16 Healthcare Bills to Full House. These bills provide additional resources to respond to the ongoing substance use disorder epidemic; improve our nation's public health systems; increase vaccine access and support programs to address maternal health and mortality. Additionally, there was strong support from Democrats and Republicans on H.R. 4406, a bill that temporarily extends increased Medicaid funding for Puerto Rico and other U.S. territories, while also implementing additional accountability measures. While some Democrats noted they still would prefer a permanent Federal Medical Assistance Percentage for Puerto Rico, this extension addressed an issue that otherwise could have been strategic leverage in a year end package or reconciliation. Because this passed outside of a major negotiation, it signals that other issues—including those related to Public Health Emergency flexibilities—could be addressed as standalone issues as well. All bills were passed to the full house by a voice vote with largely technical amendments.

Administration

CMS Released Proposed Annual Outpatient Payment Rule. The agency proposes to increase payment rates under the Hospital Outpatient Prospective Payment System (OPPS) and the Ambulatory Surgical Center (ASC) Payment Systems by a factor of 2.3%. In continuation of an existing policy, hospitals and ASCs that fail to meet their respective quality reporting program requirements are subject to a 2.0% reduction in the CY 2022 fee schedule increase factor. The rule also proposes to maintain the current reimbursement rate of Average Sales Price minus 22.5% for specified covered outpatient drugs purchased under the 340B program, as well as payment for clinic visits to off-campus provider-based departments at 60% of the OPPS rate. In a surprising and unusual move, CMS proposes to withdraw previous plans to eliminate the Inpatient Only list and expand the ASC Covered Procedures List, two policy changes that were only recently implemented by the agency. Also of note, CMS proposes to significantly [increase penalties](#) for hospitals to drive compliance with the recently established hospital price transparency program. The proposed rule included a



request for information about a soon to be established Rural Emergency Hospital designation. Consistent with other proposed payment rules this year, OPPS requested information on how to address health equity in the hospital quality programs, specifically with a focus on data use strategies. Comments on the proposed rule are due September 17, 2021.

CMS Proposed January 2022 Launch of Radiation Oncology (RO) Alternative Payment Model (APM). The RO Model is a mandatory nationwide demonstration model that will run for five years encompassing approximately 30% of eligible radiation oncology episodes. The model pays a prospective payment on a site-neutral basis, and the rate does not vary based on the modality of treatment for a 90-day episode. The agency proposes changes that included lowering the discount factors for professional and technical components from 3.75% and 4.75% to 3.5% and 4.5%, respectively, removing brachytherapy as an included modality of care, and removing liver cancer as included cancer type. It also proposes qualifying the RO Model as an Advanced APM or Merit-Based Incentive Payment System APM in Performance Year 1, rather than Performance Year 2. The proposed changes are relatively minor, but stakeholders had been hoping for more changes/flexibility in a model that is expected to have a significant impact coming on the heels of the COVID-19 pandemic.

July 16, 2021

Administration

Senate Democrats Announced \$3.5 Trillion Human Infrastructure Package. Senate Majority Leader Chuck Schumer announced the package late Tuesday night, which represents Biden Administration priorities that Democrats will seek to push through using a second attempt at reconciliation. While Democrats have not yet released any legislative text or itemized breakdowns of how the \$3.5 trillion will be spent, initial reports indicate that the package will expand Medicare benefits to cover dental, hearing and vision services and address the Medicaid coverage gap in non-expansion states. There are also likely to be numerous policies focused on the Administration's climate priorities, including investments in clean energy and reducing carbon emissions, as well as funding for childcare, paid family leave and community college. The package is rumored to be paid for in part by tax and prescription drug pricing policies, including repeal of the Trump Era "rebate rule," which sought limit the use of rebates offered by pharmacy benefit managers. These numbers mark the beginning of a potentially lengthy and strategically tenuous process where Democratic leaders will try to shepherd two significant spending packages on the thin majorities. Leader Schumer is pushing to get a bipartisan physical infrastructure package moving in the Senate next week, opening debate as early as Wednesday. Meanwhile, the House has begun the process of moving 12 appropriations bills ahead of the August recess. The House plans to pass a "minibus" with seven appropriations bills (including Labor, Health and Human Services) next week, which the Senate will also have to eventually consider, making for a crowded agenda heading into fall.

