



Blue Cross
Blue Shield
Blue Care Network
of Michigan

COVID-19 VACCINE REGULATORY UPDATE

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This document is intended to build awareness and understanding of potential changes and issues related to the future regulatory environment for health care. This document is to be used as an educational tool only - it is not intended to provide predictions of future outcomes, comprehensive implications, or to impart tax or legal advice. Further, the information contained in this document is only informed as of the date of its creation and does not replace a more rigorous review of additional guidance pending from the federal or state government.

President Biden's COVID-19 action plan includes vaccine mandate and additional mitigation strategies



Employers with 100 or more employees must:

- Ensure workers are fully vaccinated or produce a weekly negative test result
- Provide paid time off for vaccination and recovery if they are under the weather post-vaccination
- Status: Further guidance is needed from the Occupational Safety and Health Administration



Employees of certain federal contractors must be vaccinated.

- Status: Guidance issued Sept. 24 by the Safer Federal Workforce Task Force



Medical staff must be vaccinated to participate in Medicare and Medicaid programs, including but not limited to hospitals, dialysis facilities, ambulatory surgical centers and home health agencies

- Status: Awaiting regulation from Centers for Medicare and Medicaid Services



At-home tests will be sold at cost for three months by Walmart, Amazon and Kroger. Biden admin also announced Oct. 6 that it has purchased \$1 billion of at-home rapid tests for free distribution likely beginning in December.

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Entertainment venues like sports arenas, large concert halls and other venues where large groups of people gather are asked to require that their patrons be vaccinated or show a negative test for entry



Small business loan support:

- Increases the maximum funding a small business can borrow through the COVID Economic Injury Disaster Loan program from \$500,000 to \$2 million, which can be used to hire and retain employees, purchase inventory and equipment and pay off higher-interest debt
- Streamlines the approach to Paycheck Protection Program loan forgiveness using a pre-completed application SBA will send to the borrower
- Establishes a new SBA Community Navigator program to better connect small business owners to federal, state and local funding resources



The plan also includes many other initiatives to combat the virus, including:

- Access to booster shots
- Expanding access to testing
- Increasing support for hospitals
- Plans for schools (vaccines, regular testing)
- Increasing fines for non-compliance with federal masking mandates

Guidance requires federal contractors and subcontractors to conform to the following workplace safety protocols:



- Except in limited circumstances where an employee is legally entitled to an accommodation, covered contractor employees must be fully vaccinated and contractors must require covered contractor employees to provide proof of such vaccination



- Individuals, including employees and visitors, must comply with CDC guidance related to masking and physical distancing while in covered contractor workplaces



- Covered contractors must designate someone to coordinate COVID-19 workplace safety efforts at covered contractor workplaces.

These workplace safety protocols apply to all covered contractor employees: any full-time or part-time employee, including employees of covered contractors who are not themselves working on or in connection with a covered contract (e.g., human resources, billing and legal review).

Timing for when the clause requiring compliance with the workplace safety protocols must be added to contracts, and when covered employees must be fully vaccinated will depend on the contract.

Recently issued FAQs allow group health plans to offer participants a premium discount or reduction to cost sharing for receiving a COVID vaccine, if the incentive complies with applicable wellness program regulations.

- In order to qualify as an acceptable activity-only wellness program, it must meet five criteria:
 1. Eligibility open to employees at least once per year
 2. Reward (inclusive of all health-contingent wellness programs) does not exceed 30% of total cost of employee-only coverage
 3. Reasonably designed to promote health or wellness
 4. Available to all similarly situated individuals, and offer a reasonable alternative standard
 5. All terms of the program and the reasonable alternative standard must be disclosed
- Eligibility for coverage or benefits **cannot** change due to vaccine status.
- Premium discounts for receiving a vaccine would not be considered in determining affordability for employer mandate purposes. However, premium surcharges would be considered in assessing affordability.



- Primary series of two doses for ages 12 and older
- Additional dose for certain immunocompromised individuals
- Booster dose at least six months after the primary series for people ages 65 and older, at-risk populations over age 18 and those in certain occupational or institutional settings
- Meeting October 26 to discuss a primary series for ages 5 to 11



- Primary series of two doses for ages 18 and older
- Meeting October 14 to discuss a booster dose



- One dose for ages 18 and older
- Meeting October 15 to discuss a booster dose

The FDA will also discuss heterogeneity of booster doses (mixing brands) on October 15.

Questions?