



## Federal Issues

### Legislative

### White House Orders HealthCare.gov Enrollment Reopening, ACA and Medicaid Policy Reversals

The Biden administration issued an [executive order](#) to formally begin the process of reversing many Trump administration-led regulatory changes related to the Medicaid program and the individual, small group, and large group markets.

Heads of agencies are directed to review policies, practices, demonstrations, waivers or other actions that:

- Undermine protections for people with pre-existing conditions;
- Reduce coverage or undermine Medicaid or the ACA;
- Undermine the health insurance Marketplace or individual, small group, or employer markets;
- Create unnecessary barriers to individuals and families attempting to access Medicaid or ACA coverage, including for mid-year enrollment; or

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- Reduce the affordability of coverage or financial assistance, including for dependents.



The executive order directs agencies to consider whether to suspend, revise, or rescind such policies or actions that are inconsistent with the Administration's policy identified above and consider additional actions to strengthen and protect access to care.

#### **Why this matters:**

- Most immediately in terms of agency action, **CMS will reopen HealthCare.gov starting February 15 through May 15 where consumers in states utilizing HealthCare.gov to enroll in coverage in the individual market.** The special enrollment period will be available to all Marketplace-eligible consumers—individuals may newly enroll in coverage and existing enrollees may change to another plan.
- Second, the order rescinded two Trump executive orders which called for affirmative steps to repeal the Affordable Care Act and resulted in three major regulations expanding coverage to alternatives of comprehensive, subsidy-eligible qualified health plans, including short-term plans, association health plans, and health reimbursement arrangements paired with individual market coverage or expected benefits. These regulations will be reexamined and potentially re-proposed in future rulemaking to be rescinded or amended.

**Medicaid:** The Trump administration made changes to the Medicaid program by allowing states to condition eligibility on meeting work requirements, restrict retroactive eligibility, and perform midyear eligibility checks. The Trump administration also tied potential use of public benefits including Medicaid to immigration status adjustments in new ways. All of these changes (and several more) will be reexamined “as soon as practicable” per the executive order.

**Insurers supportive:** AHIP President and CEO Matt Eyles issued a [statement](#) commending the President for taking swift action to create more pathways for Americans to obtain health coverage through a targeted special enrollment period, and eliminating barriers for low-income adults to obtain Medicaid coverage.

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### **Regulatory Freeze Memo Triggers HHS Rule Delays and Withdrawals, including Medicare Part D Drug Rebate Rule**

Following on last week's memorandum from White House Chief of Staff Ron Klain to halt ongoing or recently finalized rulemaking activity in the Trump administration, several proposed rules were withdrawn formally per *Federal Register* notices, while final rules are beginning to be reexamined with at least one significant rule being delayed. Proposed rules withdrawn include those pertaining to Part A-only eligibility and enrollment, Medicare standards for dialysis centers and payment of premiums by affiliates, and hospital accrediting organization conflicts of interest.

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.

**Part D Drug Rebate Rule:** Consistent with this directive, the HHS Office of Inspector General (OIG) delayed provisions in a November 2020 final rule that were slated to take effect on Jan. 29 to March 22. The provisions created new safe harbors allowing Part D plans to pass discounts to members at the point of sale and retain protection under the Anti-kickback Statute. The November 2020 final rule is under a legal challenge, and the action may give time for the agency to initiate rulemaking to further stay the case or render it moot. **The rule was opposed by insurer groups and estimated to lead to increased federal spending and premiums for Part D beneficiaries.**

Final rules on standards for organ procurement organizations and Part D electronic prescribing standards were also delayed.

**The Campaign for Sustainable Rx Pricing (CSRxP)** issued a [statement](#) in reaction to the Administration's action, applauding the Biden Administration's decision to delay implementation of the Rebate Rule.

