

COVID-19 Vaccination: Setting Up On-Site Programs

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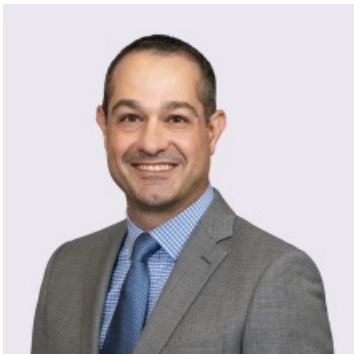
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Meet the Authors



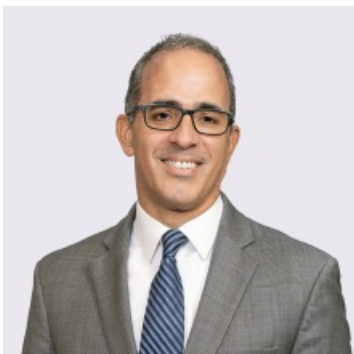
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The Biden administration [has called for](#) all people at least 18 to be eligible for the COVID-19 vaccine by April 19, 2021. [Most states have already done so.](#)

A [BenefitsPro article](#) cites a 2017 survey from the Society for Human Resource Management (SHRM) that found almost 60 percent of employers offer on-site flu vaccinations. Naturally, with expanding availability of COVID-19 vaccination doses and widespread eligibility, organizations are asking whether setting up an on-site COVID-19 vaccination program is more involved than one offering flu shots. The short answer is yes.

The country continues to operate under a national emergency due to a pandemic, not present during a typical flu season. Accordingly, concerns about safety and minimizing spread are significantly amplified. Individuals tend to be familiar with flu vaccines, not so with the current COVID-19 vaccines. Concerns over the emergency use authorization status of the COVID-19 vaccine, privacy, individual rights, school openings and childcare, effects on continued employment, liability, and so on are apparently not as prominent when getting an annual flu shot.

Taking those and other concerns into account, organizations considering setting up an on-site COVID-19 vaccination program have several issues to consider. Below is a nonexhaustive list of a few of those issues. Additionally, the Centers for Disease Control and Prevention [has provided some guidance](#) for organizations establishing a workplace vaccination program, as has the [National Institute of Health](#).

Getting Organized

Whether an organization will set up a program for one or multiple locations, it is critical to have a plan in place and responsibility assigned to carry out that plan. Many organizations will rely on a local health department (LHD) or a third-party health care provider (TPHCP) to administer the vaccine. But it is unlikely that either will just show up and start putting needles in arms. The organization will need to address a range of action items, and that will include outlining who will be responsible for what.

Vaccine Administration and Reporting

A big question is who is going to order, receive, and store the vaccine doses, administer them to patients, satisfy federal and state reporting requirements, and carry out other health-related duties and obligations. Unless the organization has an existing on-site occupational health clinic, staffed with persons who are adequately trained, it will typically look to an LHD or TPHCP who will marshal, store, dispense, and, if needed, dispose of unused vaccine doses. Additionally, that entity generally will be responsible for reporting mandates and related activities.

When partnering with an LHD or TPHCP to administer vaccines, a careful review of the



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services or other agreement is warranted to clearly set out which services are being provided and which are not being provided, among other issues.

Facility Suitability and Preparedness

Even as the pace of vaccinations continues to increase, the threat of contracting COVID-19 remains. Thus, federal and state health authorities recommend continuing health and safety measures: screening, social distancing, mask wearing, and so on. Thus, planning for on-site COVID-19 vaccine administration should include a review of how the facility can best accommodate the personnel needed to deliver the vaccine, as well as those receiving it. This should include evaluating the space and traffic flow and designating separate places for registration, vaccine administration, and recovery to ensure appropriate social distancing.

Preparing a chart of the space can help organizers maintain the applicable safety measures, as well as better plan for contingencies and adequate communication.

Liability

Whether setting up a health fair or an on-site vaccination clinic, concerns about potential liability will certainly arise, such as from an adverse reaction to the health service rendered. This is no less true for the COVID-19 vaccine. However, healthcare providers and employers may qualify for a level of immunity under the [Public Readiness and Emergency Preparedness Act](#) (PREP Act), provided the requirements of the PREP Act are satisfied. The Prep Act protects “covered persons,” such as:

- *Program planners:* individuals and entities involved in planning, administering, or supervising programs for distribution of a countermeasure (*e.g.*, state or local governments, Indian tribes, or private sector employers or community groups that establish requirements or provide guidance, technical or scientific advice or assistance, or provide a facility); and
- *Qualified persons:* persons who prescribe, administer, or dispense countermeasures such as healthcare and other providers or other categories of persons named in a declaration, that engage in countermeasures covered by the Health and Human Services Secretary’s declaration, as amended, such as “products that are approved, cleared, or licensed by FDA; authorized for investigational use, i.e. an Investigational New Drug [] or Investigational Device Exemption [], by FDA, authorized under an EUA by FDA, or otherwise permitted to be held or used for emergency use in accordance with Federal law” in a manner consistent with the requirements of the declaration, provided they have not engaged in willful misconduct.

