



2022 HEALTH POLICY OUTLOOK



McDermott+
Consulting



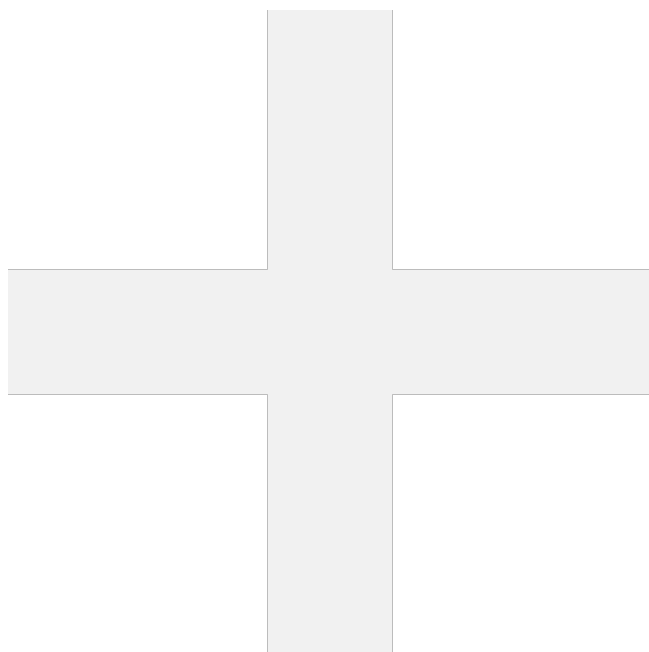
TABLE OF CONTENTS

4	COVID-19
4	Telehealth and Other Flexibility Waivers
4	Build Back Better
5	Drug Pricing
6	Surprise Billing and Transparency
6	Mental Health Policy
7	Physician Payment
7	Cures 2.0 and User Fee Reauthorization Legislation
8	Value Based Care
8	Health Equity
9	Other Priorities



OVERVIEW

As we start a new year and new congressional session, we are taking a look at the health policy priorities that are likely to dominate the agenda in 2022. Following is our top 10 list (plus a few more) of health policy topics to watch.





COVID-19

The pandemic continues to loom large (maybe larger than ever) with surges driven by new variants, soaring hospitalizations and mounting deaths, and for as long as that continues, expect strong focus from the Biden Administration and Congress. 2022 may bring relief in the form of novel treatments (e.g., anti-viral oral medications), greater access to testing and higher vaccination rates.

The Biden Administration has continued to face challenges, from testing availability to vaccine mandate enforcement. Rules requiring insurers to cover the cost of at-home diagnostic tests were recently announced, and those may be expanded to include Medicare. Additionally, the fate of the Administration's vaccine mandate policy hangs in the balance. In one of its first actions in 2022, the Supreme Court of the United States considered challenges to the employer and healthcare worker vaccine mandate requirements. Decisions in these cases are expected soon, but challenges and court consideration will continue throughout the year.

Additional legislative action is possible, as Congress will want to demonstrate a proactive response to COVID-19 challenges. That action may include more financial relief. Expect the monies remaining in the Provider Relief Fund to be distributed, and possibly supplemented by Congress.

TELEHEALTH AND OTHER FLEXIBILITY WAIVERS

Early in the pandemic, former President Trump and US Department of Health and Human Services (HHS) Secretary Alex Azar issued public health emergency (PHE) declarations that gave HHS, the Centers for Medicare and Medicaid Services (CMS) and other agencies broad authority to waive hundreds of regulatory requirements to allow healthcare providers the flexibility necessary to meet the demands of the moment. Congress also approved legislation granting other flexibilities, including, most notably, broad latitude to deliver services to Medicare beneficiaries via telehealth.

