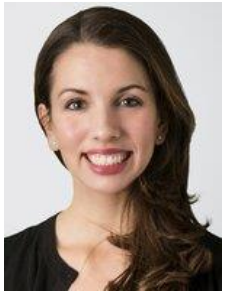
Health Care Policy Priorities To Watch In 2022

By **Miranda Franco and Robert Bradner** (January 11, 2022)



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As Congress reconvenes, it faces a packed agenda in a legislative year that will be shortened by the upcoming midterm elections and remains buffeted by the persistent coronavirus pandemic.

The list of health care priorities is notably lengthy, and how much of this crowded agenda will move forward this year through the Build Back Better Act, or BBBA, or other means remains to be seen. The following is our perspective on what to watch as we begin 2022.

The Fate of the Build Back Better Act

At the forefront of the agenda is the stalled BBBA, which contains several ambitious health care initiatives and a wide assortment of other less transformative health care funding and policy changes. As of this writing, there has been no progress in reaching an agreement on a bill that would gain the support of Sen. Joe Manchin, D-W.Va. Negotiations are being described as paused.

President Joe Biden and congressional Democrats are expected to continue their efforts to reach an agreement on a scaled-down bill that might contain child care funding, universal pre-K, more generous Affordable Care Act tax credits and public health infrastructure, while leaving out other big-ticket items such as Medicare coverage for hearing and adult Medicaid coverage in nonexpansion states. It remains to be seen whether this effort will be successful or if negotiations will falter and lose momentum.

Budget and Appropriations Outlook

In addition to the BBBA, there are other carryover items from 2021 and expiring provisions of law that need to be addressed. At the top of the list are the fiscal year 2022 appropriations bills.

The government is currently funded on a short-term basis through Feb. 18. Democrats and Republicans have been at a standoff over conflicting policy and funding priorities since the new fiscal year began on Oct. 1, 2021.

Democrats would like to secure significant increases for domestic priorities, but Republicans insist on equal treatment for defense funding and no changes in certain long-standing policy riders, such as the Hyde Amendment.

Ultimately, both sides have reasons to cooperate on resolving the appropriations standoff, hopefully in February. If so, significant funding increases for many health care programs — such as the National Institutes of Health, substance abuse programs, and public health and workforce investments — can be expected.

Meanwhile, Biden will need to put forward a proposed budget for FY 2023, followed by the U.S. House of Representatives and then the U.S. Senate adopting a budget resolution. The House would then turn its attention to annual funding bills for FY 2023, with a goal of

passing them all before the August recess.

However, getting those bills through the Senate will be a challenge, and experience suggests that they are unlikely to get done before Election Day. If so, and if control of either the House or Senate changes hands, the bills are likely to be further delayed into 2023. Any community projects (congressionally directed spending — i.e., earmarks) could be at risk under such a scenario.

The other funding bill that may materialize is an FY 2022 emergency supplemental funding bill that would likely include additional pandemic response funds and natural disaster relief funding. The measure to fund the federal government beyond the expiration of the continuing resolution on Feb. 18 could serve as a vehicle for these additional resources.

2022 Health Priorities — Top 10 Items to Watch

Outside of the health care arena, Congress will undoubtedly work on a number of items that could be supported in a bipartisan fashion, such as the National Defense Authorization Act and passage of a Water Resources Development Act.

But much remains undone in the health care space, and there will not be time for everything. Below are the top 10 health policy priorities to keep your eyes on in the coming year.

1. COVID-19 Public Health Emergency and Telehealth

As the pandemic wears on, the health care industry has found itself in an unprecedented state of flux. The U.S. Department of Health and Human Services extended the federal public health emergency through Jan. 13, and various states have their public health emergencies with differing end dates. By law, the federal public health emergency cannot be extended for more than 90 days at a time.

It is expected that an additional 90-day renewal will be announced soon, with an expectation for further extensions until at least mid-2022.

The public health emergency declaration gives HHS the authority to provide blanket waivers and Section 1135 waivers relating to otherwise applicable requirements under Medicare, Medicaid, the Health Insurance Portability and Accountability Act, Physician Self-Referral, and other laws. During the PHE, providers have entered into arrangements and set up care delivery systems that depend on these flexibilities.

The waivers for telehealth services are of particular interest, which has helped enable a significant increase in the volume of these services being provided during the pandemic.

Among the key flexibilities, telehealth services may be furnished via telephone if the device has audio and video capabilities. Audio-only communications are allowed for certain evaluation and management visits. Geographic restrictions that barred services to patients in nonrural and nonhealth professional shortage areas are no longer in effect, and patients are allowed to receive services in their homes or other nonclinical locations.

Similarly, providers may furnish services from their homes, whereas previously they would need to be in an office setting. Additionally, state licensure requirements for professionals enrolled in Medicare with an equivalent license from another state have been waived. States can similarly waive licensing requirements with respect to Medicaid.

