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M E M O R A N D U M

DATE: January 29, 2021

TO: Higher Education Clients

FROM: Education, Washington State University, and University of Washington Divisions

SUBJECT: **Vaccination Policy FAQ**

The following Frequently Asked Questions (FAQ) is intended to assist in informing decision-making as it relates to the COVID-19 vaccine protocols amongst Washington's institutions of higher education (institutions or IHE). Although the FAQ attempts to anticipate and answer general questions, each IHE's response will be controlled by their risk profile, risk tolerance, and unique characteristics, including (but not limited to) community makeup and characteristics, access to vaccine administration, contractual, and employment related obligations. This FAQ does not replace a separate legal review of individual policies and protocols and, thus, each IHE is encouraged to consult their assigned Assistant Attorney General (AAG(s)) for further guidance and clarification. Finally, the information contained herein reflects the legal precedent, interpretations, and context at the time of drafting, and is subject to change. It is important to underscore that all evaluations and decisions should be informed by current public health authority guidance, which may be fluid and require prompt re-evaluations of vaccination plans.

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1. **Can students and employees who are living, learning, working, or otherwise engaged in activities on campus, be required to receive the COVID-19 vaccination as a condition of engaging in-person on campus?**

Probably, if, after consulting with pertinent COVID-19 guidance from the Centers for Disease Control and Prevention (CDC) and local and state health officials, along with other pertinent information, the institution determines that the vaccine is necessary to protect the public health and safety of the campus community.

The authority to require vaccination when it is determined to be in the best interest of the public health is long established. *Jacobson v. Mass.*, 197 U.S. 11, 25 S. Ct. 358, 49 L. Ed. 643 (1905) (upholding mandatory vaccinations to curb the spread of smallpox). This authority is typically vested in state and local health officials with a focus on immunization of children in the K-12 system. *See Lehman v. Partlow*, 119 Wash. 316, 205 P. 420 (1922) (upholding State Board of Health regulation imposing mandatory smallpox vaccination or physician's certificate showing the person had smallpox as a condition of public school attendance); *see also* RCW 28A.210.060-170. Governing bodies of IHEs have also been held to have the authority to enforce requirements that protect the health of IHE employees and students to prevent a "grave and immediate danger." *Holcomb v. Armstrong*, 39 Wn.2d 860, 864, 239 P.2d 545 (1952) (holding that the University of Washington had authority to require student to submit to a tuberculosis test during a pandemic).[1]

Despite this authority, it is important to note that the COVID-19 vaccines are the first vaccinations ever approved under an Emergency Use Authorization (EUA), which creates some legal uncertainty and increases the risk of litigation over a vaccination requirement. This issue is discussed further below along with some considerations for situating the IHE for a strong legal defense should the IHE choose to adopt a mandatory vaccination policy. Due to the legal uncertainty, the IHE may also want to consider an approach that encourages or incentivizes vaccination, rather than requiring it, or an approach that provides employees and students with the flexibility to choose whether to participate in the IHE's activities and learning remotely or in person.

[1] Note there is no Washington case law specifically addressing whether an IHE can mandate vaccination of students or employees. In addition, Washington courts have held that the Washington State Constitution is more protective of individual rights than the U.S. Constitution. *Blomstrom v. Tripp*, 189 Wn.2d 379, 400, 402 P.3d 831 (2017). However, a recent (unpublished) case from California (which also has a more protective state constitution), supports the conclusion that a Washington court likely would uphold an IHE's mandatory vaccination program; provided it was narrowly tailored and crafted in accordance with the factors discussed below. *See Kiel vs. The Regents of the Univ. of Cal.*, No. HG20072843, 2020 WL 7873525 (Cal. Super. Sept. 30, 2020) (upholding the university's flu vaccine mandate).

2. How does the Emergency Use Authorization affect an IHE's ability to require the COVID-19 vaccination?

To date, the Food and Drug Administration (FDA) approved COVID-19 vaccines under its EUA authority. How the EUA might affect the ability to mandate a vaccination has been the subject of speculation and it is difficult to predict how a court might rule, as it is a matter of first impression. Nonetheless, after analyzing the issue, there is a strong legal argument that the COVID-19 vaccines can be required, assuming the IHE's vaccination policy satisfies established legal standards.

