

## Legal challenges threaten Biden's COVID-19 vaccine rule

Critics want to block a safety rule requiring employees of large companies to get vaccinated or be tested weekly for COVID-19 and wear masks. Susan Jaffe reports from Washington, DC.



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Almost a year after the first COVID-19 vaccine was approved for emergency use in the USA, roughly a third of adults have still not received it. After urging Americans to get vaccinated, US President Joe Biden has taken a tougher approach: under his administration's new workplace safety standard, people must get vaccinated or undergo weekly tests for the virus if they work for companies with at least 100 employees.

"The rule will protect more than 84 million workers from the spread of the coronavirus on the job", Jim Frederick, Deputy Assistant Secretary of Labor for Occupational Safety and Health, told reporters. The Occupational Safety and Health Administration (OSHA), a small agency within the Department of Labor that protects workers from safety hazards, is charged with enforcing the requirement. "OSHA estimates that this rule will save thousands of lives and prevent over 250 000 hospitalisations during the 6 months after implementation", said Frederick.

A day after OSHA's announcement on Nov 4, 2021, multiple lawsuits to block the rule started rolling in to federal courts across the country. So far, 27 mostly Republican-led states and several businesses have sued the Biden administration, claiming that OSHA exceeded its authority by issuing the rule. OSHA was created to ensure safe workplaces, they argue, not fight pandemics.

On Nov 12, a federal appeals court in Louisiana known for its conservative leanings rejected the Biden administration's defence of its rule and issued a permanent stay, prohibiting implementation. The three-judge panel declared that the rule "grossly exceeds OSHA's statutory authority" and is merely "a

work-around" to impose a national vaccine mandate. At the same time, it "threatens to substantially burden the liberty interests of reluctant individual recipients put to a choice between their job(s) and their jab(s)".

The court also objected to the form of the rule as an emergency standard

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coming nearly 2 years into the pandemic. The judges also criticised the rule's application to "virtually all industries and workplaces in America, with little attempt to account for the obvious differences between the risks facing, say, a security guard on a lonely night shift and a meatpacker working shoulder to shoulder in a cramped warehouse..."

In a statement responding to the decision, Department of Justice spokeswoman Dena Iverson said the Biden administration "will continue to vigorously defend the standard and looks forward to obtaining a definitive resolution following consolidation of all of the pending cases for further review."

However, the court apparently pre-empted the usual procedure for dealing with multiple lawsuits filed in several courts targeting the same rule or law. One court, selected by a lottery, is supposed to hold a hearing on the consolidated cases. As *The Lancet* went to press, the selection was expected to take place this week.

Meanwhile, it appears that two deadlines under the OSHA rule are frozen: one requiring unvaccinated employees of large companies to wear masks while working, starting on Dec 5, and another requiring

vaccinations or weekly COVID-19 tests, beginning Jan 4. If the rule takes effect, people working completely from home, alone, or outdoors would be exempt, along with those who cannot comply for medical or sincerely held religious reasons.

The rule was issued as a 6-month emergency temporary standard (ETS), a special procedure that has not been used since 1980, said Debbie Berkowitz, a senior OSHA policy adviser during the Obama administration and practitioner fellow at Georgetown University's Kalmanovitz Initiative for Labor and the Working Poor. In the event of a serious and urgent safety hazard, the ETS allows OSHA to bypass some steps involved in creating a permanent regulation, which can take a minimum of 7 years, she said.

The agency identified that hazard in its preamble to the standard: "OSHA has determined that many employees in the US who are not fully vaccinated against COVID-19 face grave danger from exposure to SARS-CoV-2 in the workplace."

### Enforcement

If the rule is eventually upheld by the courts, employers would be required



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### Vaccines for health-care workers

The same day that the Occupational Safety and Health Administration (OSHA) announced its policy on Nov 4, 2021, the US Centers for Medicare and Medicaid Services (CMS) issued a vaccine mandate for employees of health-care facilities and companies the agency pays to treat Medicare or Medicaid beneficiaries. To participate in both government programmes, employers must require their staff to be vaccinated, including those who do not have direct contact with patients. Staff members can decline the vaccine for medical or religious reasons. But unlike the OSHA rule, a weekly testing option and paid time off are not provided.

