



Policy Brief

January 7, 2022



Happy New Year: Health Policy Highlights from 2021

In 2021, the United States continued its battle against COVID-19, underscoring the importance of health policy to lawmakers. Health care stayed top of mind for policymakers as well; the Department of Health and Human Services (HHS) issued numerous regulations on a range of health care topics, with surprise billing, health equity and telehealth at the top of the list. Keep reading for a round-up of the most heavily discussed health policy issues of 2021.

Stopping surprise medical bills was a major theme last year...

[Unexpected medical bills](#) are costing American families thousands of dollars each year, with [two in three](#) adults citing surprise bills as a major financial concern. In 2021, HHS prioritized releasing the regulations required by the No Surprises Act, which Congress passed in late 2020. The Centers for Medicare and Medicaid Services (CMS), along with other federal agencies, released [three interim final rules](#) focused on patient protections from surprise medical bills.

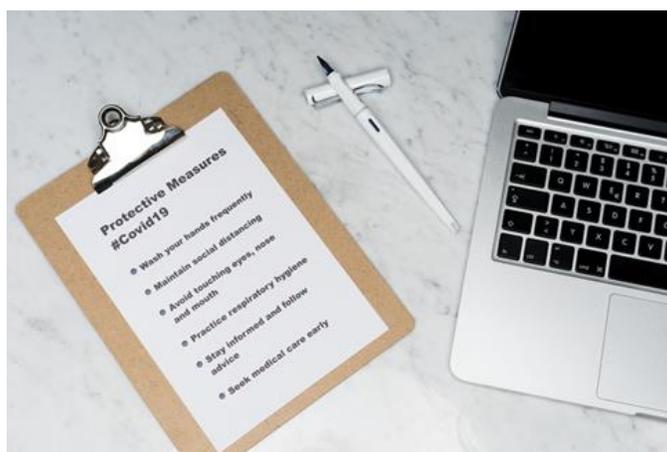
...so was advancing equitable health care for everyone.

In 2021, the Biden Administration made it clear that [health equity](#) would be a priority for HHS. In nearly every payment-related regulation released last year, CMS asked targeted questions to stakeholders on ways to better encourage health equity efforts from providers. The Agency sought information on ways to improve data collection, challenges faced in providing care for traditionally-marginalized communities and the potential use of equity-focused metrics in quality

programs and value-based payment models. The White House has also established a new [health equity taskforce](#) within the Office of Minority Health to support agencies' efforts to identify and eliminate disparities in health outcomes.

But nothing dominated health policy like the COVID-19 pandemic.

Responding to the pandemic and preserving public health were the chief concerns of policymakers in 2021. Throughout the year, federal regulatory changes were made, and [new waivers](#) issued aimed at making it easier for providers to deliver care to patients—especially via telehealth services. The Consolidated Appropriations Act and the American Rescue Plan Act of 2021 expanded funding and reimbursement for telehealth services, allowed Medicare patients to receive behavioral health services in their homes and expanded pediatric behavioral telehealth access. Some of the virtual visit flexibilities will remain after the COVID-19 Public Health Emergency, but others will expire [without congressional action](#).



COVID-19 Status Update: The First Quarter of 2022

Some of the leading public health agencies have released several new guidance as the next wave of COVID-19 swells across the nation. The Centers for Disease Control and Prevention (CDC) has updated their guidance on how to quarantine while infected, as well as on potential exposure protocol. CMS has also released a new timeline for the enforcement of the vaccine mandate; the Supreme Court plans to [begin considering arguments](#) on the legality of mandated employee vaccination today. Below are the latest federal measures on COVID-19.

CDC Guidance

- **Quarantine Update:** The CDC has shortened its [recommended](#) isolation and quarantine period for the public. People with COVID-19 are now recommended to quarantine for five days. If they are asymptomatic or their symptoms are resolved at the end of the five-day period, they are encouraged to wear a mask for an additional five days and minimize interactions with others. The CDC recommends that individuals that have had a potential exposure to COVID-19 and are unvaccinated or six months out from their second mRNA vaccine should also heed the five-day quarantine and additional five-day masking

recommendation. For fully vaccinated and boosted individuals with a potential exposure to COVID-19, the CDC only recommends 10 days of mask-wearing.

- **Vaccine Update:** The CDC has also [recommended](#) that people should prioritize receiving either the Pfizer or Moderna mRNA COVID-19 vaccines over Johnson & Johnson's shot due to rare, but sometimes fatal, cases of blood-clotting.

CMS Guidance

Last week, CMS released [guidance](#) and updated their FAQ for the Omnibus COVID-19 Health Care Staff Vaccination final rule.

- CMS is moving forward with implementation and enforcement where applicable but pushing back the compliance deadlines. Enforcement discretion will be provided to facilities that do not meet the 100% vaccination threshold within the first 90 days since the release of this guidance.
- Facilities will still receive a notice of non-compliance if they are below the 100% threshold but would *not* be subject to enforcement action within the first 90 days.
- This guidance does not apply to the AHPA states of Georgia, Kansas, Kentucky, Ohio and Texas.



