

Comments for EO 12866 Meeting
COVID-19 Vaccination and Testing ETS Rulemaking, RIN: 1218-AD42
Monday, October 18, 2021 | 1–1:30 PM
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My name is Rachel Morrison. I am an attorney and policy analyst at the Ethics and Public Policy Center. Also on the call is my colleague Roger Severino, Senior Fellow at EPPC and former Director of the HHS Office for Civil Rights.

OMB cancelled a previous EO 12866 meeting I had scheduled for a different rule,¹ so I am glad you are willing to hear my input this time.

Today there are 7 major concerns/points I want to raise of importance to OIRA and OSHA.

1. Lack of a public notice and comment period for the rule

- *Legal Standard.* As you know, under EO 12866, for most rules, an agency should give the public at least 60 days for meaningful comment. The Administrative Procedure Act (APA) suggests less than 30-days is highly suspect and problematic.
 - i. There is an exception for “good cause.” In President Biden’s edict directing OSHA “will” mandate employers require that their employees be vaccinated or subject to expensive and stigmatizing weekly testing, the failed to provide the good cause to rush such a major and economically significant rule without vital public input.² Rather, he explicitly said the OSHA mandate is merely a tool to “vaccinate the unvaccinated” across all sectors of the United States and pointed to nothing that distinguished the American workplace as being a COVID emergency danger zone.
 - ii. The timing of the mandate is suspect and undercuts the rationale that it falls within the “good cause” exception. COVID has been in the U.S. since January 2020. Vaccines, in response to President Trump’s Operation Warp Speed, were approved fall 2020 and it’s been almost 10 months since President Biden took office. Large numbers of vaccinations continue to be administered every single day, but only now is a mandate being pushed in the workplace.
 - iii. The large number of meetings requested on the rule by such a diverse group of stakeholders reiterates the massive impact any such rule will have. Without seeing the text of the rule, the public can only speculate as to what it includes, and the value of public input is unnecessarily limited.
- *Ask.* I ask that you open up the rule for public comment. Surely fairness and equity suggest the public should have a reasonable amount of time to consider and comment

¹ <https://www.nationalreview.com/bench-memos/biden-and-becerra-kill-democratic-norms-in-rush-to-fund-big-abortion/>.

² <https://www.whitehouse.gov/covidplan/#vaccinate>.

on the proposed rule, especially for such a major and self-recognized economically significant rule.

2. Effective date and compliance date of the rule

- *Legal Standard.* The Congressional Review Act (CRA) (5 U.S.C. § 804(2)) defines a “major rule” as “any rule that the OIRA Administrator finds has resulted in or is likely to result in—(A) an annual effect on the economy of \$100,000,000 or more; (B) a major increase in costs or prices for consumers, individual industries, Federal, State, or local government agencies, or geographic regions; or (C) significant adverse effects on competition, employment, investment, productivity, innovation, or on the ability of United States-based enterprises to compete with foreign-based enterprises in domestic and export markets.” The CRA (§ 801(a)(3)) requires 60 days before the final rule takes effect, and the APA (5 U.S.C. § 553(d)) requires 30 days. EO 12866 likewise requires a full regulatory cost benefit analysis for significant rules.
 - i. I can’t see how this rule is expected to be anything but a “major rule” as defined by the CRA and EO 12866 because it is likely to result in an annual effect on the economy of \$100 million or more, lead to an increase of costs and prices for consumers and employers, and have a significant adverse effect on employment, productivity, and innovation—many unvaccinated employees will be barred from working for any employer with more than 100 employees and employers will incur significant costs to ensure compliance and testing.
- *Ask.* At a minimum the rule should not go into effect immediately until after 60 days and the compliance date should be no earlier than the effective date. If the rule goes into effect immediately, it will cause mass confusion and further disrupt an already disrupted economy.

3. Major impact of the rule on small businesses

- *Legal Standard.* As you are aware, the Regulatory Flexibility Act (RFA) (5 U.S.C. 605(b)), requires agencies to analyze regulatory options that would minimize any significant impact of a rule on small entities and prepare a regulatory flexibility analysis to describe the impact of the proposed rule on small entities, unless “the head of the agency certifies that the rule will not, if promulgated, have a significant economic impact on a substantial number of small entities.” The Act requires that “the agency shall publish such certification in the Federal Register at the time of publication of general notice of proposed rulemaking for the rule or at the time of publication of the final rule, along with a statement providing the factual basis for such certification.”
 - i. It seems clear to me that the 100-employee threshold will have a significant impact on small entities across industries and regions, especially non-profits, religious organizations, and small governmental jurisdictions. HHS, for example, considers a rule to have a significant impact on a substantial number of small entities if it has at least a three percent impact on revenue for at least five percent of small entities. This minimal threshold will surely be met.