Section 564 of the Food, Drug and Cosmetics Act – 21 U.S.C. 360bbb-3(e)(1)(A)(ii)(III):

> Authorization for medical products for use in emergencies," requires the Secretary of Health and Human Services to "establish such conditions on an authorization . . . as the Secretary finds necessary or appropriate to protect the public health, including . . . Appropriate conditions designed to ensure that individuals to whom the product is administered are informed . . . of the option to accept or refuse administration of the product, or the consequences, if any of refusing administration of the product, and of the alternatives to the product that are available and of their benefits and risks.

There are some who argue that this creates a barrier to mandating a product that has received EUA and this is expected to result in litigation. This argument is bolstered by another federal statute that explicitly allows the President to waive the refusal option and require the members of the armed forces to receive/take an EUA product, if determined to be in the interests of national security. 10 U.S.C. § 1107a. The existence of this other statute, arguably, supports the argument that the vaccine cannot be required absent similar statutory authority.

There are, however, viable legal arguments that counter this interpretation. The leading counter-argument, which is supported by the FDA's interpretation and application of this provision, is that the "refusal" language is simply akin to an informed consent provision that must be given to potential recipients by the individual administering the vaccine. *See e.g.*, RCW 7.70.050(3).

In the FDA's publication Emergency Use Authorization of Medical Products and Related Authorities: Guidance for Industry and Other Stakeholders[2] the requirements of this section are construed as an informed consent requirement:

> *Although informed consent as generally required under FDA regulations is not required for administration or use of an EUA product, section 564 does provide*

[2] U.S. DHHS, et al., *Emergency Use Authorization of Medical Products and Related Authorities: Guidance for Industry and Other Stakeholders*, (January 2017) https://www.fda.gov/media/97321/download (last visited Jan. 28, 2021).

> *EUA conditions to ensure that recipients are informed about the MCM they receive under an EUA.* For an unapproved product (section 564(e)(1)(A)(ii)) . . . the statute requires that FDA ensure that recipients are informed to the extent practicable given the applicable circumstances:
>
> . . . .
>
> • *That they have the option to accept or refuse the EUA product and of any consequences of refusing administration of the product;*
>
> . . . .
>
> *Therefore, FDA recommends that a request for an EUA include a "Fact Sheet" for recipients that includes essential information about the product.* (Emphasis added.)

Id. (observing that EUA places a medical product in a hybrid status as neither full investigational or licensed by the FDA) (Emphasis added.) The FDA has developed these fact sheets for each of the COVID-19 vaccines that have received EUA. In the Fact Sheet for Healthcare Providers Administering Vaccine,[3] the FDA states, "As the vaccination provider, you must communicate to the recipient or their caregiver, information consistent with the 'Fact Sheet for Recipients and Caregivers.'" The Fact Sheet for Recipients and Caregivers[4] resembles a product insert that provides information about the risks and benefits of the vaccine.

The IHE will want to consider the uncertainty surrounding the interpretation of this provision and its potential impact on the defense of a mandatory vaccination policy in determining whether to require vaccinations and, if so, how to do so in a manner that creates a strong legal defense. Our advice concerning the impact of the EUA will be revised as the interpretation of this provision becomes more certain through guidance and/or litigation.

3. What legal standard must an IHE satisfy if it adopts a mandatory vaccination policy?

The legal standard for evaluating mandates designed to prevent the spread of a deadly disease, focuses on the nexus between the purpose of the mandate and the methods used to achieve the stated purpose. The IHE needs to demonstrate that its vaccination policy has a "real or substantial relation" to protecting public health, and is not "a plain, palpable invasion" of fundamental constitutional rights. *Jacobson*, 197 U.S. at 31. In determining whether to uphold the mandatory vaccination in *Jacobson*, the Court considered the fact that smallpox was prevalent in the area and the Commonwealth was motivated to protect against this demonstrated health threat to all its citizens. As such, IHEs may want to consider the rate of infection on campus and in its vicinity, and ensure that any vaccination policy is supported by CDC guidelines, state and local health

[3] U.S. FDA, *Fact Sheet for Healthcare Providers Administering Vaccine*, (revised January 2021) https://www.fda.gov/media/144413/download (last visited Jan. 28, 2021).