Congress

CMS Released CY 2022 Medicare Physician Fee Schedule (PFS) Proposed Rule. The annual [regulation](#) includes proposals related to Medicare physician payment and the Quality Payment Program (QPP). CMS proposed a physician conversion factor (CF) of \$33.5848, representing a 3.75% reduction from the 2021 CF of \$34.8931. However, Congress would likely need to act to increase the conversion factor to mitigate the negative impact of this reduction on care. The rule also proposed extending coverage of certain services temporarily added to the Medicare Telehealth Services List during the pandemic to the end of CY 2023, though Congressional action on originating and geographic site restrictions is required to make those policies meaningful to most beneficiaries if the public health emergency were to end. Other proposals include an update to underlying clinical labor cost data used to calculate the practice expense portion of



Medicare physician payment that may have a disproportionate positive impact on certain specialties with higher-than-average share of clinical labor costs, and a launch date of CY 2023 for the previously delayed Merit-based Incentive Payment System (MIPS) Value Pathways program which is designed as an alternative to MIPS. The agency is seeking comments on a proposal to potentially sunset the traditional MIPS by end of 2027. The agency also included a request for information on its health equity data collection initiative, which is designed to give providers a more comprehensive understanding of health disparities impacting their patients. Comments on the rule are due September 13, 2021.

President Biden issues Executive Order (EO) to Promote Competition. On July 9, 2021, President Biden issued an [Executive Order on Promoting Competition in the American Economy](#) to address competition and consolidation across the economy. The EO establishes a White House Competition Council, encourages review of licensure requirement and non-competes and identifies four specific areas for the Department of Health and Human Services (HHS) to focus on: hospitals, insurance, prescription drugs and hearing aids. The EO notes that the Administration will support enactment of a public health insurance option. Like all EOs, the policies generally require subsequent regulatory action by government agencies. Though implementation of many of the more substantive policy directives will likely take some time to materialize, we expect these issues to continue to be a focus for the Administration and HHS.

July 1, 2021

Administration

CMS Issued Proposed Rule to Advance Biden ACA Expansion Promise. The [proposed rule](#) out of the Centers for Medicare and Medicaid Services (CMS) came in addition to regular updates to payment parameters for ACA plans. The proposed rule seeks to repeal Trump era regulations that allowed states to turn over their marketplaces to direct enrollment entities and the enjoined double-billing requirement for abortion services. It also builds on the Affordable Care Act (ACA) by extending the annual open enrollment period by a month; permitting monthly enrollment by advance payment tax credit-eligible individuals with incomes at or below 150% of poverty; increasing user fees for federal marketplace states; and strengthening requirements for navigator organizations to assist consumers understand their coverage beyond initial enrollment. If finalized, these policies would bolster coverage opportunities under the ACA law and facilitate access for lower-income individuals. Comments are due July 28, 2021.

CMS Proposed to Expand Home Health Value-Based Purchasing (HHVBP) Model. The model began its first five-year performance period in 2016 in nine states. HHVBP offers Medicare payment adjustments to home health providers that improve quality of care and/or reduce utilization, while penalizing those who perform poorly. CMS' most recent assessment found a 1.3% reduction in \$604.8 million in net cumulative savings for Medicare with "modest" gains in quality around 4.6% percent. The program's performance has led the agency to [propose](#) converting the HHVBP program into a nationwide model beginning in January 2022. Comments are due August 27, 2021.

Daniel Tsai Tapped to Lead Center for Medicaid and CHIP Services (CMCS). Tsai is one of the few [appointees](#) under President Biden without previous political ties to the Obama Administration. He most recently held the roles of Assistant Secretary for MassHealth (Massachusetts' Medicaid and CHIP agency) and state Medicaid Director, where he served for six years and implemented value-based reforms and programs that enhanced supports for social determinants of health. Tsai will hold the titles of Deputy Administrator of CMS and Director for CMCS. In these roles, Tsai will be responsible administering the federal government's role in supporting low-income care for a record 80 million individuals. This includes managing the implementation of a series of state options for care expansion made possible by COVID-19 relief packages. The Biden team has not yet named a corresponding lead for the Medicare program, but rumors abound about who is on the shortlist, and a nominee is expected shortly.



Congress

INVEST in America Act Passed in House. Rep. Peter DeFazio's (D-OR) \$715 billion Investing in a New Vision for the Environment and Surface Transportation ([INVEST](#)) in America Act passed the House with a 221-201 majority, which included two Republicans. It is the first legislative move following last week's agreement among a group of 10 Democrat and Republican Senators on an infrastructure framework. However, this does not represent the final bipartisan infrastructure deal. Democratic leaders continue to underscore that a bicameral infrastructure package will not pass both chambers without a second reconciliation package that includes "human infrastructure" priorities, like investments into the workforce that directly provides care to patients. The Senate is the chamber to watch when it comes to meaningful movement on the infrastructure front, and the combination of a bipartisan infrastructure bill and a reconciliation package may not materialize until after August recess. It is likely that the Senate infrastructure bill draws on some of the proposals in INVEST in America, while reflecting other Senate priorities identified by committees and the group of 10.

June 25, 2021

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).