Together, these **flexibilities** have fundamentally altered healthcare delivery by expanding telehealth access and the ability to provide care in patients' homes, including through the acute hospital care at home waiver program, as well as flexibilities around supervision. Enhanced payment for certain services to incentivize and facilitate access, and to account for new costs associated with different delivery modalities also changed the healthcare landscape. The experience of the past two years has led many providers and policymakers to consider which regulations should be permanently suspended or revised. Meanwhile, the Biden Administration continues to extend the PHE declaration in 90-day increments. The current PHE declaration expires in January 2022. The Administration has said that it would afford 60-days' notice prior to terminating the PHE, and no such notice has been given, so we expect the current PHE declaration to be renewed for at least another 90 days. To date, Congress has declined to take legislative action on PHE-related measures since they continue in



effect while the PHE declaration remains in place. In 2022, expect stakeholders to continue to press Congress to extend or make permanent certain flexibilities beyond the PHE.

BUILD BACK BETTER

President Biden achieved two significant domestic policy wins in his first year in office with enactment of the [American Rescue Plan](#) in March 2021 and the Infrastructure Investment and Jobs Act, otherwise known as the Bipartisan Infrastructure Framework, which was enacted in November 2021. At the conclusion of 2021, the remaining piece of his infrastructure agenda—the so called “soft infrastructure” priorities contained in the Build Back Better (BBB) Act—stalled as Democrats could not rally the 51 votes needed for US Senate passage. Key BBB healthcare provisions include extension of the Affordable Care Act (ACA) subsidy expansions made by the American Rescue Plan, prescription drug pricing reforms, critical investments in home and community based services, new Medicare hearing benefits that include coverage for hearing aids, coverage through zero premium ACA plans for people in states that haven’t expanded Medicaid, continuous eligibility for children in Medicaid, one year of Medicaid eligibility for postpartum women and permanent reauthorization of the Children’s Health Insurance Program (CHIP). In addition to significant healthcare policy investments, BBB also includes major resources for childcare, early childhood education, climate change, paid family leave and revisions to federal tax policies, including extension of the expanded child tax credit.

The US House of Representatives approved a version of BBB on a party line vote (220–213) on November 19, 2021. On December 19, 2021, Senator Joe Manchin (D-WV) publicly announced

that he would not support “this piece of legislation,” depriving Democrats of the majority necessary to advance the bill. We enter 2022 with uncertainty regarding the future of the BBB, as Senator Manchin has continued to oppose the existing bill. The way forward may be a reconfigured smaller package that sheds some of the aspects he finds objectionable. It is also possible that pieces of the broader bill—such as the child tax credit extension—may be advanced through different packages. Adding another layer of uncertainty, if a revised BBB package does get through the Senate, it must be able to pass the House again with only Democratic votes.

DRUG PRICING

Addressing prescription drug pricing remains one of the most prominent policy and political issues in healthcare. In November 2021, the House passed a significant prescription drug pricing reform package as part of the BBB. The most controversial provision would give the federal government authority to negotiate drug prices with pharmaceutical manufacturers. The House-approved version would allow HHS to enter into negotiations on a limited number of drugs each year in Medicare with some extension into the private sector. The provision appears to have the support to move forward in the Senate, but may be limited to government programs and not directly affect the private market because of the Senate’s procedural rules governing reconciliation. The BBB also includes provisions related to pharmacy benefit managers and reform of the Medicare Part D program. If some form of the BBB does not come to fruition, more limited prescription drug pricing reform could be considered on a bipartisan basis in 2022, but that prospect is unlikely given the political sensitivity of the issue and election year politics. In either event, expect the Biden Administration to continue to pursue its own administrative



authorities to achieve progress in this arena, given that the unaffordability of prescription drugs is a top issue for US consumers, particularly senior citizens.