[4] U.S. FDA, *Fact Sheet for Recipients and Caregivers*, (revised January 2021) https://www.fda.gov/media/144414/download (last visited Jan. 28, 2021).

officials, and other information from expert organizations, such as the American IHE Health Association. The fact that SARS-CoV-2 has caused a pandemic leading to federal and state officials declaring a public health emergency and the need to implement countermeasures to curb disease spread is likely to be given weight by a court.

Given that the COVID-19 vaccine was authorized under an EUA and has been politicized, the IHE should anticipate a legal challenge to a vaccination requirement. The IHE should narrowly tailor its vaccination policy to achieve a clearly identified and compelling governmental purpose (e.g., to protect the health and safety of those living, learning, or working on IHE premises, involved in IHE sponsored, in-person activities, or coming to the community where the IHE is located to attend the IHE). The purpose may also include other considerations, such as reducing the community infection rate to prevent the overwhelming of local and regional health systems necessary to provide adequate inpatient care. The IHE also should be prepared to demonstrate why a voluntary vaccination program would be insufficient to protect health and safety.

4. How can my IHE narrowly tailor its COVID-19 vaccination policy?

To be narrowly tailored, the scope and measures imposed by a COVID-19 vaccination policy must be designed to achieve the identified compelling purpose. Narrow tailoring also provides the means for ensuring that a vaccination policy can withstand challenges that allege that the policy violates individual rights. For example, if a blanket vaccination requirement were applied to students and employees who are solely engaged in remote work and learning, it would be difficult to demonstrate that vaccination furthers the purpose of reducing the spread of COVID-19 among the campus community.

A narrowly tailored vaccination policy should:

- Identify the compelling governmental interest that will be served by the policy;
- Be clearly crafted to apply in a manner that seeks to accomplish the identified interest;
- Be tailored with respect to location, duration, and the individuals to whom it applies;
- Have a process for granting exceptions or exemptions (e.g., for medical, disability, religious, or philosophical objection[5]);

[5] Washington's mandatory immunization programs have focused on requiring vaccination of children in order to attend school or daycare centers. *See* RCW 28A.210.090. This law allows for medical, religious, and philosophical exemptions. Interestingly, RCW 28A.210.090 specifically rejects the use of "philosophical or personal objection[s]" as a basis for exempting a child from the measles, mumps, and rubella vaccine. While this law does not apply to institutions of higher education, a court may consider the law in evaluating the reasonableness of any mandatory vaccination program. However, *Holcomb* and some other non-binding legal precedent have upheld policies that have not offered the religious or philosophical exemptions. *See also Jacobson*, 197 U.S. at 13-14 (allowing individuals to avoid the mandatory vaccine if they qualified for an exemption).

- Consider local conditions and circumstances (including directives and guidance from state and local health authorities); and
- Be revisited and/or updated in light of evolving law, recommendations, guidance, and understanding relating to COVID-19.

In crafting a policy, the IHE should be mindful that the ability to require members of different groups within the campus community to be vaccinated may vary and is shaped by the laws governing those relationships. For example, dental, nursing, and medical students may be subject to vaccination requirements in order to participate in clinical components of their programs; these programs may already have policies that govern the unique obligations governing student participation. Some of the unique obligations relating to employees as compared to students will be discussed later in this FAQ.

5. What are the considerations and legal requirements associated with requiring employees to be vaccinated for COVID-19?

If the IHE decides to pursue a mandatory vaccination policy for employees, it will be important to ascertain the extent to which employees and, for represented employees, the unions, support such a policy. This information can then be used to gauge whether the IHE will experience resistance to a broad mandate on vaccinations and to determine the extent to which the IHE will be able to offer, or commit to, in-person versus remote learning opportunities. Until the IHE has gathered this information from unions and employees, there is a risk that the IHE could incur liability if it over-promises the scope or extent to which it can offer in-person learning or activities, and students rely on those representations in selecting or enrolling at the IHE.

There are some relevant employer obligations that an IHE may want to consider in evaluating whether to adopt a mandatory vaccination policy. The Occupational Safety and Health Act of 1970 and the Washington Industrial Safety and Health Act require employers to provide a safe workplace "free from recognized hazards that are causing or are likely to cause death or serious harm to [their] employees." 29 U.S.C. 654(a)(1); RCW 49.17.060(1). Also, collective bargaining agreements (CBAs) for classified employees often include provisions requiring the employer to provide a safe workplace, and some CBAs require the employer to take additional steps to protect employees from infectious disease. (IHEs should check applicable CBAs.)

