

COVID-19 Provider Enrollment FAQs

The Michigan Department of Health & Human Services (MDHHS) sent to hospitals and health systems the official provider enrollment agreement form required for participation in COVID-19 vaccination efforts for the state of Michigan. These efforts will initially focus on vaccinating healthcare workers and first responders, and health systems/hospitals will be the primary recipients of dosages to vaccinate these populations. Health systems/hospitals have been asked to submit their enrollment forms by Oct. 16 for the primary recipient sites. The questions below have been submitted by members; to assist all members, the MHA is sharing these FAQs with all hospitals to assist in your enrollment efforts and planning purposes. This document will continue to be updated as the process continues.

Topic: Form Completion

Question: Our health system owns multiple non-hospital sites of care. Should a separate form be submitted for all those non-hospital sites that will eventually administer vaccine to patients?

Answer: Forms should only be submitted for the Oct. 16 deadline for sites that wish to receive and administer vaccine to healthcare personnel and should include any personnel that could be at risk of exposure and include EMS/other healthcare workers from the community or agencies associated with the healthcare system. To ensure the storage and use requirements of the initial shipments of vaccine, sites should not separately enroll that cannot receive, handle and administer the initial batches of 975 vaccine dosages in a short time period to accommodate the vaccine's expiration dates. At a later date, hospitals may enroll additional sites of care that will vaccinate patients if they want those sites to receive shipments directly, or the system may distribute dosages to the site from their larger allocations.

Question: Which/how many providers should be listed on page 7, section B, asking for providers with prescribing authority?

Answer: Per the MDHHS letter, organizations should only list those providers with prescribing authority that will be leading your COVID-19 vaccine effort/issuing standing orders for the listed location.

Question: Can our health system leadership complete Section A for all hospital sites?

Answer: Yes, a health system CEO/chief medical officer may complete section A for all locations within the system enrolling in the COVID-19 vaccine program. Section B must be completed for all enrolling locations that wish to receive and administer vaccine to healthcare personnel. The form cannot be split and sections cannot be left empty even if your organization is submitting multiple forms, therefore Section A should be completed for all forms submitted even if the information is repetitive.

Question: Why is the form asking about patients served on page 5 of Section B, if this effort is focused on vaccinating healthcare personnel?

Answer: Questions about each location's number of patients served on page 5 are to provide the state with information about *future* capacity of each location to vaccinate community members. **Please answer this question including *patients served by the location*.**

Topic: Operations

Question: How should we vaccinate employees of non-hospital sites if we cannot have vaccine shipped directly to them?

Answer: Hospitals should not redistribute the initial batches of vaccine that require ultracold storage. Hospitals should arrange for those offsite employees to come to a hospital setting/the hospital's designated vaccine administration sites to receive the vaccine. When smaller batches of the vaccine are available in batches of 100 that do not require such stringent storage/usage, hospitals may be able to distribute those to their ancillary facilities for administration at those sites to additional personnel, patients and others in the community.

Question: Will our health system/hospital be charged for the vaccines/kits we receive? Should patients be charged?

Answer: No. Vaccines and kits will be shipped to you at no cost. Recipients of the vaccine should not be asked for any payment or financial contribution and no recipient may be turned away if they are uninsured or for any other reason. It is expected that administering providers will be permitted to charge a recipient's insurer a small administrative fee for giving the vaccine, but the details about how this fee is structured, the amount and more are not yet available.

Question: What will the state provide beyond the vaccine itself?

Answer: Supply kits will automatically arrive to support vaccination efforts which will include 105 needles (various sizes), 105 syringes, 210 alcohol prep pads, 4 surgical masks, 2 face shields, and 100 COVID-19 vaccination record cards for vaccine recipients. If vaccine requires reconstitution with diluent or mixing with adjuvant, mixing kits with supplies will be included. Kit quantities will coordinate with the number of vaccine dosages sent to a location as closely as possible. Kits will NOT include sharps containers, gloves and bandages, or other PPE.

Question: The form never asks how many employees we have; how do we know we will receive enough dosages for our employees?

Answer: The state has official sources of employment data for health systems and hospitals that will be used to initially estimate how many dosages your organization/sites will need to vaccinate all your employees. If your location(s) may also receive additional doses to help vaccinate other healthcare workers not affiliated with your organization, and first responders in your area. Additional guidance on assisting with vaccinating these populations will be forthcoming from MDHHS.

Question: Can we have our vaccine shipments sent to an out-of-state location for storage and/or distribution?

Answer: No. Michigan is only able to ship COVID-19 vaccines and kits to Michigan sites. If your organization has enrolling sites in other states, those sites must register in the state in which it is located.

Question: How should we plan to prioritize vaccinations among our employees?

Answer: The Advisory Committee on Immunization Practices (ACIP), a group within the CDC, is finalizing vaccine prioritization recommendations that will be issued as soon as possible. These can be used to guide your organization's employee vaccine efforts. We expect these to recommend those workers who are in higher risk, direct patient care roles receive vaccine first. Higher priority groups may also include older employees or those with comorbidities that place them at higher risk of severe illness. Please watch for ACIP guidance as you develop your internal vaccine plans.

Question: Should our hospital(s) attempt to purchase ultracold storage units to accommodate receipt of the vaccine, if we don't have such storage now?

Answer: Not at this time. The vaccine will be shipped in special storage containers including dry ice that should keep the vaccine at the appropriate ultracold temperature. Additional dry ice can be used to maintain storage temperature requirements. MDHHS is working to identify dry ice suppliers in certain regions of the state that do not have strong suppliers locally at this time.

Question: Does the PREP Act apply to COVID-19 vaccines and other services?

Answer: The Public Readiness and Emergency Preparedness Act (PREP Act) authorizes the Secretary of the U.S. Department of Health and Human Services to issue a declaration to provide liability immunity in the event of a public health emergency. The PREP Act extends protection to covered entities and individuals against claims under federal and state law relating to the manufacture, distribution, administration, or use of medical countermeasures.

In March, Secretary Azar issued a Declaration retroactively effective to February 4, 2020, which currently extends its protections through October 1, 2024.

For COVID-19, the Declaration offers immunity under federal and state law against all claims of loss "caused by, arising out of, relating to, or resulting from" the "manufacture, testing, development, distribution, administration, and use" of "covered countermeasures." "Covered Countermeasures" are defined in Section VI of the Declaration to include drugs, biological products, or devices used to treat, diagnose, prevent, or mitigate COVID-19. The immunity extends not only to COVID-19 drugs, but to other products and technologies intended to enhance the use or effect of a drug, biological product, or device, or to protect against adverse effects from those products. For a product to qualify as a covered countermeasure, it generally must be either approved, licensed, or authorized by the FDA; cleared for investigational or emergency use under an Investigational Drug Application or Investigational Device Exemption by the FDA; authorized for emergency use under an Emergency Use Authorization; or described in the Emergency Use Instructions issued by the CDC.

Both the PREP Act and the June 4, 2020 Second Amendment broadly define "Covered Countermeasures" to include qualified pandemic and epidemic products that "limit the harm such pandemic or epidemic might otherwise cause."

Members with additional questions may contact Ruthanne Sudderth, senior vice president, Public Affairs & Communications at the MHA at rsudderth@mha.org. Members with question may also contact the state directly at MDHHS-COVIDVaccineProviders@michigan.gov.