Organizations should review the scope of this immunity with legal counsel, along with other steps for mitigating potential exposures not covered by the PREP Act, such as insurance and contract negotiation.

Communications

There are several areas of communication that must be considered, including what needs to be communicated, who is responsible for communicating, and when to communicate. For example, it is important to ensure those eligible to get the vaccine have been provided sufficient information to make an informed decision about getting vaccinated. Often the LHD or TPHCP will provide employers information that will need

to be shared with employees prior to the on-site vaccination day. Further, questions may arise in the process from employees, the third-party provider, or even the media concerning the organization's vaccination program. Anticipating and planning response strategies to these inquiries will help avoid potentially damaging miscommunications while building confidence in the program.

Employment Issues

Bringing COVID-19 vaccinations on-site for employees will raise several employment issues that organizations should be thinking about, such as:

- *Whether vaccination should be mandatory or voluntary.* This is a difficult decision for many organizations that requires careful examination of several factors, including employee morale and applicable federal and state law. For employers moving forward with an on-site COVID-19 vaccination program, additional considerations exist if they intend to mandate the vaccine. Since pre-screening questions required as part of the on-site administration will include medical inquiries, whether an employer can mandate that employees receive the vaccine will be limited. Generally, employers who administer or contract with an administrator to come on-site to vaccinate employees can only mandate if the pre-vaccination screening questions do not include inquiries about genetic information and vaccination is job-related and consistent with business necessity.
- *COVID-19 vaccine incentives.* As an alternative to mandating vaccinations, employers who wish to strongly encourage vaccinations, may choose to *offer* employees an [incentive to get the vaccine](#). Depending on the incentive, employers, will need to be prepared to provide reasonable accommodations for persons with disabilities and religious objections, and to assess the appropriateness of the incentive.
- *Informed consent.* Employers holding on-site COVID-19 vaccination programs may wish to have employees sign an informed consent as a condition of receiving the vaccine on-site. An informed consent should contain appropriate disclosures about the vaccine and the vaccination process, a statement that the employee understands the process as well as an acknowledgment that receipt of the vaccination was the employee's free choice.
- *Employee benefit.* An arrangement sponsored by an employer to provide vaccines for employees may be structured to be part of or itself an employee welfare benefit plan under the Employee Retirement Income Security Act of 1974 (ERISA). Employers should seek legal counsel on whether ERISA applies, as well as other laws regulating benefit plans, such as HIPAA and the Affordable Care Act.
- *Eligibility.* Organizations may want to consider whether persons other than common law employees based at the administration site will be eligible to get the vaccination on-site. Other categories of individuals to consider might include employees working and living in other states, non-U.S. employees, family members, contractors, and contingent workers.
- *Scheduling, leave management.* Offering a COVID-19 vaccination program on-site could raise logistical challenges regarding scheduling – when to schedule the first and second doses, the amount of lead time needed to maximize participation, how to stagger scheduling to avoid business interruption, providing time for employees who may experience adverse effects, and the like. Working ahead of time to address these issues could go a long way to maximizing vaccination rate and

minimizing business interruption and dissatisfied employees.

- *Labor relations.* Offering a COVID-19 vaccine to employees represented by a labor union may require negotiations with that union.

Data Privacy and Security

The ongoing [debate over privacy and “vaccine passports”](#) illustrates the sensitivity about information relating to a person’s vaccination status. Accordingly, an organization’s plan for on-site delivery of COVID-19 vaccines to employees should carefully consider how information about vaccination status will be shared. Some sharing of information in such an environment may be unavoidable (“Hey, I saw you getting a vaccination, how did it go?”). Organizations should be doing what they can to minimize unnecessary and unauthorized access and acquisition of such information. This includes coordinating with third-party vendors where applicable and ensuring appropriate privacy and security safeguards are in place. If an employer requires proof of vaccination from employees, such information should be treated as confidential medical information.

There is quite a bit to think about when setting up a COVID-19 vaccination program. While flu vaccination programs likely differ, prior experience with health fairs and flu vaccination offerings can be helpful reference points. Having a good team in place, careful planning, and the support and collaboration of an LHD or TPHCP, among other things, will help lead to a successful program.

If you have questions or need assistance, please reach out to the Jackson Lewis attorney with whom you regularly work, or any member of our [COVID-19 team](#).

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