A mandatory vaccination policy will affect working conditions. For represented employees, the IHE should review its CBAs to ascertain whether such a policy is authorized or contemplated under the CBA provisions. As with any change in working conditions, the IHE will also need to provide the union sufficient advance notice of the new policy and be prepared to engage in appropriate bargaining over the vaccination requirement. Failure to do so could result in allegations of an unfair labor practice, and/or grievances. *See, e.g., Virginia Mason Hosp. v. Washington State Nurses Ass'n*, 511 F.3d 908 (9th Cir. 2007) (upholding arbitrator's award against an employer for unilaterally implementing a mandatory flu vaccine policy).

Any vaccination policy will also need to provide for accommodations. This should be managed through the IHE's existing processes for employees to request reasonable accommodations for disability and religious reasons. The U.S. Equal Employment Opportunity Commission (EEOC) has issued guidance[6] to employers relating to the COVID-19 vaccines. The IHE should review and adhere to this guidance. The EEOC guidance assumes that employers may require vaccinations as a safety-based qualification standard as long as the employer complies with certain legal requirements relating to reasonable accommodations. The pertinent portion of the guidance states:

> **K.5. If an employer requires vaccinations when they are available, how should it respond to an employee who indicates that he or she is unable to receive a COVID-19 vaccination because of a disability?** *(12/16/20)*
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> The ADA allows an employer to have a qualification standard that includes "a requirement that an individual shall not pose a direct threat to the health or safety of individuals in the workplace." However, if a safety-based qualification standard, such as a vaccination requirement, screens out or tends to screen out an individual with a disability, the employer must show that an unvaccinated employee would pose a direct threat due to a "significant risk of substantial harm to the health or safety of the individual or others that cannot be eliminated or reduced by reasonable accommodation." 29 C.F.R. 1630.2(r). Employers should conduct an individualized assessment of four factors in determining whether a direct threat exists: the duration of the risk; the nature and severity of the potential harm; the likelihood that the potential harm will occur; and the imminence of the potential harm. A conclusion that there is a direct threat would include a determination that an unvaccinated individual will expose others to the virus at the worksite. If an employer determines that an individual who cannot be vaccinated due to disability poses a direct threat at the worksite, the employer cannot exclude the employee from the workplace—or take any other action—unless there is no way to provide a reasonable accommodation (absent undue hardship) that would eliminate or reduce this risk so the unvaccinated employee does not pose a direct threat.
>
> If there is a direct threat that cannot be reduced to an acceptable level, the employer can exclude the employee from physically entering the workplace, but this does not mean the employer may automatically terminate the worker. Employers will need to determine if any other rights apply under the EEO laws or other federal, state, and local authorities. For example, if an employer excludes an employee based on an inability to accommodate a request to be exempt from a vaccination requirement, the employee may be entitled to accommodations such as performing the current

[6] What You Should Know About COVID-19 and the ADA, the Rehabilitation Act, and Other EEO Laws, https://www.eeoc.gov/wysk/what-you-should-know-about-covid-19-and-ada-rehabilitation-act-and-other-eeo-laws (last visited Jan. 28, 2021).

position remotely. This is the same step that employers take when physically excluding employees from a worksite due to a current COVID-19 diagnosis or symptoms; some workers may be entitled to telework or, if not, may be eligible to take leave under the Families First Coronavirus Response Act, under the FMLA, or under the employer's policies. See also Section J, EEO rights relating to pregnancy.

Managers and supervisors responsible for communicating with employees about compliance with the employer's vaccination requirement should know how to recognize an accommodation request from an employee with a disability and know to whom the request should be referred for consideration. Employers and employees should engage in a flexible, interactive process to identify workplace accommodation options that do not constitute an undue hardship (significant difficulty or expense). This process should include determining whether it is necessary to obtain supporting documentation about the employee's disability and considering the possible options for accommodation given the nature of the workforce and the employee's position. The prevalence in the workplace of employees who already have received a COVID-19 vaccination and the amount of contact with others, whose vaccination status could be unknown, may impact the undue hardship consideration. In discussing accommodation requests, employers and employees also may find it helpful to consult the Job Accommodation Network (JAN) website as a resource for different types of accommodations, www.askjan.org. JAN's materials specific to COVID-19 are at https://askjan.org/topics/COVID-19.cfm.

