Brownstein

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TO:	Johnson & Johnson
FROM:	Brownstein Hyatt Farber Schreck, LLP
RE:	Biden Administration Health Care Regulatory Plans

Introduction

With President Biden's legislative agenda likely stalled for the time being, along with the upcoming midterm elections possibly shifting Congress to Republican control, it is likely that the administration will turn to regulation and rulemaking to achieve their political and policy priorities. Here we will examine the potential health care regulations and rules that officials may publish within the Department of Health and Human Services (HHS), Centers for Medicare and Medicaid Services (CMS), and the Center for Medicare and Medicaid Innovation (CMMI) during the rest of President Biden's term.

Advancing Health Equity

CMS has stated their commitment to using regulatory means to address health disparities. In the 2022 CMS Strategic Vision, the administration highlighted potential areas where they might act. For example, CMS suggested expanding Accountable Care Organizations (ACOs) in rural and underserved communities, and increasing transparency around Medicare Advantage supplemental health care benefits. CMS has cited housing, food and transportation assistance as supplemental benefits that deserve more study and consideration. Starting in plan year 2019, CMS expanded primarily health-related benefits to include nonmedical services. For example, many Medicare Advantage (MA) plans now offer home-delivered meals and transportation options to a hospital or doctor's office as a supplemental benefit. Since 2019, beneficiary enrollment in MA plans offering prepared meals has grown, with nearly half of all Medicare beneficiaries enrolled in a plan that offers meals in 2020. CMS has said that it is a priority to target more benefits to individuals who live in rural areas, cannot afford broadband access, lack access to reliable transportation, have increased risk of COVID-19 infection due to disability, ESRD, or other chronic health conditions, or may experience other barriers to accessing the care they need.

One of President Biden's first actions when he took office was signing an executive order that directed the whole of government to promote policies that advance "equity for all, including people of color and others who have been historically underserved, marginalized, and adversely affected by persistent poverty and inequality." Since that executive order was signed, regulations and policies issued by the various agencies within HHS assess their impact on equity. Maternal health has been a topic of importance to Vice President Harris. Beginning with discharges on Oct. 1, 2021, CMS adopted a new structural quality measure for the Hospital Inpatient Quality Reporting Program that asks hospitals whether they participate in a statewide and/or national maternal safety quality collaborative and whether they have implemented the recommended patient safety practices or bundles to improve maternal outcomes. In December 2021, CMS announced that they intend to propose a "Birthing-Friendly" designation for hospitals to drive improvements in perinatal health outcomes and maternal health equity. The designation would initially identify hospitals that provide perinatal care, are participating in a

maternity care quality improvement collaborative, and have implemented recommended patient safety practices. We expect HHS and CMS to provide regulations and rules that address health equity and maternal health in the coming years.

Expanding Access to Affordable Health Coverage and Care

It has been a goal of the Biden administration, as well as past administrations, to expand health care access to all populations. CMS has said that they want to use regulatory authority to make it easier for people to enroll in Medicare, eliminate delays in coverage and to increase the Medicare Savings program. It is possible that CMS will issue regulations addressing these areas in order to increase access, although no specific proposals have been made public at this time. Additionally, HHS and CMS want to use lessons they learned from the COVID-19 pandemic to improve access to care. Legislation passed during the pandemic has expanded and increased health care provisions that are tied to the public health emergency (PHE) that the administration would like to draw from.

COVID-19 and the Public Health Emergency (PHE)

COVID-19 cases have continued to remain at high levels in the United States through 2021 and into 2022 due to new variants such as delta and omicron. On Jan. 14, 2022, the Secretary of Health and Human Services renewed the declaration of the COVID-19 public health emergency (PHE) for an additional 90 days. Many believe that the PHE will continue for a significant portion of 2022, if not for the entire year, and the administration is determining which gained flexibilities it would like to continue and what they can do through regulatory authority alone. HHS has stated that they would give a 60-day notice before they roll back the PHE declaration.

Telehealth use due to the PHE has grown significantly and has improved access to care. Last year, CMS extended and expanded certain telehealth provisions for the 2022 Medicare Physician Fee Schedule. Specifically, CMS extended coverage of Category 3 Medicare telehealth services through 2023 (e.g., home visits for established patients, emergency department visits, critical care services, and hospital and nursing facility discharge day management services), permanently extended coverage of the tele-behavioral health services in home and via audio-only technology, and allowed for rural health centers and federally qualified health centers to virtually deliver mental health visits. CMS will look to see if there is more that they can do in this space, or if it will have to be done legislatively. Congress is considering a legislative fix to extend the current telehealth flexibilities for two years after the PHE declaration ends, giving the body more time to evaluate telehealth claims data from the pandemic in order to craft a long-term solution.

Additionally, the Families First Coronavirus Response Act provided a 6.2 percentage point increase in the federal share of certain Medicaid spending with requirements to meet certain maintenance of eligibility (MOE) requirements for the duration of the PHE. CMS, under the Trump administration, has released guidance for states on how they can transition out of the increased federal spending in December 2020. The Biden administration could revise these as well as the Trump administration's interim final rule governing the MOE provisions. The Trump administration never finalized the interim final rule following the comment period, which allows the Biden administration to review comments and make modifications prior to finalizing the rule.

Promote Value-Based Care

CMS has listed another goal as part of their refresh of CMMI, which is to ensure that more Medicare and Medicaid enrollees are in an accountable care relationship by 2030. Additionally, they want to ensure that value-base care programs are aligned between Medicare and Medicare Advantage. When the programs are not aligned, it can be confusing for providers who see patients across an array of payers. To address this, CMS is working with CMMI to align accountable care initiatives and test payment and service delivery models.