- *Ask*. Regardless, OSHA must explain its reasoning either way. It must explain the impact on small businesses and why it is justified. Or if OSHA does not think that the rule will have such a significant impact, Secretary of Labor Martin Walsh *must* certify there is no such impact and provide sufficient analysis in the rule supporting such a claim.

4. Federalism concerns of the rule

- *Legal Standard*. As you are familiar, E.O. 13132 from the Clinton Administration establishes certain requirements that an agency must meet when it issues a rule that imposes substantial direct requirement costs on State and local governments, preempts State law, or otherwise has Federalism implications. The impending mandate will clearly have Federalism implications and preempt State laws (such as the ban on vaccine mandates in Texas).
 - i. Section 3(c) of the EO states that “with respect to Federal statutes and regulations administered by the States, the national government shall grant the States the maximum administrative discretion possible.”
 - ii. Section 3(d) explains how to implement policies that have federalism implications. Specifically, agencies “shall” (1) “encourage States to develop their own policies to achieve program objectives and to work with appropriate officials in other States,” (2) “where possible, defer to the States to establish standards,” and (3)/(4) consult with States and officials.
 - iii. Executive Order 12866 (§ 6(a)(3)(B)) also directs that significant regulatory actions avoid undue interference with State, local, or tribal governments, in the exercise of their governmental functions. Executive Order 13175 (§ 2(a)) also from President Clinton further directs that Agencies respect Indian tribal self-government and sovereignty, honor tribal treaty and other rights, and strive to meet the responsibilities that arise from the unique legal relationship between the Federal Government and Indian tribal governments.
 - iv. A federal vaccine mandate takes away all administrative discretion and does not defer to States to establish standards for their communities. I am aware of no meetings that OSHA held with States or Indian tribal governments to explore impacts of and alternatives to a federal vaccine mandate. Moreover, 24 States have already sent a joint letter to President Biden stating that they oppose any such federal mandate and plan to challenge the mandate in court.³

5. Problem the rule addresses

- *Legal Standard*. EO 12866, section 1(b) establishes the principles of regulation, including that “Each agency shall identify the problem that it intends to address (including, where applicable, the failures of private markets or public institutions that warrant new agency action) as well as assess the significance of that problem.”

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[https://ago.wv.gov/Documents/AGs%27%20letter%20to%20Pres.%20Biden%20on%20vaccine%20mandate%20\(FINAL\)%20\(02715056xD2C78\).PDF](https://ago.wv.gov/Documents/AGs%27%20letter%20to%20Pres.%20Biden%20on%20vaccine%20mandate%20(FINAL)%20(02715056xD2C78).PDF).

- i. There is no statute requiring this action. What data compelled OSHA to take this action? To the extent it was a political response to the President, a problem must still be identified that a federal vaccine mandate for certain employers and employees intends to address. Vaccinations are not a compelling government interest in and of itself. The underlying problem vaccines seek to address has to be linked to public health and safety (something that is reserved to the States by not being delegated to the federal government in the Constitution), such as by minimizing hospitalizations, serious illness, and deaths. First, OSHA must establish the parameters of the problem. Second, a vaccine mandate must be proven to address this problem. A federal vaccine mandate does not seem the best or most effective way to address the problem.

6. Uncertain risks of vaccination the rule ignores

- The COVID-19 vaccines are not without risk and lead to adverse events in a significant number of cases. It is unclear, however, to what extent these adverse events are occurring because (a) the FDA has so far refused to release its COVID vaccine safety data,⁴ (b) the CDC Wonder database and the FDA VAERS database are inconsistent and report significantly different numbers of adverse events, and (c) adverse events are known to be underreported to VAERS.⁵ Without this data, the federal government cannot credibly mandate employers with over 100 employees to force their employees to be vaccinated, regardless of region, industry, current vaccination rates, potential for transmission, or existing risk of hospitalization, serious illness, and death, because it cannot make the proper comparison of expected health benefits of the mandate to expected health costs.