Employers may rely on CDC recommendations when deciding whether an effective accommodation that would not pose an undue hardship is available, but as explained further in Question K.7., there may be situations where an accommodation is not possible. When an employer makes this decision, the facts about particular job duties and workplaces may be relevant. Employers also should consult applicable Occupational Safety and Health Administration standards and guidance. Employers can find OSHA COVID-specific resources at: www.osha.gov/SLTC/covid-19/.

Managers and supervisors are reminded that it is unlawful to disclose that an employee is receiving a reasonable accommodation or retaliate against an employee for requesting an accommodation.

Section K.6. of the EEOC guidance addresses the requirements associated with religious exemptions. Once the employer is on notice that an employee's sincerely held religious belief, practice, or observance prevents the employee from receiving the vaccination, the employer must provide a reasonable accommodation for the religious belief, practice, or observance unless it would pose an undue hardship as interpreted under Title VII of the Civil Rights Act. An IHE that

mandates vaccination and is confronted with notice of a religious objection should consult with an AAG on a case-by-case basis.

While the EEOC has found that an individual with COVID-19 may pose a direct threat, which affords employers with some flexibility under the Americans with Disabilities Act, that determination is linked to the fact that COVID-19 is a pandemic.[7] Like all things related to the COVID-19 pandemic, the situation and circumstances are fluid. Therefore, any IHE policy or approach should build in similar flexibility so that the IHE can adjust to changing circumstances and to comply with any mandates or guidance issued by the CDC, state and local health authorities, or required by legal developments.

IHEs also have practical and policy considerations that will inform their policy development. For example: (1) will the IHE centralize the determinations about who will be required to be vaccinated, or will it be the responsibility of the department or office where the employee works; (2) will the IHE centralize determinations about whether an employee qualifies for an accommodation or exemption from the general policy, or will it be the responsibility of the department or office where the employee resides; (3) what will the IHE require from employees to demonstrate that they have been vaccinated and where will that information be maintained; (4) how will the policy be reviewed in light of developing circumstances in order to ensure that the compelling interest that supports the policy continues to be valid; and (5) how will the policy be reviewed and revised as the campus transitions to more in-person work and the vaccine becomes more widely available. This just scratches the surface of some of the practical and policy considerations associated with developing a mandatory vaccination policy.

Due to the complexities associated with implementing COVID-19 vaccination policies for employees, IHEs are encouraged to work closely with their human resources representatives and AAGs, once they have determined how they would like to approach the subject.

6. **If an employer administers the vaccine to an employee or requires an employee to show proof of vaccination, is that a "medical examination" or a "disability-related inquiry" under the ADA?**[8]

No. The vaccination itself is not a medical examination according to EEOC guidance (*See* K.1 and K.3 for more information) because the employer is not seeking information about the employee's current health status or impairments. Likewise, asking an employee if they have received the

[7] The existence of the pandemic, on its own, is unlikely to satisfy the requirement that the policy be narrowly tailored to meet a compelling governmental interest, and the EEOC's direct threat determination should not form the sole basis of any mandatory vaccination policy. Instead, each IHE should consider the circumstances and needs of its own campus and community to ensure that the policy is narrowly tailored to satisfy a compelling governmental interest. *See* sections 4 and 7 for additional discussion of this standard and some considerations.

[8] There are a number of legal implications if the IHE itself is administering the vaccine that are not discussed in this document, as it will be a highly fact-specific analysis. If the IHE is considering administering the vaccine, rather than simply requiring proof of vaccination, the IHE should consult with its assigned AAGs.

vaccination is not a medical examination or disability-related inquiry under the ADA. However, follow up questions about why an employee has not received a vaccination may elicit health information from the employee, which would constitute a disability-related inquiry under the ADA.

Also, if an employer is mandating vaccination for its employees and is directly administering the vaccine to its employees, any pre-vaccine medical screening questions would constitute disability related inquiries under the ADA. In that case, the employer must show that these screening inquiries are "job-related and consistent with business necessity." If an employer is offering vaccination to its employees on a voluntary basis, then the employer does not need to demonstrate that the medical pre-screening is "job-related and consistent with business necessity" because the employee can decline to complete the medical pre-screening (in which case the employer can decline to vaccinate the employee). *See* EEOC guidance, K.2.

