



## Federal Issues

### Regulatory

#### Health Plans to Cover the Cost of At-Home COVID-19 Tests

The Biden administration last week announced it will require insurance companies and group health plans to cover the cost of over-the-counter, at-home COVID-19 tests during the COVID-19 public health emergency (PHE). Starting January 15, those with private health coverage can receive these tests for free. The over-the-counter COVID-19 diagnostic test must be authorized, cleared, or approved by the U.S. Food and Drug Administration (FDA) in order to be covered by their plan or insurance. Insurance companies and health plans are required to cover eight free over-the-counter at-home tests per covered individual per month.

- The new coverage requirement allows individuals with private health coverage to purchase up to 8 free OTC at-home tests per month. Health plans may pay for these tests up front or reimburse individuals via the claims process. Guidance “strongly encourage[s]” plans to reimburse sellers of OTC COVID-19 tests directly, including providing payment to pharmacies or through direct-to-consumer (DTC) shipping arrangements, to avoid requiring upfront expenditures for consumers.

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- The guidance specifies that insurers must cover these purchases without a health care provider's order and without imposing any cost-sharing requirements, prior authorization, or other medical management requirements. This guidance does not modify previous guidance limiting coverage requirements to diagnostic testing situations and does not require coverage for OTC tests for surveillance purposes including employment.

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- **Preferred Pharmacies:** The guidance provides a safe harbor regarding preferred pharmacies or retail locations (including in-person or online locations). Under the safe harbor, the Departments will not take enforcement action if plans arrange for direct coverage of OTC COVID-19 tests through both its pharmacy network and a DTC shipping program. In this case, the plan may then choose to limit reimbursement for OTC COVID-19 tests from nonpreferred pharmacies or other retailers to no less than the actual price, or \$12 per test (whichever is lower).
- **Medicaid & CHIP:** Medicaid and Children's Health Insurance Program plans are already required to fully cover the cost of at-home tests. However, Medicare beneficiaries will not be able to have their at-home COVID-19 tests reimbursed through the program. At this time, only COVID-19 diagnostic tests performed by a laboratory when ordered by a physician, non-physician practitioner, pharmacist, or other authorized health care professional are covered for Medicare beneficiaries.

More details can be found in the [guidance](#) released by the administration and here:

<https://faqs.discoverhighmark.com/over-the-counter-test-reimbursement/>

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## **Update on Biden Administration At-Home Rapid Test Distribution Plan and High-Quality Mask Distribution**

The Biden Administration released a [fact sheet](#) detailing the Administration's plans to distribute 500 million at-home, rapid COVID-19 tests to Americans at no cost. Starting January 19, 2022, Americans will be able to order their tests online at COVIDTests.gov.

According to the fact sheet, the number of tests sent to each residential address is limited to four tests, with the tests shipping typically within 7-12 days of ordering. The White House also said it was prioritizing processing orders to households experiencing the highest social vulnerability and in communities that have experienced a disproportionate share of COVID-19 cases and deaths.

President Biden [stated](#) last week that the Administration was procuring an additional 500 million tests to distribute for free. He also stated the Administration would soon make an announcement on how they would make high-quality masks available to the public for free.

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## **Supreme Court Halts OSHA Vaccine Rule, Allows Health Care Worker Vaccine Mandate**

The U.S. Supreme Court issued two separate decisions addressing Biden Administration rules seeking to establish various workplace requirements related to COVID-19 vaccinations and testing.

- In a [6-3 decision](#), the Court halted an OSHA rule requiring businesses with at least 100 employees to either adopt a vaccination mandate or require unvaccinated workers to be tested weekly.
- In a separate [5-4 decision](#), the Court allowed CMS's emergency rule requiring vaccination of health care workers at hospitals, nursing homes and other facilities that participate in Medicare and Medicaid to go into effect nationwide while the parties continue to litigate the rule in the courts.