2022 Regulatory Agenda

Last month, the Biden Administration released its regulatory agenda, outlining the Administration's health care priorities for 2022. Included in the agenda were [regulatory plans](#) for HHS on major health care issues, including telehealth, behavioral health and provisions implementing the 21st Century Cures Act. In 2022, HHS will also be issuing several rules, including implementing a 340B dispute resolution process and allowing the OIG to impose civil monetary penalties for information blocking. Overall, the issues on the regulatory agenda have been consistent with the Biden Administration's previous priorities and direction. Below is more insight into key health care issues the Biden Administration plans to tackle in 2022. Please visit the [HHS agenda](#) for additional changes.

COVID-19

HHS plans to build on previous vaccination requirements by issuing a final rule that will provide the CDC with the authority to require individuals to show proof of vaccination at any port of entry.

Health Equity

HHS is planning on issuing a rule that will implement a provision from the [No Surprises Act](#) ensuring that insurance plans do not engage in unlawful discrimination against health care providers. HHS also plans to expand [Title X family planning funds](#) and issue more rules regarding accessing the [Catastrophic Health Emergency Fund](#) for Indian Health Services (IHS). Additional rules are planned to limit menthol cigarettes and regulate what can be labeled as healthy, as these issues disproportionately impact underserved communities.

Access to Drugs

Through the FDA, the Administration is planning to release rules called the *Nonprescription Drug Product with an Additional Condition for Nonprescription Use* and *Biologics Regulation Modernization*. These policies will be aimed at establishing requirements for a drug being marketed as non-prescription and for biosimilar and interchangeable biological drugs.

340B Drug Discount Program

The Biden Administration will issue a rule to establish new requirements and procedures for the Program's Administrative Dispute Resolution (ADR) process, aimed at making the process more equitable and accessible. This upcoming rule is intended to replace the previous administration's rule that was finalized in December 2020.

Behavioral Health and Telehealth

HHS plans to extend telehealth flexibilities for opioid programs. The Agency also plans to clarify insurance plans' obligations to prevent the imposition of additional coverage limitations on mental health or substance use disorder benefits. Another rule is planned to update [42 CFR part 2](#) requirements to better align with HIPAA laws.

Information Blocking and Interoperability

HHS plans to issue several rules implementing provisions of the [21st Century Cures Act](#). This includes a rule from the Office of Inspector General (OIG) that allows the agency to impose civil monetary penalties for information blocking. Another rule will also be implementing the Electronic Health Record (EHR) Reporting Program condition and maintenance of certification requirements under the ONC Health IT Certification Program.

Requirements for Rural Emergency Hospitals

CMS is expected to release a proposed rule that creates health and safety requirements for rural emergency hospitals, a new provider type intended to help improve emergency care in rural

areas. A 2020 spending bill created the new designation, which will allow rural hospitals to convert into such facilities.

IPPS: Part 2 Key Takeaways

CMS has released [part 2](#) of the FY 2022 Final Inpatient Rule, finalizing policies impacting Medicare teaching hospitals as well as organ procurement and organ transplants. The rule also finalized and modified several of their proposals for Graduate Medical Education (GME) slots. CMS will allocate 200 GME slots beginning in 2023 and each subsequent year until 1,000 have been [distributed](#).

OSHA Withdraws Occupational Exposure Emergency Temporary Standard (ETS)

The Department of Labor's Occupational Safety and Health Administration (OSHA) announced that it is withdrawing its [June 21, 2021 ETS](#). OSHA [indicated](#) that it will continue to work towards a permanent regulatory solution and encouraged providers to continue implementing the ETS' requirements. OSHA will continue to enforce the general duty clauses, respiratory protections and usage requirements for personal protective equipment. Other reporting requirements, such as the COVID-19 log, will also remain in place.



AHPA Resources

Missed a recent AHPA Webinar?

Visit AHPA's [YouTube channel](#), where members can stream webinars on demand at their convenience.

Below is a directory of the recent regulatory work that AHPA has conducted:

	Initial Summary	AHPA Comment	AHPA Summary
IPPS	X	X	X
OPPS	X	X	X
PFS	X	X	X
Surprise Billing: Part 1	X	X	X
Surprise Billing: Part 2	X	X	X
OSHA ETS		X	
CMS Vaccine Mandate	X		
Behavioral Health RFI		X	X
SDOH RFI		X	

WHAT WE'RE READING...

[10 Key Global Health Moments from 2021](#) – The World Health Organization

[FDA Authorizes COVID Vaccine Boosters for Children 12-15](#) – NBC News

[Build Back Better on Senate Stage](#) – Washington Post

[3 Ways Remote Work Could Remake America](#) – Vox

[Marketplace Enrollment Outpaces Prior Years](#) – Health Affairs