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## Coronavirus Updates

- Moderna [announced](#) it will develop a COVID-19 booster shot designed to be more effective against emerging strains of the coronavirus.
- Merck [announced](#) it is ending work on potential COVID-19 vaccines after weak results from early trials. The company will stop development of two vaccine candidates because the immune responses they produced in Phase I studies were weaker than those elicited by other COVID-19 vaccines and those seen in people infected with the virus.
- President Biden [issued](#) an Executive Order to restrict and suspend the entry of noncitizens into the United States who were physically present within the Schengen Area, the United Kingdom (excluding overseas territories outside of Europe), the Republic of Ireland, the Federative Republic of Brazil, and the Republic of South Africa during the 14-day period preceding their entry or attempted entry into the United States.
- The Office for Civil Rights (OCR) [announced](#) that it will exercise its enforcement discretion and will not impose penalties for violations of the HIPAA Rules on covered health care providers or their business associates in connection with the good faith use of online or web-based scheduling applications (collectively, "WBSAs") for the scheduling of individual appointments for COVID-19

vaccinations during the COVID-19 nationwide public health emergency. This exercise of enforcement discretion is effective immediately but has retroactive effect to December 11, 2020.

- President Biden [announced](#) new steps to help increase the national vaccine supply and increase transparency for state, Tribes, and territories. The Administration plans to:
  1. Increase weekly vaccine supply to states, Tribes, and territories from 8.6 million doses to a minimum of 10 million doses.
  2. Provide allocation estimates for the upcoming three weeks to increase transparency.
  3. Purchase 200 million additional doses of COVID-19 vaccines, 100 million from Pfizer and 100 million from Moderna, expected to be delivered this summer.
- The Department of Health and Human Services (HHS) [issued](#) a fifth amendment to the Declaration under the Public Readiness and Emergency Preparedness Act (PREP Act) to add additional categories of qualified persons authorized to prescribe, dispense, and administer COVID-19 vaccines authorized by the Food and Drug Administration (FDA). The amendment authorizes administration across state lines, and by those whose license or certification expired within the past five years, and requires any healthcare professional described above to complete Centers for Disease Control and Prevention (CDC) COVID-19 Vaccine Training with a possible on-site observation period.
- Johnson & Johnson [announced](#) its coronavirus vaccine was 72% effective in the first data from a late-stage U.S. trial. However, the vaccine's efficacy fell to 52% against the South African variant of the virus. Johnson & Johnson said it plans to file for emergency use authorization in early February and expects to have "product available to ship" immediately following authorization. The U.S. has purchased 100 million doses of the Johnson & Johnson vaccine with an option to buy an additional 200 million doses.
- Novavax [announced](#) its Covid-19 vaccine is more than 89% effective in a late-stage trial. However, the shot is significantly less effective against the coronavirus strain first found in South Africa

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## Federal Issues

### Regulatory

#### Federal Emergency Declaration to Remain in Effect through 2021

The public health emergency likely will remain in place throughout the current calendar year, and **the Biden Administration has committed to giving states 60 days' notice before it terminates the emergency or allows it to expire.** Acting U.S. Department of Health and Human Services (HHS) Secretary Norris Cochran shared this information in a January 22, 2021, [letter to governors](#), and it comes shortly after HHS [renewed](#) the national emergency declaration for 90 days, the maximum length of time permitted by law, effective January 21, 2021.

“Predictability and stability are important given the foundation and flexibilities offered to states that are tied to the designation of the public health emergency (PHE),” the letter states, noting that the designation allows the HHS secretary to waive or modify certain Medicare, Medicaid, Children’s Health Insurance Program, and Health Insurance Portability and Accountability Act Privacy Rule requirements.

With the PHE extension, Cochran said states also can expect the continued use of other emergency authorities, including Public Readiness and Emergency Preparedness Act declarations and emergency use authorizations for diagnostics, treatments and vaccines.

**Why this matters:** Hospitals have requested clarity about how the national public health emergency will be ended to ensure that they will have adequate time to resume normal operations in an orderly manner and without negative impacts to the patients they serve.