When the public health emergency ends, the authority for these waivers will expire. However, there is bipartisan congressional support to extend these flexibilities, at least temporarily. There are also numerous introduced bills seeking more enduring extensions. Accordingly, Congress may enact a series of short-term extensions while it gathers data to address concerns about quality, effectiveness, cost and fraud.

2. Provider Relief Fund

Congress appropriated a total of $178 billion to HHS to distribute to health care providers who incurred COVID-19-related response costs and economic losses. After several distributions during the Trump administration, the Biden administration is now making its first allocation — the so-called Phase IV funding — under a formula that provides greater relief to small providers and those with high Medicaid caseloads.

As of this writing, there are approximately $20 billion to $26 billion of unallocated funds in the Provider Relief Fund. Given the uptick in hospitalizations due to the omicron variant and related cancellation of elective services, there will be a push to expedite the release of remaining funds — less those set aside of uninsured claims — and perhaps provide additional resources a supplemental appropriation.

However, this legislative discussion will have to navigate a split narrative consisting of some providers perceived to have weathered the pandemic fairly well and received significant assistance, and others still experiencing severe economic stress.

3. Health Equity and Improving Data Collection

Equity in health outcomes continues to be a top priority for the Biden administration and Congress, driven in part by overwhelming evidence of how the pandemic has disproportionately affected historically marginalized and low-income groups.

Further, concerns remain regarding the incompleteness of racial and ethnic data for COVID-19 cases, and few states are reporting broader demographic data such as sexual orientation or gender identity. There is a continued push for comprehensive data, including data on social needs critical to understanding disparities and informing planning and decision-making.

Regarding legislation, several bills addressing health equity are under consideration in Congress. The BBBA presently carries a package of related proposals to address maternal mortality and morbidity.

Known as the Momnibus, these bills promote outreach and culturally competent services, greater diversity in the maternal and child workforce, and grants to improve maternal health and reduce maternal mortality, especially among groups who are the most severely affected by adverse outcomes before, during and after the delivery of a child.

If enacted, these changes would complement Medicaid reforms that would replace the American Rescue Plan state option to create a 12-month postpartum coverage period with a 12-month postpartum coverage requirement. These policies would be a high priority for Congress to pass in the event that the BBBA does not end up carrying them.

Deferred care has also underscored the impact of health disparities, and Congress is pushing stakeholders to develop targeted data analytics to potentially mitigate these

impacts.

As noted above, further efforts to address health equity will require the integration of data on social determinants of health in electronic health records. Modernizing and enhancing public health data collection and sharing, while protecting individual privacy, will likely be another continued focus in 2022 as we await major rules on data sharing and removing barriers to care coordination.

Also, the Center for Medicare and Medicaid Innovation, or CMMI, a branch of the Centers for Medicare & Medicaid Services charged with creating new alternative payment models, continues to make more equitable health outcomes a central pillar of its new strategies. CMMI has a great interest in models that can identify at-risk beneficiaries and provide targeted outreach and interventions.

4. Surprise-Billing Implementation

HHS released a controversial new rule implementing the No Surprises Act dictating that the median contracted in-network rate, known as the qualifying payment amount, in a geographic area would be presumed to be the correct payment rate for an out-of-network provider absent credible evidence demonstrating that the correct rate is materially different from the qualifying payment amount.

Several major provider organizations, including the American Medical Association and American Hospital Association, have sued over the HHS interpretation, arguing that other clinical and market factors included in the original legislation should be considered.

The No Surprises Act went into effect on Jan. 1, 2022. It is expected that some providers and insurers may begin to trigger the negotiation and independent dispute resolution process set out in the law. Meanwhile, many others are waiting to see how the issue plays out in the courts and whether requested injunctions are granted.

5. Medicare Payment Reductions

Last month, Congress passed a bill that mitigated looming cuts that collectively threatened to reduce Medicare Part B payments for many providers by nearly 10%. The cuts included a reduction to the Medicare Physician Conversion Factor due to 2021 coding changes, resuming the 2% Medicare sequester cuts, and 4% in cuts under so-called PAYGO rules to offset 2021 congressional spending.

Specifically, the legislation provided a 3% increase in all Part B payments, postponed PAYGO cuts for one year, and provided partial sequester relief (no sequester in the first quarter of 2022, a 1% reduction for the second quarter and a return to the prepandemic 2% sequestration level for the balance of the year).

This was the second consecutive year that Congress had to act to stave off major payment cuts for physicians and other providers, and further relief will be necessary to avoid cuts in 2023. Interest is growing in finding a more permanent solution to the problem.

Potential solutions include tying the Medicare update factor to the medical economic index or some other inflation measure, revisiting the budget-neutral nature of the Medicare Physician Fee Schedule so that adding new billable codes doesn't trigger across-the-board reductions, or simply replacing the current 0% update factor with a small positive update.

Expect to likely see a Senate Finance Committee hearing on this topic in 2022.

