



Federal Issues

Regulatory

Biden Releases National COVID-19 Response Strategy and Executive Orders

Newly inaugurated President Joe Biden wasted no time in his first days to push forward policies to address his number one priority, the COVID-19 public health emergency. He signed executive orders, published a [200-page "National Strategy for the COVID-19 Response and Pandemic Preparedness,"](#) and released a draft COVID-19 legislative proposal. He concurrently signed 10 executive orders aimed at ramping up COVID-19 testing and vaccinations, tightening enforcement of workplace and school safety rules, and increasing federal funding to states.

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The complete list of Executive Orders signed by President Biden:

- Invoking the Defense Production Act (DPA) to increase the supply of all the materials needed to get the vaccines into arms and ramp up testing.
- Directing the Federal Emergency Management Administration (FEMA) to increase federal reimbursement to states and Tribes from 75% to 100% of the cost for National Guard personnel and emergency supplies.
- Creating the COVID-19 Pandemic Testing Board, which will be tasked with expanding testing capacity.
- Directing studies, including large-scale randomized trials, to identify treatments for COVID-19 and to ensure that such studies address the needs of diverse populations, bolstering health care provider capacity, and promoting insurance coverage of COVID-19 treatments and care.
- Tracking and analyzing data from state, local, Tribal, and territorial governments on COVID-19 data and creating a public dashboard with real-time data on cases, testing, vaccinations, and hospital admissions.
- Providing guidance on safe reopening and operation of schools and educational institutions as well as workplace safety.
- Imposing a mask-wearing mandate on airplanes and other forms of interstate transportation.
- Deploying FEMA to set up 100 community vaccination sites in the next 30 days and establishing a federal pharmacy program to make vaccines available in communities.
- Establishing a COVID-19 Health Equity Task Force to ensure an equitable pandemic response and recovery.

Biden Administration Issues Regulatory Freeze

Similar to prior administrations, Ron Klain, President Biden's Chief of Staff, issued a memorandum halting ongoing or recently finalized rulemaking activity in the Trump administration. Except for limited circumstances, any new rulemaking action must be approved by a Biden political appointee or other authorized person designated by the administration. In addition, in general, rules that have not been published yet in the Federal Register are immediately withdrawn.

Why this matters: Rules that are expected to be subject to this withdrawal order include a CMS final rule requiring Medicaid/CHIP and qualified health plans in the federal Exchange to automate prior authorization and build in new data elements and standards to existing application programming interfaces (APIs), as well as two rules posted by the Equal Employment Opportunity Commission amending regulations governing employer wellness programs. Other rules that could be impacted include the point-of-sale drug rebate final rule, the Notice of Benefit and Payment Parameters rule (NBPP), the Medicare Advantage/Part D Rate Notice, and the Medicare Advantage/Part D Policy and Technical rule.

For rules that were published in the Federal Register before President Biden took office, the memorandum directs each agency to consider delaying the effective date for 60 days from January 20 to review questions

of fact, law, and policy. An agency that postpones any rule is directed to consider soliciting public comments for a 30-day period and further delay the rule's effective date as appropriate.

HHS Finalizes Rulemaking on Regulatory Reform through Retrospective Review

The Department of Health and Human Services officially published the final rule, "[Securing Updated and Necessary Statutory Evaluations Timely](#)". The final rule requires HHS to assess its regulations every 10 years to determine whether they are subject to review under the Regulatory Flexibility Act (RFA), which requires regular review of certain significant regulations. Under this regulation, regulations not assessed and (if required) reviewed in a timely manner would expire.

In response to comments, the Department extended the timeframe under which the initial regulations would automatically sunset by an additional three years. The Department also exempted the Notice of Benefit and Payment Parameters and other regulations, like Medicare payment rules, which are updated annually. In addition, the FDA's food standard, device-specific, and over-the counter drug regulations that specify characteristics of certain foods, devices, and over-the counter drugs are exempt.

CMS Releases Part D Payment Modernization (PDM) Model Application for CY 2022

CMS released the Calendar Year (CY) 2022 [Request for Applications \(RFA\)](#) for the Part D Payment Modernization (PDM) Model. CMS is testing the impact of an updated Medicare Part D payment structure focused on the catastrophic phase of the Part D benefit.

