for the entire health care ecosystem

# Health Policy Topics to Watch in 2022

The legislative, regulatory, and judicial outlook for health policy in 2022

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The Biden administration's first year in office was unsurprisingly dominated by the Covid-19 pandemic. While Democrats in Congress were able to pass part one of President Biden's infrastructure package, other health care priorities were largely sidelined. As we look to 2022, there are 10 key health care topics that are ripe for congressional or regulatory action. If and how Congress and the Biden administration move on those actions will have strategic implications for industry executives across the health care ecosystem.





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### The health policy landscape

January 20th marks the conclusion of President Biden's first year in office. As expected, the Biden administration's first year was dominated by the Covid-19 pandemic, but key agencies and Congress laid the groundwork for deeper health policy shifts in 2022. Advisory Board outlines the top 10 policies health care industry executives should watch in 2022.



# O 1 Covid-19 relief and waiver flexibilities

In 2021, the health care industry continued to benefit from federal funding related to the Covid-19 pandemic. While there appears to be early appetite within Congress for an additional Covid-19 relief package, any new Covid-19 relief package would need to be bipartisan. This means any potential bill is likely to be narrowly designed with funding priority given to public health, schools, and certain businesses. As part of those negotiations, Congress is likely to face pressure to supplement the Provider Relief Fund and rural funds, which the Health Resources and Services Administration will continue to distribute in 2022.

At the administrative level, federal agencies are expected to continue revising policies as the Covid-19 pandemic evolves throughout 2022. Key policies to watch include those to address supply chain shortages, as well as payment policies for Covid-19 vaccines, therapies, and diagnostic tests.

#### The future of the Public Health Emergency

On January 14th, HHS Secretary Xavier Becerra renewed the Public Health Emergency (PHE) and related waivers for an additional 90 days. Throughout the pandemic, health officials have authorized flexibilities related to telehealth coverage, post-acute care, enhanced federal Medicaid reimbursement, and more. Without action from Congress, those waivers will end when the PHE lapses. As such, the Biden administration has promised to provide at least 60 days' notice before letting the PHE expire. While lawmakers have introduced several measures that would make certain telehealth flexibilities permanent, Congress has yet to take legislative action. If the PHE were to expire in 2022, there will be additional pressure on Congress to put in place short-term or permanent solutions.

The end of the PHE also could trigger a shift in the coverage landscape, as state Medicaid programs will be able to resume redeterminations. This could lead to an enrollment bump for the Affordable Care Act's exchanges, as many Medicaid beneficiaries may newly qualify for the ARP's enhanced exchange subsidies, which are currently scheduled to end in 2022.



# O2 Build Back Better

Progress on President Biden's human infrastructure bill, called the Build Back Better (BBB) Act, stalled in 2021 after Sen. Joe Manchin (D-W. Va.) said he would not vote for the existing version of the bill. The wide-ranging package contains several health care initiatives, including extending the American Rescue Plan's (ARP) exchange plan subsidy increases, adding new Medicare benefits, expanding Medicaid coverage in non-expansion states, prescription drug pricing reforms, new investments in home and community-based services, policies to improve equity and strengthen mental health parity, and provisions to bolster the provider workforce.

While Manchin's opposition appears to have killed the current version of BBB, it is possible Democratic leadership will pursue a scaled-down version ahead of Biden's State of the Union address March 1. This means policies that Manchin has raised concerns about, such new Medicare benefits and Medicaid expansion, could be left out. Other policies where Democratic lawmakers have struggled to reach an agreement also could be sidelined or scaled back, such as giving Medicare negotiating authority over prescription drug prices (more on that to come). It's also important to remember any new version of BBB would need to be re-approved by the House.

If a revised BBB leaves out any health policies or Congress ultimately fails to pass a new version, lawmakers also could seek to incorporate individual policies into other legislative packages. For example, the ARPs enhanced exchange subsidies are set to end in 2022, and if Congress does not act to extend that funding as part of BBB, lawmakers likely will face pressure to do so by the end of the year.



### O3 Drug pricing reforms

Drug pricing reform continues to be a popular topic among both policymakers and voters. The BBB package contains several drug-pricing provisions that could be included in a revised package, including redesigning the Medicare Part D benefit and capping monthly out-of-pocket costs related to insulin. However, more ambitious policies, such as giving Medicare the authority to negotiate certain drug prices, face an uphill battle and could be significantly scaled back if they are included at all.

On the regulatory side, CMS in 2021 canceled the Trump-era Most Favored Nations policy that would have tied domestic drug payments to international prices. While it's unclear if similar policies are on the horizon for 2022, updates to the 340B program, such as a new dispute resolution process, are expected to come early in the year.