6. Public Health Legislation

Only a short time after the onset of COVID-19 in February/March 2020, discussions began on Capitol Hill regarding how to shore up the nation's public health system to more effectively respond to future pandemics.

These discussions have involved topics such as more stable and permanent funding for public health infrastructure and how to ensure a more nimble response to future public health threats.

Significant funding has been poured into federal, state and local public health agencies as part of the various COVID-19 relief bills passed by Congress. This includes substantial funds for public health data modernization efforts.

Several bills have been introduced in the Senate for consideration by the Senate Health, Education, Labor and Pensions Committee on a wide range of topics, including proposals to create a commission on the COVID-19 pandemic, incentivizing domestic manufacturing capacity to prevent future supply chain issues, and laying out manufacturing policies that would create systems to ensure supply of generic medicines and active pharmaceutical ingredients chronically in shortage.

In addition, given the uncertainty around the BBBA, which includes funding and provisions to shore up public health infrastructure, this public health package could serve as a vehicle for those provisions should they drop out of the reconciliation measure.

7. Cures 2.0

In November, Reps. Diana DeGette, D-Colo., and Fred Upton, R-Mich., introduced the highly anticipated Cures 2.0 Act. Among other things, this bipartisan bill contains provisions to accelerate medical research, increase patient access to novel therapeutics, remove current barriers to telehealth services, and codify a modified version of a recent rulemaking that would accelerate Medicare coverage of breakthrough devices.

This bill would also create a semi-autonomous Advanced Research Projects Agency for Health agency within NIH to generate cutting-edge research across numerous fields and agencies. The sponsors of the bill requested input and redlined edits on the proposal until Dec. 31, 2021.

Additional discussions with stakeholders are expected to take place in 2022. Although it is popular among House members committed to biomedical research and its sponsors are pressing for passage, the bill has an uncertain future given the lack of a corresponding Senate bill. Some or all of the bill could be considered as part of the user fee amendment reauthorization process.

8. Drug Pricing and User Fee Agreements

Drug pricing reform continues to be a hotly debated topic. Democrats find it difficult to agree on the scope of provisions. If a narrower BBBA prevails, there is the potential for the inclusion of several drug pricing provisions, such as restructuring of the Part D benefit and a new cap on monthly insulin out-of-pocket expenses. If the BBBA does not advance, these provisions could move in other legislation or possibly on their own.

For now, it looks like more comprehensive approaches, such as allowing Medicare to negotiate drug prices or overhauling pharmacy benefit manager rebates, appear to be out of reach. Approaches to provide for value-based payments for innovative drugs also seem unlikely.

Additionally, CMS recently canceled a Trump-era model that tied domestic drug payments to international pricing. Despite HHS objections, drug manufacturers also continue to limit the number of contract pharmacies they will provide discounts to under Medicare's 340B program. Expect this issue to continue to play out in the courts as well as in Congress.

In addition, legislation implementing user fee agreements for most medical products — including prescription drugs, generic drugs, medical devices and biosimilars — must be reauthorized prior to their expiration on Oct. 1.

Without this reauthorization, medical product review divisions cannot collect user fees attached to new product applications, significantly reducing funding for these divisions and preventing or considerably delaying approvals on new products.

Seen as a must-pass piece of legislation, other health care provisions in the biomedical research and health technology spaces, among others, may be joined into the final package before passage. This is seen as a potential vehicle for certain provisions of Cures 2.0 should the stand-alone bill not be approved.

9. Graduate Medical Education and the Physician Workforce

Health systems across the country face severe staffing shortages exacerbated by the omicron wave. Recently, HHS finalized a rule that will add 1,000 new Medicare-funded graduate medical education positions — capped at 200 new positions per fiscal year — to be distributed beginning in FY 2023, with priority given to hospitals in four categories, including those located in rural and underserved areas.

These new slots were included in last year's Consolidated Appropriations Act. The BBBA bill pending in the Senate would allow another 4,000 Medicare graduate medical education slots to be funded.

Another 1,000 slots would eventually be added under a career pathway program that finances medical education for individuals from populations underrepresented in the physician workforce. The new GME slots have not been a subject of controversy in the BBBA negotiations, but if the bill does not materialize, it could be difficult for them to find another way to the president's desk.

10. Market Consolidation

Vertical and horizontal consolidation in numerous segments of the health care industry continues to draw federal attention. This trend includes market participants diversifying into different niches — for example, insurers acquiring physician practices and other providers or pharmacy benefit managers acquiring pharmacies and drug manufacturers.

The Biden administration has made clear it intends to aggressively police industry consolidation by stopping proposed mergers that would hurt competition. So far, the administration has increased budgets for the Federal Trade Commission and U.S. Department of Justice, adjusted standards for future mergers and barred noncompete

clauses, and is taking a closer look at past mergers.

This trend toward tighter scrutiny is expected to continue. The Medicare Payment Assessment Commission, an advisory commission to Congress, is also taking a close look at industry consolidation and its role in driving up prices for health care services and products.

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