### **Why this matters:**

- In the main opinion issued in the OSHA case, the Court observed that Congress had empowered the agency "to set workplace safety standards, not broad public health measures" and found that while "COVID-19 is a risk that occurs in many workplaces, it is not an occupational hazard in most." The Court observed that OSHA could issue targeted, occupation-specific regulations in instances "where the virus poses a special danger because of the particular features of an employee's job or workplace," but that OSHA's current standard was instead an "indiscriminate approach" that was more akin to a "general public health measure, rather than an occupational safety or health standard." Chief Justice Roberts and Justices Kavanaugh and Barrett joined in the decision, while Justices Gorsuch, Thomas and Alito joined in a concurring opinion.
- In a separate challenge involving CMS's health care worker vaccination requirement, the Court found that one of CMS's core functions is to "ensure that the health care providers who care for Medicare and Medicaid patients protect their patients' health and safety" and that the agency had a long history of issuing regulations that relate to the qualifications and duties of health care workers, including vaccinations. The Court went on to find that the agency had appropriately considered other options, including testing, but given the circumstances acted reasonably when it decided to instead require vaccinations. The Court also found that given the pandemic and related concerns over patient safety, CMS had good cause to issue the rule on an emergency basis and without prior notice and comment. Chief Justice Roberts and Justice Kavanaugh joined with Justices Breyer, Kagan and Sotomayor in the 5-4 decision.

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## **COVID-19 Updates**

- The Biden Administration [announced](#) a new COVID-19 testing plan, which would provide 10 million tests for schools each month. The White House said it would distribute 5 million free, rapid tests to

schools each month. States can work with the Centers for Disease Control and Prevention to submit requests for additional tests, the White House said. An additional 5 million lab-based PCR tests would also be available this month, via an effort to expand laboratory capacity from a Department of Health and Human Services program funded through the American Rescue Plan Act. The first shipments of the rapid tests are expected to be delivered to campuses later this month.

- The Administration [extended](#) the COVID-19 public health emergency (PHE) for an additional 90 days, effective January 16, 2022. The declaration has been extended repeatedly since it was announced Jan. 27, 2020.
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### **CMS Proposes to Cover Monoclonal Antibodies for the Treatment of Alzheimer’s Disease**

The Centers for Medicare & Medicaid Services (CMS) [issued a proposal](#) to cover FDA-approved monoclonal antibodies directed against amyloid for the treatment of Alzheimer’s disease under Coverage with Evidence Development (CED). **The proposal specifies FDA-approved drugs in this class would be covered for people with Medicare only if they are enrolled in qualifying clinical trials conducted in a hospital-based outpatient setting.**

**Why this matters:** If the proposed National Coverage Determination (NCD) is finalized, CMS will review each submitted clinical trial to determine whether it meets the criteria specified in the proposed NCD. In addition to CMS-approved trials, National Institutes of Health-sponsored clinical trials would also be covered under this proposal.

Currently, Aduhelm is the only approved monoclonal antibody directed against amyloid beta approved by the FDA for the treatment of Alzheimer’s disease. HHS Secretary Xavier Becerra requested a recently announced Medicare premium increase be re-calculated based on a reduction in the cost of Aduhelm that was announced by the drug’s manufacturer, Biogen, in December. It is unclear how this NCD will impact that analysis and estimates of the cost of coverage to the Medicare program.

The proposal includes a 30-day comment period. Please see the [proposed National Coverage Determination decision memorandum](#) for more information. CMS will announce its final decision by April 11, 2022.

- AHIP President and CEO Matt Eyles issued comments on the NCD: “Americans deserve access to prescription drugs that are safe and effective, and we applaud CMS for putting patients first in their proposed coverage policy for monoclonal antibodies for treating patients with Alzheimer’s. We agree with CMS that there is a need to obtain more clinical data on efficacy, which will be essential to ensuring these new medications deliver real value to patients before broadening access. We look forward to commenting in greater detail during the comment period.”

- The Campaign for Sustainable Rx Pricing (CSRxP) also released a [statement](#). The statement reads, “CMS’ balanced approach rightfully focuses on ensuring covered medications deliver better health outcomes for patients. The proposed policy will help protect seniors, taxpayers and the U.S. health care system from shouldering undue costs from the outrageous Big Pharma pricing of this medication.”
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## **HHS Secretary Instructs CMS to Reassess Recommendation for 2022 Medicare Part B Premium**

HHS Secretary Xavier Becerra [requested](#) the Centers for Medicare & Medicaid Services (CMS) reassess the 2022 Medicare Part B premium. Becerra cited the price change of the Alzheimer’s drug, Aduhelm, as “a compelling basis for CMS to reexamine the previous recommendation.”