7. What are the considerations and legal requirements associated with requiring students to be vaccinated for COVID-19?

In some ways, the issues associated with adopting a mandatory vaccination policy for students are easier to navigate on the front end because the IHE can incorporate vaccine requirements into prospective residential living agreements and registration requirements; in other words, the vaccine can be contractually required in order for students to live and learn on campus.

In deciding whether or how to move forward with a vaccine mandate for students, among the numerous policy considerations, the IHE should also consider:

- For existing students who have invested a significant amount of time and money into their education at the IHE, would a mandatory vaccination policy interfere with a student's ability to continue and graduate? What are the student's options if they cannot, or are unwilling to, be vaccinated? Will they have the ability to complete their degree through remote learning? Will they be required to transfer to another institution?
- Whether the requirement will be linked to being on campus or participating in activities held in-person or some other circumstances, such as participation in a clinical program, a professional certification program, an internship, or sports? If it is required for these subsets of students (and this may actually not be within the complete control of the institution) how will that impact the ability of those students to continue in their chosen program and/or receive financial aid/scholarships?
- For students who are required to be vaccinated, what information will the student be required to submit to prove that they have been vaccinated? Where and how will that information be stored/maintained?
- Revising or crafting language of the IHE's website, catalogues, and other literature to accurately describe the experiences and services offered by the IHE to vaccinated

> students, while, at the same time, preserving flexibility, given the uncertainty of circumstances in this pandemic. Uncertainties include, but are not limited to, the limited availability of the vaccine and distribution timeline, potential mutation of the virus, and the possible rescission of the EUA of one or more of the vaccines. Accurate and appropriately conditioned descriptions of educational services and experiences are of particular importance. Failure to update IHE representations reflecting pre-COVID-19 expectations and services in a post-COVID-19 setting is risky. Disgruntled students whose education has been impacted by the pandemic have used these types of IHE representations to form the basis for lawsuits around the country alleging breach of contract, false representation, and fraud.

Reasonable accommodations should be provided for in accordance with the IHE's standard disability and religious accommodation policies and procedures. Depending on the increase in workload, the IHE may want to consider whether the office that determines whether a request for accommodation is reasonable and should, therefore, be granted, will require additional resources in order to process all accommodation requests in a timely manner.

The IHE will want to actively monitor guidance and requirements from the CDC, state and local health authorities, and other entities so that it can adjust any vaccination policy to satisfy its legal obligations. Please consult with your AAG as you develop any such policy, language, or related documents to help mitigate legal risk.

8. **If a student health clinic administers the vaccine to students, will FERPA govern any data collected from the students receiving the vaccine?**

Probably. The clinics will be bound by the same conditions as all providers administering the vaccine. All clinics, pharmacies, and hospitals interested in administering COVID-19 vaccine must enroll in the federal COVID-19 Vaccination Program and sign a Vaccination Program Provider Agreement. One of the conditions of the Agreement is that providers submit vaccine administration data through either their state's immunization information system (IIS) or another system designated by CDC according to CDC documentation and data requirements. The organization must preserve these records for at least three years following vaccination. If maintained by the IHE, this data likely falls under the protection of the Family Educational Rights and Privacy Act (FERPA). Therefore, we strongly recommend that the clinics incorporate a FERPA-compliant notice and consent to limited data disclosure to the Washington State Department of Health (DOH) and CDC as part of the informed consent process prior to vaccination. Our understanding is that data reported from DOH to the CDC will be in de-identified form, but DOH will maintain personally identifiable data supplied by all providers.

If a student does not consent to the disclosure of information in satisfaction of this obligation, the institution will still have the ability to satisfy the documentation and data requirements under FERPA's health or safety exemption. *See* 34 C.F.R. § 99.36; 34 C.F.R. § 99.31(10). However, the

logistics of performing an accounting of disclosures documenting the threat would be more burdensome. *See* 34 § 99.32(a)(5); *accord*, 73 Fed. Reg. at 74837.

9. Are there alternatives to mandatory vaccination programs?

Yes. IHEs may want to consider other alternatives to a mandatory vaccination program, such as:

- Programs that encourage and/or incentivize voluntary vaccination; and
- Continued teleworking, online classes, social distancing, face coverings, and safeguards for any in-person interactions.[9]

10. What factors should an IHE consider if it intends to adopt a mandatory vaccination program for some or all of the campus community?