Legal challenges to the 340B program also will continue to play out in 2022. In 2021, several pharmaceutical manufacturers filed lawsuits challenging the way the program views contract pharmacy arrangements. In a separate case brought by the American Hospital Association, the Supreme Court is considering whether to uphold a 2018 policy that cut reimbursements under the program by nearly 30%.

Health care executives should play close attention to legal decisions in these cases as they could prompt additional regulatory or legislative action.



## Shoring up the physician workforce

One of the most pressing issues for the health care industry in 2022 is addressing the provider staffing crisis. Workforce burnout is a long-standing challenge for hospitals and health systems. But when Covid-19 emerged, the challenge magnified as the health care workforce simultaneously managed their own health concerns, added work, and emotional stress presented by the pandemic.

Among its many provisions, the current version of BBB would fund an additional 4,000 Medicare graduate medical education (GME) slots. The Medicare program funds a portion of the cost to train medical residents incurred by teaching hospitals through both direct GME and indirect medical education (IME). Medicare imposes resident caps that limit the number of residents hospitals can count when calculating GME and IME payments.

The BBB provision builds on the 2021 Consolidated Appropriations Act, which added 1,000 new Medicare GME slots. Provisions targeting the provider workforce have generally been uncontroversial, but lawmakers would need to find a new vehicle for the residency slot funding if they do not reach a final deal on BBB.

### 4,000 slots

If passed, the Build Back Better package would fund another 4,000 Medicare-funded GME residency slots with specific criteria for how the slots would be allocated to hospitals.

### 1,000 slots

Congress in 2021 passed the Consolidated Appropriations Act, which funded an additional 1,000 GME residency positions. This marked the first meaningful increase in Medicare-funded GME positions in over a decade.



# Surprise billing and price transparency

#### Surprise billing

Throughout 2021, the Biden administration issued rules implementing the No Surprises Act, which took effect Jan. 1. But by New Year's Day, the administration faced four lawsuits challenging various aspects of the rules and seeking to change how arbiters approach the new dispute-resolution process for out-of-network payments. The outcome of those lawsuits will be closely watched, as they could trigger additional regulatory or legislative changes to the process. Additional rulemaking around implementing the No Surprises Act is also expected in 2022, since CMS missed several key rulemaking deadlines in 2021 and sought more time to clarify areas of overlap between price transparency requirements in the No Surprises Act and separate price transparency rules impacting hospitals and insurers.

### **Price transparency**

Industry executives also should be mindful of CMS' hospital and transparency in coverage rules. As of Jan. 1, many hospitals face higher penalties for not complying with CMS' hospital price transparency rule. And while CMS has not yet issued penalties for noncompliance, the agency in 2021 did begin sending out warning letters and it's possible we could see the first fines this year. Payers also face a July 1 deadline for disclosing their pricing data—a potential watershed moment that could indicate whether the regulations will spur meaningful change.



## Medicare cuts and physician pay

In December 2021, Congress passed a bill that mitigated a trifecta of cuts that threatened to reduce Medicare Part B payments for many physicians by nearly 10%. The bill increased Medicare payments under the physician fee schedule by 3%, mitigating most of a scheduled 3.75% rate cut. It also postponed a 4% PAYGO cut for one year and partially delayed a 2% sequester cut. Without additional congressional action, the sequester cut will be phased back in throughout 2022. The table below shows the current landscape for physician payment cuts in 2022.

Type of cut	<b>Phase 1</b> Q1 2022	<b>Phase 2</b> Q2 2022	<b>Phase 3</b> Q3-4 2022
Medicare Physician Conversion Factor	.75%	.75%	.75%
Medicare Sequestration	0%	1%	2%
PAYGO Sequestration	0%	0%	0%
Total cut	.75%	1.75%	2.75%

The December bill, marked the second consecutive year Congress had to step in to alleviate major payment reductions to providers, and additional action will be required to avoid cuts in 2023. While Congress could pass another one-time payment bump, health system and physician group leaders should expect to hear more debate in 2022 on broader reforms to mitigate this issue and be prepared to weigh in on potential changes.



# O7 Cures 2.0 and FDA user fee agreements

Last year, House lawmakers unveiled a bipartisan bill deemed Cures 2.0, which is designed to build upon the 21st Century Cures Act passed in 2016. The legislative package includes provisions to increase diversity in clinical trials, permanently remove Medicare's geographic and originating site restrictions, create new pathways for innovative technology to be covered by CMS programs, and more.

While policy analysts believe the entire package is unlikely to make it through Congress in 2022, at least some policies, such as funding for Biden's Advanced Research Projects Agency for Health (ARPA-H), could be included in legislation to reauthorize FDA user fees. Congress must pass the user fee agreements before the current bill expires on Oct. 1.