**Why this matters:** Aduhelm, manufactured by Biogen, was priced at roughly \$56,000 annually, when first marketed following FDA approval. Medicare administrators in November announced a nearly 15% increase in beneficiaries’ Part B premiums for 2022, citing Aduhelm’s potential cost to the program. Biogen reduced the drug’s annual cost to about \$28,000 on January 1.

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## **State Issues**

### **Delaware**

#### Legislative

### **Delaware General Assembly Begins the Second Half of the 151<sup>st</sup> General Assembly**

Delaware legislators returned to session this month in a mostly virtual setting. Delaware’s legislative session runs two years, so any bills that didn’t pass in 2021 rolled over in 2022. Lawmakers’ deadline to pass bills is June 30.

#### **Top health related issues the General Assembly is expected to take up this year:**

- Legislation to help hospitals facing a staffing shortage in the midst of the COVID-19 pandemic.
  - Gov. John Carney’s latest emergency order enabled Delaware National Guard members to work as certified nursing assistants to care for patients currently in Delaware hospitals, which lawmakers plan to codify this month to make it permanent.
  - Lawmakers may also make it easier for other people, such as formally credentialed health professionals, to become certified nursing assistants at the Department of Health and Social Service’s discretion.
- Statewide paid family and medical leave insurance program. The original [bill](#), [Senate Bill 1](#), provided Delaware workers up to 12 weeks of paid family and medical leave. Amendments will

include changes to eligibility and parameters of leave, among other changes. This impacts employers with 20 or more employees and is funded through a payroll deduction.

- Suppression of EOBs - allowing members to opt out of receiving EOB's to protect access to confidential health care information.
  - Expanding cap removal for chiropractic and PT visits beyond the current diagnosis of lower back pain.
  - Surprise Billing, [House Bill 39](#). Sponsor has indicated he wants to amend to include ground ambulance services.
  - End of Life Options, [House Bill 140](#): Permits a terminally ill individual who is an adult resident of Delaware to request and self-administer medication to end the individual's life.
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## State Issues

### New York

Legislative

#### Governor Delivers Budget Address

Governor Hochul delivered her budget address Tuesday, noting it was a “once in a generation opportunity” to emerge from the pandemic and also address some long-standing issues the state has faced since before COVID-19. This is possible, she said, because of the very positive financial situation in the state due to higher than expected tax revenues and the infusion of federal pandemic and infrastructure funds.

#### In health care, highlights include:

- \$10 billion investment in health workforce
    - \$1 billion in bonuses for health care workers
    - \$1.6 billion in capital investment in facilities
  - \$400 million multi-year investment in opioid addiction services
  - \$224 million in gun violence prevention
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## State Issues

### West Virginia

Legislative

#### Senate Advances Prior Authorization Legislation

On Wednesday, January 12, the Senate unanimously passed [Senate Bill 40](#) (Strollings, D-Boone) which would prohibit insurance coverage from requiring prior authorization for tests to stage cancer. Senate Bill 40

now awaits consideration from the House where it was referred to the Health and Human Resources Committee.

Similar legislation passed the West Virginia Senate in 2021, but the House did not take action.

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## **Industry Trends**

Policy / Market Trends

### **New ASPE Report Shows 14.2 million Americans Have Signed Up for Coverage Through HealthCare.gov**

The Department of Health and Human Services (HHS) Assistant Secretary for Planning and Evaluation (ASPE) [released](#) a new report this week showing that 14.2 million people have selected plans for health coverage in 2022 since the Open Enrollment Period (OEP) began on November 1, 2021.

The report shows that through January 12, 2022, over 10 million people enrolled in the 33 states using Healthcare.gov and 4.2 million enrolled in the 18 states with State-based Marketplaces. The report also states 51 percent of HealthCare.gov consumers who enrolled during the 2021 OEP received cost-sharing reductions (CSRs).

Open enrollment in Healthcare.gov states ended January 15.

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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/>.

New York Legislation: <https://nyassembly.gov/leg/>

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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