Factors to consider when developing and implementing any mandatory vaccination program include the following:

- Identifying and linking the vaccine requirement to campus health and safety;
- Whether a voluntary vaccination program would be sufficient to meet the IHE's goal of protecting campus health and safety;
- The availability of the vaccine;
- The vaccines currently available require two inoculations over the course of either three or four weeks. Mandatory vaccination programs should consider the time it takes to administer the vaccine and for the recipient to develop immunity;
- Since there will be a delay before the vaccination will be widely available, consider offering alternatives to in-person attendance for both students and employees as part of contingency planning, such as online courses, hybrid courses, and cohorts;
- Avenues for requesting exemptions, such as disability and/or religious accommodations (Access Services for students/HR for employees);
- If the policy only applies to certain employees and/or students, establish a link between the vaccine requirement and the employee's duties or the student's activities. Be prepared to revise position description forms, class syllabi, and student handbooks to make it clear when vaccination is linked to an essential function of the employee (first

[9] There is not yet sufficient information about the extent to which vaccination impacts an individual's ability to transmit COVID-19. Information currently available indicates that, even after vaccination, face covering and other social distancing requirements are likely to be necessary. As such, until further information becomes available, the IHE may want to presume that the vaccination will increase safety on campus but will not replace existing face covering and social distancing requirements. Like all matters relating to COVID-19, this is likely to be subject to review and revision as more is learned about the virus and the efficacy and impact of the vaccine.

responders, travel, close interaction with others, etc.) or activities of a student (clinical position, in-person labs, student athletes);

- Engage in bargaining. *Virginia Mason Hosp.*, 511 F.3d 908;
- If an IHE already has vaccination requirements (*e.g.*, measles and mumps), ensure that the COVID-19 and existing vaccination requirements and policies, as well as the accommodations offered, are administered consistently.
- Consider the extent to which mandatory vaccination needs to be combined with masking and social distancing, which may be required by state or nationwide restrictions/health authorities. Also consider the extent to which students who have a medical, religious, or philosophical objection to being vaccinated can or will be allowed on campus and what protections and/or restrictions are necessary to protect the campus community from the risk of spread and/or outbreak.

11. Could an IHE face liability if it does not adopt a mandatory vaccination program?

The answer to this question is very context-specific and subject to future developments. One factor will be whether there is a standard established by the CDC, state or local health authorities, or other governmental entities. Another factor may also include the standard of care involving mandatory vaccines that evolves over time and whether a mandatory vaccination program becomes the *de facto* "standard of care" for IHEs for certain groups (*e.g.*, students living in on-campus residential facilities). However, given that the impact of COVD-19 is in flux and there can be localized surges, the advice and assessment of local health authorities may be afforded some deference.

12. Could an IHE face liability if it adopts a mandatory vaccination program and an individual experiences health issues as a result of the vaccination?

To the extent an IHE engages in distributing or administering the vaccine, the federal Public Readiness and Emergency Preparedness (PREP) Act may come into play. Under the PREP Act, the Secretary of the Department of Health and Human Services (the Secretary) is authorized to issue declarations providing immunity from liability for losses or damages arising out of, relating to, or from the administration or use of countermeasures for diseases, threats, and conditions that constitute a present or credible future risk of a public health emergency. 42 U.S.C. § 247d-6d. "Countermeasures" include vaccines developed to combat a disease. This immunity extends to entities and individuals involved in the development, manufacture, testing, distribution, administration, or use of countermeasures as set forth in the Secretary's declaration.

The Secretary issued the initial declaration under the PREP Act for COVID-19 in March 2020, and has updated it several times over the past year.[10] *See* Declaration Under the Public Readiness and Emergency Preparedness Act for Medical Countermeasures Against COVID-19, 85 Fed. Reg. 79190 (March 17, 2020). The administration of COVID-19 vaccines clearly falls within the scope of the immunity granted by this declaration. Entities and persons covered by the declaration include the United States government, manufacturers, distributors, program planners, qualified persons, and their officials, agents, and employees, as those terms are defined in the PREP Act.[11] Although IHEs may qualify, the immunity will apply only to the extent the IHE is actually engaged in distributing, administering, planning for, or providing services or facilities related to administration of the vaccine. Note, for those IHE engaging in administration, distribution, or planning, as described above, the PREP Act will not cover willful misconduct. To avoid a willful misconduct claim, an IHE must report any discovery of a serious injury or death to local public health authorities within seven days.