Additionally, 340B policy will be front and center in 2022. The 340B program provides access to lower cost prescription drugs to certain safety net providers and continues to be a source of controversy. Much of the focus in the early part of the year will be on the courts. In 2021, in response to an advisory opinion related to contract pharmacy arrangements issued by the Health Resources and Services Administration (HRSA), which oversees the 340B program, several pharmaceutical manufacturers sued the agency in federal district courts challenging HRSA's policy, among other things. Some decisions emerged late in the year, but more litigation is expected. In a separate matter, the Supreme Court is presently reviewing a lower court decision upholding a 2018 policy from CMS cutting Medicare payments to hospitals for certain drugs purchased under the 340B program. At issue in *American Hospital Assn., et al. v. Becerra* is whether CMS exceeded its statutory authority by reducing payments for 340B drugs under the Medicare Outpatient Prospective Payment System from average sales price (ASP) plus 6% to ASP minus 22.5% beginning in 2018—a reduction of approximately 30%. The decision in the case may have far-reaching implications not just for hospitals that participate in the Medicare program given the reimbursement impact of the 340B-specific payment cuts, but also for the administrative procedures review doctrine known as *Chevron* deference. Changes to that doctrine could upset decades of administrative law precedent. Outcomes in these cases may prompt legislative or regulatory action regarding the 340B program. Legislative action is unlikely while legal action is pending.

SURPRISE BILLING AND TRANSPARENCY

Congress enacted the No Surprises Act in December 2020. HHS, the US Departments of Labor and the Treasury, and the US Office of Personnel Management spent much of 2021 devising and announcing implementing regulations that protect patients from surprise medical bills and establish a payment dispute resolution process for payers and providers. The debates in Congress continued into 2021 as stakeholders on opposite sides of the issues praised and condemned the final regulations and pushed dueling members of Congress back into the discussion (hundreds of members of Congress signed onto nearly a dozen letters to the departments supporting or challenging agency policy decisions). As 2022 dawned, four lawsuits were pending in federal district courts challenging various aspects of the regulations and seeking to expand discretion available to independent dispute resolution arbiters charged with resolving provider-insurer/plan payment disagreements. Meanwhile, almost every healthcare provider and payer scrambled to implement and operationalize requirements that became effective on January 1. In 2022, watch for decisions on the pending lawsuits, which could upend implementation and operation of the dispute resolution programs and require the departments to revise key aspects of the regulations. Certain camps in Congress are likely to continue to press the agencies for more changes, and some may seek to advance legislative changes. Additional rulemakings are also expected, as the departments have not yet issued regulations for major components of the rules (mostly concerning charge transparency) or responded to requests to clarify certain aspects of the rulemakings unveiled in 2021.



MENTAL HEALTH POLICY

The pandemic has taken a toll on the nation's mental health and increased demand for services, and Congress is focusing attention on these policy issues. In fall 2021, the Senate issued three comprehensive requests for information, including one from the bipartisan leaders of the Senate Finance Committee, seeking stakeholder feedback on efforts to address mental and behavioral healthcare barriers and improve how mental and behavioral healthcare are delivered. Such efforts are expected to produce further action in 2022, including hearings and draft legislation, we are likely to be bipartisan. The ongoing COVID-19 pandemic has also resulted in a continued focus on ensuring that mental health services are available through telehealth.

In July 2022, the new three-digit nationwide suicide prevention hotline number, 988, will be fully implemented. Lawmakers are working to ensure that states and local systems have the resources they need for this implementation. Bipartisan legislation to expand the capacity of the suicide prevention lifeline and mental health crisis centers is pending and may advance this year.

Healthcare workers caring for COVID-19 patients report high levels of exhaustion and trauma. In 2020, Dr. Lorna Breen, an emergency room physician who treated COVID-19 patients, died by suicide. In December 2021, the Lorna Breen Health Care Provider Protection Act (HR1667) passed the House after the Senate unanimously approved a companion measure earlier in the year. Look for the House and Senate to reconcile technical differences in the two bills and complete work in 2022.

BBB also would strengthen the Mental Health Parity and Addiction Act of 2008, which requires that insurance coverage for mental health and

substance use disorder services be offered with the same access as other health services. BBB also would increase the number of clinicians working in behavioral health by adding residency training slots for psychiatry, providing funding for grants to establish programs to grow and diversify the maternal health/substance use disorder treatment workforce, and providing funding for the Substance Abuse and Mental Health Services Administration Minority and Fellowship program.