More than 17 million health-care workers must receive a vaccine by Dec 5, and be fully vaccinated by Jan 4. More than 17 000 health-care providers must comply, including hospitals, nursing homes, hospices, ambulatory care centres, outpatient rehabilitation facilities, and home health-care agencies.

Last week, ten mostly Republican-led states—including some who also sued OSHA—filed a lawsuit in a Missouri federal district court to overturn the CMS vaccine requirement. They claimed that CMS lacks the authority to force health-care workers to get the vaccine and if those who refuse it lose their jobs, staffing shortages will get worse.

“When workers are sick and can’t work, or have to quarantine because they’ve been exposed [to COVID-19], that creates a staffing shortage”, countered Jonathan Blum, CMS principal deputy administrator and chief operating officer. “Our primary motivation with these regulations is for us to improve patient care and patient access to care.”

The Service Employees International Union, which represents about 1 million health-care workers in hospitals, nursing homes, and home-care industry, supports universal vaccination. “That means ensuring that working people in all settings of care have the education, access, and support they need to take the vaccine”, said the union’s executive vice president Leslie Frane. But she also wants workers to have paid time off to get the vaccine and if they experience any side-effects. “No one should be losing money from their paycheck in order to take the vaccine”, she said.

to provide paid time off to workers to get the vaccine and paid leave if they cannot work due to any side-effects. Employers can choose whether to require vaccinations or weekly testing or both. They will be responsible for verifying employees’ vaccination status and keeping records of test results. Employers can be fined US\$13 653 per employee for violating any aspect of the requirement, and \$136 532 per employee for each wilful

violation, said Michael Felsen, the former solicitor for the Department of Labor’s New England regional office.

Because OSHA’s roughly 1850 inspectors are vastly outnumbered by the 10.2 million workplaces under their purview, the agency typically focuses its limited resources by relying on confidential complaints from workers or their representatives about potential violations, which could include compliance with the vaccine requirements.

Although OSHA regulations prohibit retaliation against workers who report safety hazards, “they are very scared about filing complaints”, said Berkowitz. “That’s why it was so amazing to see thousands of complaints filed within the first 10 months of the pandemic”, but she said the Trump administration investigated very few.

However, Frederick expects most companies and workers will cooperate because they already abide by other OSHA regulations. He said OSHA chose the 100-employee threshold because large companies “have the administrative capacity to implement the requirements promptly”. Enforcement measures will likely involve “the outliers that do not comply”, he said.

About half of the 100 large companies surveyed by Bloomberg News in September already required vaccinations for at least some of their employees. Some offer cash rewards—as much as \$1000—for employees who receive the vaccine. But some companies have said they will dismiss employees who do not comply, including United Airlines, Kraft Heinz, and *The Washington Post*.

The federal government also requires most of its employees to be vaccinated, including members of the military. Chicago, Los Angeles, and New York City have mandates for their workers along with several hundred universities and hospitals across the country.

“Making COVID-19 vaccination a requirement to work at Mayo Clinic will help ensure we have a healthy workforce and that Mayo Clinic is a safe place to receive care, just as our patients expect”, said the clinic’s spokeswoman, Kelley Luckstein. However, its 71 350 employees nationwide will be able to request medical or religious exemptions from vaccination.

### OSHA’s mission

The agency regulates a wide range of safety and health hazards from deadly toxic chemicals to excessive noise and working in confined spaces. However, as former OSHA director and epidemiologist David Michaels notes, a workplace hazard can also be the person who can transmit an infectious disease to co-workers. “The reason that there’s a sharps box in every hospital room is because OSHA requires it”, Michaels said, a requirement put in place in response to the HIV/AIDS epidemic. And if health-care workers are at risk of exposure to hepatitis B virus, OSHA requires employers to offer them the vaccine that prevents the disease.

But unlike those infectious diseases, which pose a threat mostly in health-care settings, “COVID-19 is a risk in many types of workplaces”, said Michaels. OSHA’s COVID-19 vaccine or testing mandate is not unprecedented and not beyond its authority, he said. “Congress gave OSHA authority to make sure workplaces are safe”, he continued. “And if you’re going to be in the workplace, you can’t be making other people sick. Every worker should be able to leave work at the end of the day in the same condition that they started.” Although COVID-19 deaths are down to about 1000 a day, he said, that figure is still equivalent to about three jumbo jet crashes killing every passenger every day. “So the idea that we’re not in the greatest danger right now is ludicrous.”

Susan Jaffe