Additionally, the temporary 6.2 percentage point increase in the Medicaid Federal Medical Assistance Percentage included in the Families First Coronavirus Response Act also expires at the end of the quarter during which the PHE ends.

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## State Issues

### Delaware

Legislative

#### House Introduces Coverage Mandate for Epinephrine Auto-injectors

[House Bill 95](#) would require that individual, group, state employee, and public assistance insurance plans provide coverage for epinephrine auto-injectors for individuals who are 18 years of age or under and must include at least one formulation of epinephrine auto-injectors on the lowest tier of the drug formulary developed and maintained by the carrier if the insurance plan has tiers.

**Why this matters:** This legislation is currently under review for impact, however, Highmark formularies already permit access to at least one formulation at our lowest generic copay tier without any Utilization Management requirement.

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#### Governor Proposes 2022 Budget

Governor Carney presented his fiscal year **2022 recommended budget**. The spending plan comes in at **\$4.71 billion** and holds spending growth to **3.5%**, adhering to his austere fiscal strategy by limiting extra revenues toward one-time expenses. The General Assembly has as much as **\$5.15 billion** that they could appropriate.

The fiscal year 2022 recommended budget package consists of three bills. The proposed operating budget is [House Bill 105](#), the additional one-time **\$35.7 million** supplemental appropriations bill which is [House Bill 106](#), and the capital spending plan, [Senate Bill 50](#).

Governor Carney wants \$30 million in one-time spending for COVID-19 testing, contact tracing, vaccinations or any other virus-related issues next fiscal year, a sign that Delaware does not expect to be

through with the pandemic in six months when that spending would go into effect. He also wants \$3 million to expand the Public Health laboratory, which officials say will be needed for the pandemic and any future health crises. That \$3 million would be matched by \$8 million in federal funds. His recommended budget also includes \$500,000 for [House Bill 48 –House Amendment 1](#), the primary care student loan repayment program legislation that Highmark supports.

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## State Issues

### Pennsylvania

#### Legislative

#### State Legislature Returns to Work in Harrisburg

Ahead of the Governor's budget address on February 2, the Pennsylvania General Assembly had a busy schedule last week.

The House and Senate sent each other identical bills to amend the Pennsylvania Constitution to limit the power of the executive branch when declaring a disaster emergency. The amendment would limit any gubernatorial emergency disaster declaration to 21 days, down from 90 days, and would require approval of the General Assembly to renew any substantially similar declarations moving forward. An amendment to the constitution requires the same bill to pass both chambers in consecutive sessions, followed by a referendum by the voters. [House Bill 55](#) and [Senate Bill 2](#) could appear on the ballot as early as May 2021.

The Senate also passed [Senate Bill 109](#), which assists schools and the hospitality industry, and expands renters and utility support to Pennsylvanians impacted by COVID-19.

In addition, several bills were introduced or circulated for co-sponsorship requests. Many of these were initiatives from last session. Important bill to hospitals include, for example:

- State False Claims: [House Bill 42](#)
- Workforce Priorities
  - Streamlining International Graduate Requirements: [House Bill 245](#)
  - Interstate Medical Licensure Compact Update: [House Bill 192](#)
  - Nurse Licensure Compact: co-sponsorship memos have been circulated
  - Transitioning veterans with medical backgrounds into the workforce: co-sponsorship memos have been circulated
- Informed Consent: co-sponsorship memos have been circulated in the House and Senate
- Prior Authorization: co-sponsorship memos have been circulated in the House and Senate

The House and Senate are in session this week and will then break for budget hearings. The House Appropriations committee has indicated it will proceed as it has in the past with budget hearings held throughout February (schedule coming soon), while the Senate has indicated it could hold hearings later during the year as it gains a clearer sense of the federal funding that could be coming to the commonwealth.

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**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](http://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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