**ARPA-H,** allocates more than \$6.5 billion for the new research agency

 $Innovative\ Technology\ Coverage,$ 

codify a Medicare Coverage of Innovative Technology (MCIT) pathway

Clinical trials, increase diversity in clinical trials, collect patient experience data, additional Medicare funding

Cures 2.0 details

Part D E-Prescribing Standards, directs agencies to establish a Generally Accepted Standard for Electronic Prescribing

**Telehealth,** permanently removes Medicare's geographic and originating site restrictions

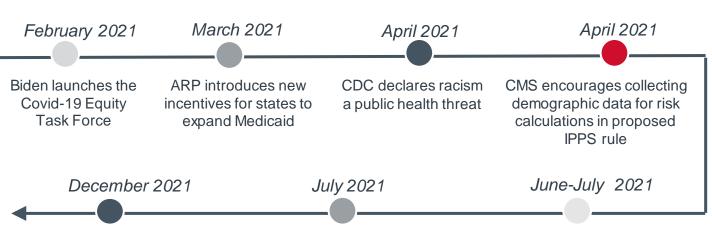
Clinician led data registries, creates a database to provide timely and broad access to claims data for clinician led data registries



## **S** Equity in health care

The Biden administration has made equity a top health care priority, and efforts to improve equity will continue at both the legislative and regulatory levels in 2022. In Congress, lawmakers have introduced several bills to improve health equity, including provisions of the stalled BBB that seek to address inequities in maternity care and coverage. Congress likely will seek to advance these policies even if they are not included in a revised version of BBB that is passed by Congress.

As the image below shows, the Biden administration was busy laying the regulatory groundwork for equity in 2021, and those efforts are expected to continue in 2022. Similarly, the Center for Medicare and Medicaid Innovation (CMMI) is expected to place a greater emphasis on equity as it examines new and existing value-based payment models, and the Biden administration is likely to issue new rules to improve data-sharing and care coordination.



Vice President Harris issues call to improve maternal health and equity CMS proposes adjusted benchmarks and a Health Equity Incentive for the ESRD Treatment Choices Model CMS requests information on incorporating equity measures into provider quality reporting programs



## O Value-based payment

In 2021, the Biden administration unveiled its strategy for CMMI and the future of value-based payment models. CMMI's new strategy aims to have all Medicare and most Medicaid beneficiaries in accountable care arrangements by 2030. CMMI hopes to re-examine and streamline the overall number of alternative payment models it oversees and incorporate equity into existing and future models.

In 2022, health care leaders should expect to learn more about potential new payment models, find out next steps for the Oncology Care Model (which is set to end in 2022), and see applications for a new cohort of the currently paused Direct Contracting (DC) model. While CMMI could make changes to the DC model, recent pushback from House Democrats suggests legislative changes also may be looming.



Moving forward, we are committed to create a more cohesive articulation of how all the models fit together. ... We need to set benchmarks in the future that balance encouraging participation while sustainably generating savings.

Liz Fowler, Director
CMS' Center for Medicare and Medicaid Innovation



## 1 Market consolidation

The Biden administration has made health care industry consolidation a regulatory priority. In 2021, Biden issued an executive order that suggests the administration will be taking a closer look health care mergers and acquisitions. Both the Department of Justice and Federal Trade Commission (FTC) are committed to reexamining their M&A guidelines. In line with that order, the FTC rescinded a 1995 policy statement that effectively restored pre-approval requirements for health care mergers.

As we look ahead to 2022, questions loom over how the Biden administration will approach M&A activity in the health care space and potential updates to antitrust policy.

Legislative action on antitrust laws and health care M&A activity is not expected in 2022.



While we're still awaiting the potential updates to M&A guidelines, health care leaders in 2022 should expect a higher bar for proving the value of their proposed mergers and acquisitions—and that cost structure alone is unlikely to be sufficient going forward.



### Parting thoughts

The outlook for health policy in 2022 could move in multiple directions and industry executives should take note of shifts that impact their strategic plans. And remember, legislative priorities not tackled early in 2022 are likely to be impacted by the midterm congressional elections in November.

In addition to our top 10health policies to watch, Congress and the Biden administration are likely to focus their attention on several other health care issues in 2022.

- Multiple Senate committees have signaled a desire to explore policies to improve mental and behavioral health care delivery, strengthen the 2008 mental health parity law, and fund grants to support the mental and behavioral health workforce.
- Congress in 2022 will need to address federal funding for fiscal year 2022.
   Currently, the federal government is funded by a continuing resolution set to expire on February 18. Democrats and Republicans so far have failed to reach agreements on how to balance domestic and defense funding increases, suggesting lawmakers could still be dealing with FY 2022 funding when they begin work on FY 2023 appropriations measures later in the year. These delays could have implications for health system and community health care projects funded via congressional earmarks.
- Health care industry executives should also pay close attention to policies
  enacted closer to home. State-level policies dictate licensing for most health
  professionals, health plan certification, public health measures to mitigate the
  spread of Covid-19, and more. The landscape on these issues varies across
  the country.



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