PHYSICIAN PAYMENT

Medicare payments to physicians were threatened by the prospect of a 3.75% cut in calendar year 2022. However, at the end of 2021, Congress passed the [Protecting Medicare and American Farmers from Sequester Cuts Act](#), which was signed into law on December 10. This legislation directed Medicare to make a 3% positive adjustment to 2022 physician payments, offsetting some of the scheduled reduction. In addition to mitigating the cut to Medicare physician payments, this bipartisan legislation staved off other Medicare cuts, including a phased-in delay of the Medicare and PAYGO sequestration cuts that impact all Medicare payments. These provisions are only authorized for 2022 and, in the case of Medicare sequestration, will be phased out starting April 1, 2022. Given the time-limited nature of this relief, Congress undoubtedly will be under considerable pressure later in 2022 to revisit these cuts.

CURES 2.0 AND USER FEE REAUTHORIZATION LEGISLATION

Every five years, the US Food and Drug Administration (FDA) and FDA-regulated industries (including prescription drugs, biosimilars and medical devices) negotiate user



fee agreements (UFAs) that re-authorize the user fees that those industries pay to the FDA. These user fees fund approximately 80% of the FDA's personnel-related costs. The UFA deals can also serve as vehicles for other FDA-related programmatic and policy changes, such as setting targets for the number of FDA approvals for each industry. After the FDA and the industries reach initial agreement, the measures move to Congress. During that process, the House Energy and Commerce Committee and the Senate Health Education and Labor Committee consider legislation that may include other policy priorities. This process can be lengthy but has been consistently completed on time.

The FDA and affected industries have already reached agreements and sent packages to Congress. Generally, policies related to FDA jurisdiction over prescription drugs, biologics or medical devices are most likely to be attached to the UFAs, but it's also possible that Congress could add policies related to CMS coverage. One large piece of legislation that could be added is HR 6000, also known as Cures 2.0. In 2016, the 21st Century Cures Act was spearheaded by House Energy and Commerce Committee Members Upton (R-MI) and DeGette (D-CO), and was signed into law. Cures 2.0 seeks to build upon the 2016 law and is focused on expanding opportunities for innovative healthcare products and services to come to market and receive coverage under public insurance programs. While it's unlikely that the entirety of Cures 2.0 will advance in 2022, various policies within Cures 2.0 could be pulled out and attached to the UFAs, given the related nature of the policies. Various sections of Cures 2.0 that enjoy strong bipartisan support also could be considered on their own during the 2022 legislative session. One such section is the president's signature policy, the Advanced Research Projects Agency for Health or ARPA-

H, which would fund especially innovative medical research, similar to how the Defense Advanced Research Projects Agency funds novel research through the US Department of Defense.

VALUE-BASED CARE

In 2021, the Biden Administration released its long-awaited [strategy refresh](#) for the CMS Innovation Center. The new vision for delivery model reform focuses on ensuring that all Medicare and the vast majority of Medicaid beneficiaries are in an accountable care relationship by 2030. The strategy also focuses on advancing health equity, investing in innovative care delivery strategies, addressing healthcare affordability and fostering partnerships to achieve delivery system transformation. Notably absent from the strategy document is a focus on specialty care models or financial risk, both of which have been central to previous Innovation Center strategic approaches. In 2022, stakeholders anticipate another cohort of the Innovation Center's most advanced accountable care organization offering, the Direct Contracting model. However, recent pushback from House Democrats could mean that changes to the model are on the horizon. We also anticipate learning more about the Administration's intent to use model design to address health equity and whether any new models will be announced. While early signals from the Administration focused on mandatory models, the rhetoric around the concept has faded as the pandemic has surged. Early this year, we expect to learn more about the Biden Administration's approach to Medicare Advantage, including policy around risk adjustment, quality and health equity. Lastly, in 2022, the Medicare Access and CHIP Reauthorization Act bonuses for participation in an advanced Alternative Payment Model expire. Extension of the bonus payments could be on the



table as other physician payment issues are addressed this year.