7. Cost-benefit analysis of the rule

- *Economically Significant.* The OSHA rule is a self-proclaimed economically significant rule, that requires meaningful economic analysis under EO 12866 and OMB Circular A-4. Skipping over the public notice and comment period does not alleviate the agencies of responsibility to have reasoned decision-making. Rather it places an even higher bar on the agency to have sound analysis.
- *Legal standard.* EO 12866 states: “In deciding whether and how to regulate, agencies should assess all costs and benefits of available regulatory alternatives, including the alternative of not regulating. Costs and benefits shall be understood to include both quantifiable measures (to the fullest extent that these can be usefully estimated) and qualitative measures of costs and benefits that are difficult to quantify, but nevertheless essential to consider. Further, in choosing among alternative regulatory approaches, agencies should select those approaches that maximize net benefits

⁴ <https://www.forbes.com/sites/davidgortler/2021/08/24/how-the-fdas-lack-of-transparency-undermines-public-trust/?sh=7605296e13ba>.

⁵ See, e.g., <https://www.sirillp.com/wp-content/uploads/2021/10/Letter-Re-First-Hand-Account-of-Covid-19-Vaccine-Injuries-and-Underreporting-to-VAERS-1.pdf>.

(including potential economic, environmental, public health and safety, and other advantages; distributive impacts; and equity), unless a statute requires another regulatory approach.”

- *Baseline*. I am concerned that an incorrect baseline for analysis will be used. Any potential benefits of the mandate cannot be attributed to the current vaccination rate, which is expected to continue, and all the voluntary and state-imposed employer-vaccination mandates. Any benefits of the rule can only be attributed to those who would get vaccinated *solely* because their employer required vaccination *solely* because of the OSHA rule. In calculating who would receive a health benefit from the mandate I am concerned that the rule will attribute to itself benefits it cannot claim.
- *Alternatives*. Instead of a federal mandate, the agency must consider alternatives and provide that analysis. Since the goal should be to prevent hospitalizations, serious illness, and death, some alternatives are: (a) tax incentives for employers or making COVID-related expenses tax deductible; (b) more focus on therapeutics to treat COVID-19; (c) other methods to decrease transmission that have been employed throughout the pandemic such as testing, temperature taking, social distancing, masking, enhanced cleaning, working from home, etc.; and (d) a more narrowly tailored approach that only applies to certain regions, businesses, industries, and only certain job categories. I’m sure OIRA staff can easily come up with even more alternatives.
- *Costs, benefits, transfers*. As part of its regulatory impact and economic analysis of the costs, benefits, and transfers, the rule should take into consideration the following key inputs:
 - i. **Economy**
 - The number of unvaccinated people currently employed by covered employers.
 - The number of people who will quit or be terminated from their job because of the mandate.
 - The number of jobs that will be lost due to the mandate.
 - The financial and health impacts of job loss due to the mandate on those employees and their families.
 - The number of people who will seek employment with employers not covered by the mandate.
 - The impact on economy as a whole from loss of employees and jobs due to the mandate, including disruption to already suffering supply chains, including food chains.
 - The impact on the availability of access to health care. There are already reports of shortages of health care personnel. One article discussed a rural Texas hospital CEO warning that a vaccine mandate could lead to the hospital closing, which would have vast

negative health impacts in that community.⁶ This hospital is not alone.

- The impact of the mandate in different industries and in different regions.
- Projected compliance rates.
- The mandate's real-world effectiveness to solve the problem of hospitalizations, serious illness, and death of employees, not the public at large.
- Costs to employers to create policies and systems for vaccine compliance and testing.
- The impact on unemployment benefits for those who are fired because of the mandate.
- Environmental costs from increased commutes for discharged employees who must find more distant work as a result of the mandate.
- The costs on taxpayers for OSHA to ensure enforcement.

ii. **Health**

- The number of increased adverse events due to vaccination as a result of the mandate. Presumably many of those who have not yet taken the vaccine have done so because they are at higher risk of adverse events.
- The health impact on younger employees without pre-existing conditions who are at minimal risk to COVID.
- The underreporting of adverse events to the VAERS database.
- The effectiveness of non-vaccine risk mitigation strategies, such as social distancing, masking, double-masking, increased cleaning, and telework that can help prevent transmission and illness.
- The effectiveness of early intervention and existing therapeutics to treat COVID to minimize or prevent hospitalization and death.
- The high vaccination rates and the voluntary employer mandates already are in place.
- The growing number of state mandates.
- The number of unvaccinated employees who work from home, outdoors, or not in close contact with others.
- The waning effectiveness of the vaccines over time. As the CDC has found, vaccines do not prevent infection or transmission, and the vaccinated and unvaccinated can be infected at the same rate and have the same viral load.⁷

⁶ <https://www.lifesitenews.com/news/texas-hospital-ceo-warns-his-facility-might-have-to-close-because-of-bidens-vaccine-mandate/>.