An IHE's status as either an employer or an IHE alone is not sufficient to qualify for PREP Act immunity. Therefore, a litigant will likely argue that their COVID-19 injuries resulted from the IHE's requirement that they receive the vaccination, rather than the actual administration of the vaccination.[12]

Eligible individuals (or their survivors) who sustain a serious physical injury or die as a direct result of the administration or use of the COVID-19 vaccine can seek compensation from the Countermeasure Injury Compensation program (the CICP). 42. U.S.C. § 247d-6e. Recoverable benefits include medical expenses, lost income, and survivor death benefits. To prevail, a claimant must prove their claim with "compelling, reliable, valid, medical and scientific evidence." 85 Fed. Reg. 15203. The CICP is a payer of last resort and, therefore, it only provides benefits that other third-party payers are not obligated to pay.

Given that these statutory limitations on liability do not apply to implementation of a vaccination policy (absent administration of the vaccine by the IHE), an IHE could be sued or face the potential for liability if it is negligent or discriminatory in its implementation of a vaccination policy or broader set of health and safety measures aimed at reducing COVID-19 risk for those who are on

[10] The declaration is currently effective through the final day of the Declaration of Emergency or October 1, 2024, whichever occurs first.

[11] The sole exception to immunity from suit and liability of Covered Persons "is an exclusive Federal cause of action against a Covered Person for death or serious physical injury proximately caused by willful misconduct by such Covered Person."

[12] Employees who are required to be vaccinated by their employers will receive coverage for adverse reactions to the vaccine under Washington's Industrial Insurance Program (worker's compensation), which is an exclusive remedy for workplace injuries. IHEs should be prepared to process any such alleged injuries in accordance with their standard worker's compensation procedures. Additionally, it is currently unknown whether worker's compensation will cover adverse reactions to the vaccine if an employer does not mandate the vaccine, but benefits from the employee's decision to be vaccinated.

campus.[13] Proof of negligence would require a plaintiff to prove that the IHE had a duty of care, breached that duty of care and, as a result, the plaintiff suffered injury. *See* sections 5, 6, 7, and 9, above; each of which provides information about the obligations to accommodate individuals with disabilities and/or on religious grounds. In order to safeguard against the potential for these types of allegations, the IHE should have any policy reviewed by its AAG before implementing to ensure it relies on guidance from the CDC, and state and local health authorities, along with input from those on campus with health, employment, and accommodation expertise when developing the policy.

13. If an IHE decides to advertise that it will be holding in-person classes during the 2020-21 academic year, what can it do to mitigate potential liability in light of uncertainties about how the pandemic and the vaccination program will progress?

The IHE will want to include qualifying language that informs both prospective and returning students of the policy that the IHE has adopted relating to in-person classes. This could include contingent language that reflects that in-person classes are expected to be available to vaccinated students. Consider identifying the alternative platforms that are available to students or that may be implemented if insufficient vaccinations are not available or are ineffective. Consider language that gives the IHE flexibility in selecting the modes and platforms best suited under the circumstances.

[13] Courts have rejected claims of immunity under the PREP act for failure to implement adequate controls or protocols to minimize COVID-19 spread. *See Baskin v. Big Blue Healthcare, Inc.*, Case No. 2:20-cv-2267-HLT-JPO, 2020 WL 4815074 (D. Kan. Aug. 19, 2020) (PREP Act does not protect against claims for alleged failures to take preventative measures); *Sherod v. Comprehensive Healthcare Mgmt. Servs., LLC*, No. 20cv1198, 2020 WL 6140474 (W.D. Pa. Oct. 16, 2020) (PREP Act does not protect against a decision not to provide or distribute available countermeasures); *Gunter v. CCRC OPCO-Freedom Square, LLC*, No. 8:20-cv-1546-T-36TGW, 2020 U.S. dist. LEXIS 201622 (M.D. Fl. Oct. 29, 2020) (failure to implement adequate controls or protocols to minimize COVID-19 spread has "nothing to do with the administration of a qualified pandemic or epidemic product, drug, biological product, or device for which the PREP Act provides immunity.").