Innovation in Medicare and Medicaid

Across both Medicare and Medicaid, the Biden administration is likely to use CMMI to advance the administration's policy agenda. In October 2021, the Biden administration outlined CMMI's outlook for the next decade and may now engage in activities to meet these outlined goals. This may include: increasing the number of patients in a care relationship with accountability for quality and total cost of care, working toward alignment across CMS and HHS to improve quality, and increasing the number of beneficiaries from underserved communities who receive care through value-based payment models. Additionally, Liz Fowler, director of CMMI, has said they will do more to address affordability, particularly looking at strategies that target health care prices or reduce unnecessary care. She also noted that CMMI will be placing a premium on multicare alignment and is committed to having a more streamlined model portfolio that articulates how they fit together.

CMMI is also working across CMS to align a more coordinated portfolio and is looking into how their models can work cohesively, and looking more toward ACOs and less toward bundled payments for discrete episodes (i.e., a hip or knee replacement). Fowler has said that CMMI is currently examining its portfolio for promising models that have enough participants for evaluation to keep, and it will soon begin implementing a very specific criteria to consider new models in accordance with its new strategy.

On Sept. 13, 2020, former President Trump signed an Executive Order to create a "most favored nation" drug pricing system in Medicare Part B. This would let the secretary of HHS create a demonstration program in which Medicare would pay no more money for a drug under Medicare Part B than the lowest price in countries in the Organization for Economic Cooperation and Development. A combination of rulemaking and CMMI demonstrations would have been used. Following several lawsuits, CMS proposed a rule in late 2021 stating that they would not implement the policy. Prior to pulling the proposal, Dr. Fowler said in June 2021 that CMMI would continue to "take a look" at the issue but was hopeful prescription drugs reductions would be handled legislatively.

Promoting Affordability and Sustainability

CMS has acknowledged concerns about the solvency of the Medicare Trust Fund, projected to be insolvent and unable to fully cover the cost of beneficiaries' hospital bills as soon as 2026. CMS has pointed to the Build Back Better Act as a way to address affordability in Medicare, primarily through drug pricing reform. Additionally, CMS has been working on implementation of the No Surprises Act and increasing transparency regarding hospital prices.

Prescription Drug Prices

On Jan. 10, 2022, CMS released a proposed regulation that would require Medicare Part D plans to apply all discounts they receive from network pharmacies at the point of sale effective Jan. 1, 2023. Further, the proposed rule would redefine the negotiated price as the baseline, or lowest possible, payment to a pharmacy.

CMS and the CMMI may look outside of regulations, to demonstration projects, in order to address prescription drugs. Oregon has proposed a demonstration project that would implement a closed formulary and limit coverage of drugs approved under the FDA's accelerated approval pathway for Medicaid. A similar model was approved in Tennessee in 2021 but hasn't been implemented. More states may follow suit and propose their own demonstration models. If the Build Back Better Act does not pass, that may put more pressure on CMMI or the Medicaid state waivers process to address areas such as price inflation.

Surprise Medical Billing

In 2020, Congress passed the No Surprises Act, which was signed into law by former President Trump. The legislation, starting on Jan. 1, 2022, provides new federal consumer protections against surprise medical billing by requiring private health plans to treat these out-of-network services as if they were in-network when calculating patient cost-sharing. In 2021, the Biden administration began implementing the No Surprises Act by releasing a series of rules aimed at shielding patients from financial hardships occurred from surprise billing. HHS and CMS will continue to work through surprise billing and most likely will release new rules and regulations in the future. One such area that may be addressed is the requirement that health plans verify their network provider directory every 90 days. Additional rulemaking is expected as the agency will have to clarify certain aspects of already released rules and also to finish implementation of the bill. One area that still hasn't been addressed surrounds charge transparency. Dr. Ellen Montz, deputy administrator and director of the Center for Consumer Information and Insurance Oversight, has indicated that continued implementation of the No Surprises Act remains a primary goal for the agency.

Unified Agenda

On June 11, 2021, the Biden administration released its first Unified Agenda of Federal Regulatory and Deregulatory Actions, an outline of agency priorities released every fall and spring. The unified agendas set nonbinding goals for regulatory actions, providing insight into the administration's priorities for the upcoming year. The goals that are listed here may never make it to fruition. There are several noteworthy rules listed from CMS (see table below).

Rule Name	Description
Clinical Laboratory Improvement Amendments (CLIA) Fees (CMS-3356)	This proposed rule follows the notice with comment published on Dec. 31, 2018. This rule would update fees for determination of program compliance and additional fees for laboratories established under the Clinical Laboratory Improvement Amendments (CLIA) regulations as well as

	the collection of other fees authorized to collect, such as fees for revised certificates, post-survey follow-up visits, complaint investigations, and activities related to imposition of sanctions.
Alternative Payment Model (CMS-5535)	This rule would propose a new mandatory Medicare payment model under section 1115A of the Social Security Act. This model would test ways to further CMS' goals of reducing Medicare expenditures while preserving or enhancing the quality of care furnished to beneficiaries.
Assuring Access to Medicaid Services (CMS-2442)	This rule proposes to ensure and monitor equitable access in Medicaid and the Children's Health Insurance Program (CHIP). These activities could include actions that support the implementation of a comprehensive access strategy as well as payment specific requirements related to particular delivery systems.
Medicaid Drug Misclassification, Beneficiary Access Protection, and Drug Program Administration (CMS-2434)	This proposed rule would implement section 6 of the Medicaid Services Investment and Accountability Act of 2019, which created new penalties related to manufacturers' misclassification of covered outpatient drug products under the Medicaid Drug Rebate Program (MDRP) including civil monetary penalties, suspension of a manufacturer's drug, and the ability of states to recover unpaid rebates. In addition, it proposes beneficiary protections relating to access to drugs under value-based purchasing programs, as well as MDRP program integrity and administration changes.