⁷ <https://www.cdc.gov/mmwr/volumes/70/wr/mm7031e2.htm>.

- The transmission and infection rates between the vaccinated and the unvaccinated, including the unvaccinated who already recovered from COVID and have natural immunity.
 - The number of unvaccinated who have already recovered from COVID and have natural immunity.
 - The effectiveness of natural immunity compared to vaccination.
 - The effect of unvaccinated employees being more likely to have symptoms and thus more likely to stay home from work and avoid spreading, than vaccinated people who have fewer symptoms but can still transmit the virus.
- iii. **Civil rights**
- The disparate impact perpetuating inequality on those in rural areas, on certain racial or ethnic minorities, on certain religious groups, or on certain people with disabilities, such as those who are medically unable to receive the vaccine.
 - The impact of the mandate on conscience and religious rights in violation of First Amendment, RFRA, Title VII of the Civil Rights Act of 1964, as well as state laws. The rule should protect the free exercise of religious employers to choose not to mandate the vaccine for their employees, and of religious employees who cannot take the vaccine based on their sincerely held religious beliefs.
 - A simple solution would be for religious organizations to be exempt from any such mandate and robust protections for those with religious or conscience objection to taking the vaccine.
 - Stigmatization or social ostracization of people who are not vaccinated and required to submit to weekly testing, constant pressure, and potential lost job advancement or retaliation.

All of these things, and more, must be taken into consideration, and quantified or estimated to the maximum extent possible for a sufficient analysis of impact, costs, benefits, and transfers.

Conclusion

In sum, vaccinations can be an important tool to combat pandemics. But the problem the rule should be addressing is not vaccination rates themselves, but the minimization of hospitalizations, serious illness, and death of employees due to *workplace conduct or conditions*. The status of being unvaccinated is the natural human condition. It is not workplace conduct or a workplace condition. There is nothing remotely unique about the dangers of “workplaces” (or workplaces of employers with 100 or more employees) when it comes to infectious diseases, because workplaces come in all shapes and sizes, including work done in well-ventilated areas,

outdoors, masked, remotely, seasonally, or in places that can be modified to adopt any of the above.

But under the proposed rule, the federal government is mandating a one-size-fits-all approach and forcing employers to coerce employees to undergo a medical intervention, potentially against the advice of a doctor or in violation of an employee's religious beliefs or conscience, or face intrusive weekly testing indefinitely (for those employees who would allow it) and concomitant stigmatization. Mandating vaccinations for all does not take into account the risk-benefits calculus for any individual person, and the attendant negative impacts on employees who will no longer work for covered employers and on the economy. Finally, OSHA seems to be ignoring the fact that, according to President Biden's own logic, people who are vaccinated are already protected in the workplace which means those mostly young, healthy employees who are choosing not to be vaccinated (many of whom have already had COVID) have knowingly assumed the risk.

We all know that President Biden wants a national vaccine mandate and is only using OSHA because it is the closest thing he can get to lawful action. But it is still unlawful as there is not a grave danger in the workplace under the OSH Act justifying such a drastic action, most especially without public input. For a thorough analysis of the "grave danger" standard and how the mandate fails to meet it, please see the letter from 24 State Attorneys General of September 16, 2021.⁸

I ask that you also consider the attached studies and articles substantiating and discussing many of the points I raised.

I urge OMB to ensure that the statutory and regulatory process is upheld and that any final rule has sufficient legal and economic analysis that is rationale, reasoned, and scientific, not political, rushed, or prejudged.

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[https://ago.wv.gov/Documents/AGs'%20letter%20to%20Pres.%20Biden%20on%20vaccine%20mandate%20\(FINAL\)%20\(02715056xD2C78\).PDF](https://ago.wv.gov/Documents/AGs'%20letter%20to%20Pres.%20Biden%20on%20vaccine%20mandate%20(FINAL)%20(02715056xD2C78).PDF).