For CY 2022, the PDM Model is being updated with the following reforms in light of the changes:

1. **Part D Formulary Flexibilities:** All of the existing, comprehensive Part D formulary checks and enrollee protections other than the protected class requirement and two-drugs per class requirement, including the coverage determination and appeal process and other Part D formulary requirements, will remain in place. In addition, each Part D sponsor that applies to implement the formulary flexibilities will be required to provide an enhanced transition process for enrollees affected by proposed formulary changes for drugs in the protected classes. This transition process must include both proactive outreach to current enrollees and an extended transition supply that provides for multiple temporary fills for new and current enrollees who have not been able to switch to a formulary medication or complete the coverage determination process.
2. **Removal of downside Model risk for CY 2022:** CMS will not apply the current 10% downside Model risk for Part D sponsors participating in the Model in CY 2022. CMS intends to apply 10% downside Model risk in CY 2023 and for the duration of the model thereafter

Interested Part D sponsors should submit a non-binding Notice of Intent (PDF) to apply by March 1, 2021. More information can be found at the [PDM Model webpage](#).

Coronavirus Updates

- The Centers for Disease Control and Prevention (CDC) issued new [guidance](#) on the use of mRNA-COVID-19 vaccines. While the agency still recommends a period of three weeks between the first and second shot of the Pfizer vaccine and four weeks for the Moderna vaccine, second shots can be given up to six weeks (42 days) after the first dose when that's not possible.

- The CDC is [tracking](#) the number of reported cases of COVID-19 caused by virus variants in the U.S.
 - The CDC updated [guidance](#) for expanding screening testing for SARS-CoV-2, though it does not dictate the determination of payment decisions or insurance coverage of such testing, except as may be otherwise referenced (or prescribed) by another entity or federal or state agency.
 - The National Governors Association announced three new bipartisan task forces:
 - Connecticut Gov. Ned Lamont (D) and Tennessee Gov. Bill Lee (R) will co-chair the pandemic and disaster response task force, overseeing FEMA deployments and other emergency public health efforts;
 - South Carolina Gov. Henry McMaster (R) and Kentucky Gov. Andy Beshear (D) will chair another task force on the post-pandemic economic recovery; and
 - A third task force on community renewal will be chaired by U.S. Virgin Islands Gov. Albert Bryan (D) and Missouri Gov. Mike Parson (R).
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CMS Issues Transitional Plan Guidance, Risk Adjustment

On Tuesday, the Centers for Medicare & Medicaid Services (CMS) [announced it will extend the transitional policy](#), which allows people to keep certain pre-Affordable Care Act (ACA) non-grandfathered coverage through January 1, 2023. The agency also posted additional data on the risk adjustment program, Appendices G and H, under the July 17, 2020 report for benefit year (BY) 2019.

HHS Releases Vaccine National Strategic Plan for 2021-2025

Earlier last week, the Department of Health and Human Services (HHS) released the [Vaccines National Strategic Plan 2021-2025](#), a five-year roadmap on the coordination of vaccine development and use in the United States. This roadmap builds on the [2010 National Vaccine Plan](#), two mid-course reviews of the 2010 Plan, and the [2016 National Adult Immunization Plan](#). The Vaccine Plan sets forth a clear vision for how the U.S. will be a place where vaccine-preventable diseases are eliminated through safe and effective vaccination across the lifespan. The five goals of the Vaccine Plan include:

- Foster innovation in vaccine development and related technologies;
 - Maintain the highest possible levels of vaccine safety;
 - Increase knowledge of, and confidence in, routinely recommended vaccines;
 - Increase access to and use of all routinely recommended vaccines; and
 - Protect the health of the nation by supporting global immunization efforts.
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State Issues

Pennsylvania

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New Pennsylvania Secretary of Health Nominated

Gov. Tom Wolf announced that he is nominating Alison Beam, his deputy chief of staff, to succeed outgoing Secretary of Health, Dr. Rachel Levine. Dr. Levine has been nominated by President Joe Biden to be the Assistant Health Secretary. The new Secretary of Health's priority will be the distribution of the COVID-19 vaccines. She assumed the role of acting secretary on January 23, 2021.

Gov. Wolf stated that Beam has helped to coordinate the state's pandemic response through coordinated initiatives with the departments of Health, Human Services, Drug and Alcohol Programs, Aging, and Insurance. He also praised her efforts in helping to roll out, "Pennie," Pennsylvania's health insurance marketplace. Prior to her role as the Governor's deputy chief of staff, she served as chief of staff to Insurance Commissioner Jessica Altman.

The Pennsylvania General Assembly is in session January 25-27.

The Delaware Legislature is in session January 26-28.

The West Virginia Legislature began January 13 and recesses for 30 days. Session runs from February 10 through April 10, 2021.

Congress

The U.S. House is in session January 25-28. The U.S. Senate is in session January 25-29.

Interested in reviewing a copy of a bill(s)? Access the following web sites:

Delaware State Legislation: <http://legis.delaware.gov/>.

Pennsylvania Legislation: www.legis.state.pa.us.

West Virginia Legislation: <http://www.legis.state.wv.us/>

For copies of congressional bills, access the Thomas website – <http://thomas.loc.gov/>.

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