HEALTH EQUITY

One of President Biden's first actions when he took office was signing an executive order on "[Advancing Racial Equity and Support for Underserved Communities Through the Federal Government](#)" on January 20, 2021. This order 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 and throughout the Biden Administration assess their impact on equity. Health equity is also a priority for Democrats in Congress. In October 2021, the House Ways and Means Committee Democratic staff released a [report](#) examining role of race in clinical algorithms and exploring potential strategies to address inequities in clinical decision support tools that may lead to disparities in patient outcomes. Expect this committee to continue to explore these issues as well as the maternal health priorities long championed by Committee Democrats.

Vice President Harris also is focused on maternal health. In December 2021, the vice president announced a new call to action to reduce maternal morbidity, including through the creation of a new quality designation for hospitals for maternal health services. CMS plans to propose the establishment of a "birthing-friendly" hospital designation, which would be the first-ever hospital quality designation by HHS specifically focused on maternity care. This designation would be awarded to hospitals that participate in a collaborative program aimed at improving maternal outcomes and implement patient safety

practices. CMS would add the designation to its "Care Compare" website to allow consumers to choose hospitals that have implemented best practices.

OTHER PRIORITIES

Beyond our top 10, dozens of other important health policy priorities will receive attention and make progress in 2022. For example, look for potential action on post-acute care reimbursement. In 2014, Congress passed the Improving Medicare Post-Acute Care Transformation (IMPACT) Act to start a process to consolidate the different payment systems for skilled nursing facilities, long-term care hospitals, inpatient rehabilitation facilities and home health agencies into one unified post-acute care payment system. Since that time, CMS and the Medicare Payment Advisory Commission have been working to develop prototypes of a unified payment system that would span the four post-acute care settings. CMS is expected to release its prototype sometime in 2022, and that may prompt legislative action.

The ongoing COVID-19 pandemic has accelerated and exacerbated healthcare workforce shortages. Legislative initiatives in 2021 to alleviate these workforce issues included several bills, many of which were bipartisan, related to increasing Medicare-supported graduate medical education slots. The Protecting the Right to Organize (PRO) Act also has implications related to the healthcare workforce. The PRO Act is a comprehensive bill to expand various labor protections related to employees' rights to organize and collectively bargain in the workplace, and is a priority for congressional Democrats and the White House. The House passed its version of the PRO Act (HR 842) largely along party lines in March 2021, but the bill has not advanced in the closely divided Senate given the lack of support among



Republicans and the 60-vote threshold necessary to avoid a filibuster. As a result, Democrats included key provisions of the PRO Act in the BBB package, including the authorization of civil monetary penalties for employers that commit unfair labor practices related to collective bargaining and workers' rights to form a union. BBB also includes a number of provisions to address ongoing healthcare workforce shortage issues, including funding for the creation new graduate medical education residency training programs and the expansion of existing programs, scholarship and loan repayment efforts through the National Health Service Corps and Nursing Corps, a new Health Professions Opportunity Grant program, and incentives for physicians to practice in rural and underserved communities. While the fate of BBB remains uncertain, these aspects of the bill may advance independently, and key healthcare committees in the House and Senate may take additional steps to address healthcare workforce shortages in 2022.

Abortion politics also will color 2022. Last year saw some of the most restrictive state-level abortion policies yet and set the stage for an impending decision on the constitutionality of these laws by the Supreme Court later this year. That forthcoming decision could fundamentally alter the abortion landscape nationwide and influence congressional policy in the process.

In sum, we expect another significant year for health care policy. Of course, action on these items will be colored by the mid-term congressional elections, and the politicking around the elections may push policymakers to identify additional policy opportunities. Depending on the outcome of the elections, health care stakeholders may face significant changes in many of the priorities outlined above, making this a potentially volatile year.

McDermott+Consulting LLC is an affiliate of the law firm of McDermott Will & Emery LLP. McDermott+Consulting LLC does not provide legal advice or services and communications between McDermott+Consulting LLC and our clients are not protected by the attorney client relationship, including attorney-client privilege. The MCDERMOTT trademark and other trademarks containing the MCDERMOTT name are the property of McDermott Will & Emery LLP and are used under license.