

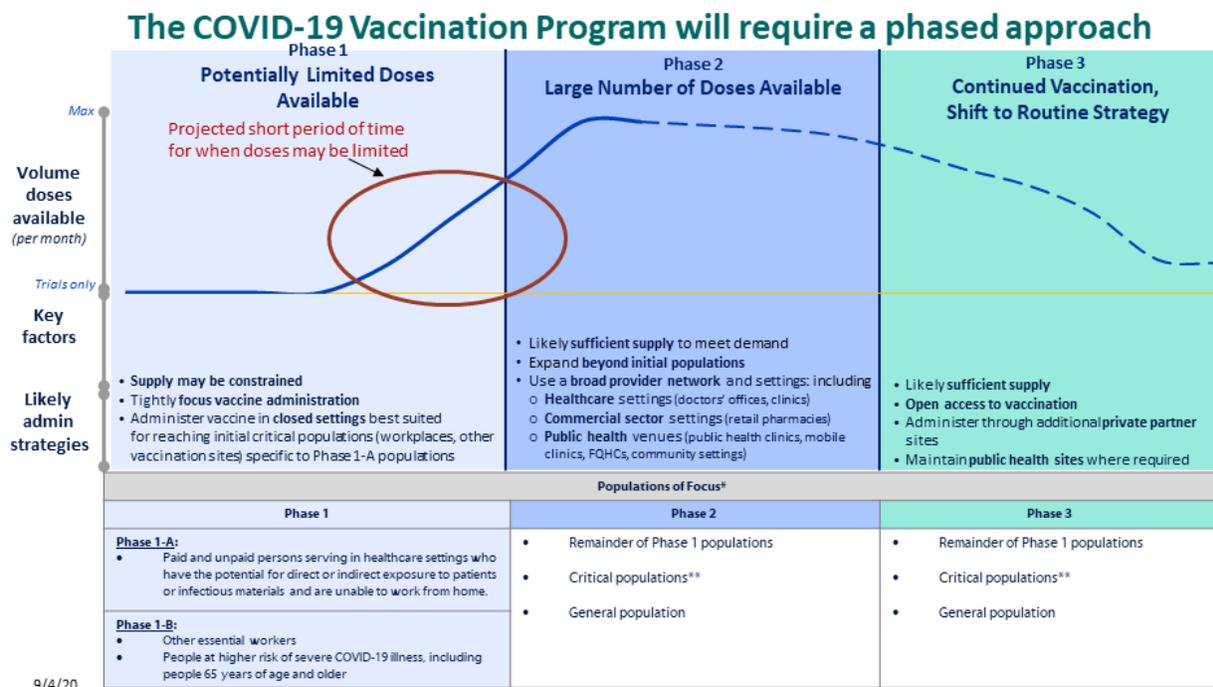
Missouri COVID-19 Vaccination Preliminary Provider Info

Mission: Deliver a safe and effective vaccine to Missouri citizens to reduce morbidity and mortality of COVID-19.

Background: The CDC produced planning tools to develop a mass vaccination plan and provided them to states to facilitate creation and delivery of a state plan by 15 October. HHS published a news release with documents outlining the framework for the plan on 16 Sep 2020.

<https://www.hhs.gov/about/news/2020/09/16/trump-administration-releases-covid-19-vaccine-distribution-strategy.html>

The CDC planning documents anticipate a three phase approach: a first phase of vaccinations when vaccines have very limited availability, a second phase of increasing availability, and a third phase of widespread availability (similar to routine vaccinations). Based upon these assumptions, the state is currently finalizing targeted, critical populations for early phases, based on CDC guidance.



Asks:

1. Review this document and the attached CDC provider agreement (which will not be able to be changed). The CDC is working on making the forms electronically available to allow easy submission, but the requirements and expectations will not change as that becomes available.
2. If potentially interested, please complete the COVID 19 Vaccine Survey accompanying this message. These answers will provide planning visibility into potential availability of providers for CoVid vaccination.
3. Whether interested or not, please provide feedback to your provider organization on any concerns or any additional information needed. This feedback will help guide future FAQ documents.

FAQ:

1. **Can a system, or group, sign up to participate en masse?** Yes. The provider agreement (Part A) may be signed by a group CMO/CFO on behalf of the entire group. However, each separate vaccination site (and the supervising physician of the vaccinations at that site) must complete a separate site survey and Part B enrollment.
2. **What legal liability exists from providing the CoVid Vaccination?** While you should consult counsel for your unique situations, the CoVid vaccination has been determined to be a medical counter-measure under the PREP Act, providing immunity from liability for delivery of the immunizations. Likewise, any patients affected will NOT be covered under the Vaccine Injury Compensation Fund, but will be managed under a separate federal program.
3. **Is there reimbursement for vaccine administration?** Yes. Providers are allowed to charge an administration fee in the range of \$10-15. Medicaid, Medicare, and private insurers may cover these immunizations at no cost to the patient. Providers may NOT charge for the COVID-19 Vaccine itself, or any ancillary supplies provided by the federal government. HRSA is currently establishing a program to provide reimbursement to providers for unreimbursed vaccine administration.
4. **Can vaccine be withheld from someone who does not have the ability to pay?** No. As part of the provider agreement vaccine should be provided without regard to ability to pay. This is designed to be provided at no cost to the patient.
5. **Can Paramedics, Nursing students, Medical students, Pharmacy students and Paramedic students administer the vaccine?** Yes with appropriate supervision that is in accordance with the school's curriculum with oversight by a prescribing provider enrolled on Part B of the provider agreement. For paramedic students the be able to provide vaccinations would require a clinical contract between the school and the agency administering the vaccinations. The school should provide the training, with the school's medical director approving the training module. The agency administering the vaccination would then provide preceptor oversight. Any EMS agency who would like to provide vaccines, but does not do so currently, would have to have their medical director write a policy an protocol, as well as provide the education, training, and quality improvement policy for them to do so.
6. **Will there be training on how to administer the vaccine?** Yes. CDC is currently in the process developing the training that will be disseminated and available at the Missouri COVID Vaccine website ([web address here](#)).
7. **Is it required to document the administration of the vaccine in an Immunization Information System (IIS)?** Yes. Within 24 hours it is required to have the information placed into the IIS. Missouri will utilize VAMS for phase 1 and ShowMeVax for phases 2 and 3. ShowMeVax is Missouri's Immunization Information System. VAMS does not have the capability to accommodate mass vaccination for phases 2 and 3. Only providers

that will administer vaccine during phase 1 will require VAMS access. All providers in phases 2 and 3 will require ShowMeVax.

8. **Can the flu vaccine be given with the COVID-19 Vaccine?** Tentatively yes. However, all routine vaccinations other than influenza are permitted beginning >30 days after last dose of study intervention. Licensed influenza vaccines are permitted at any time per protocol.
9. **How will the vaccine be delivered?** A number of scenarios are being developed, but the two tables below describe potential situations, dependent on individual vaccines.

Vaccine A	
<p>SHIPMENT <i>3 separately acquired components (mixed on site)</i></p> <ol style="list-style-type: none"> 1. Vaccine <ul style="list-style-type: none"> • Direct to site from manufacturer (on dry ice) • Multidose vials (5 doses/vial) 2. Diluent <ul style="list-style-type: none"> • Direct to site from the US Government (USG) at room temperature) 3. Ancillary supply kits (for administration and mixing) <ul style="list-style-type: none"> • Direct to site from USG (at room temperature) 	<p>ON-SITE VACCINE STORAGE <i>Frozen (-70 °C ± 10 °C)</i></p> <ul style="list-style-type: none"> • Must be used/recharged within 10 days • Storage in shipping container OK (replenish dry ice within 24 hours of receiving shipment and again 5 days later) <p><i>Thawed but NOT reconstituted (2–8 °C)</i></p> <ul style="list-style-type: none"> • Must use within 5 days (discard unused doses after 5 days) <p><i>Reconstituted (room temperature)</i></p> <ul style="list-style-type: none"> • Must use within 6 hours (discard any unused, reconstituted vaccine after 6 hours)
<p>ORDERS <i>Large quantities, to large administration sites only</i></p> <ul style="list-style-type: none"> • Minimum order: ~1,000 doses • Maximum order: ~5,000 doses 	<p>ADMINISTRATION <i>2-dose series (21 days between doses)</i></p> <ul style="list-style-type: none"> • On-site mixing required; reconstitute with diluent just prior to administration • Administer by intramuscular (IM) injection
Vaccine B	
<p>SHIPMENT <i>2 separately shipped components</i></p> <ol style="list-style-type: none"> 4. Vaccine <ul style="list-style-type: none"> • To central distributor (at -20 °C) • Multidose vials (10 doses/vial) 5. Ancillary supply kits <ul style="list-style-type: none"> • Direct to site from USG (at room temperature) 	<p>ON-SITE VACCINE STORAGE <i>Frozen (-20 °C)</i></p> <ul style="list-style-type: none"> • Storage in shipping container OK <p><i>Refrigerated (2–8 °C)</i></p> <ul style="list-style-type: none"> • Must use within 14 days <p><i>Room temperature</i></p> <ul style="list-style-type: none"> • Must use within 6 hours (discard any unused vaccine after 6 hours)
<p>ORDERS <i>Central distribution capacity required</i></p> <ul style="list-style-type: none"> • Required by Dec 2020 • Maintained at -20 °C 	<p>ADMINISTRATION <i>2-dose series (28 days between doses)</i></p> <ul style="list-style-type: none"> • No on-site mixing required • Administer by IM injection

10. **Where can I find more information?** Updated information will be provided via the Missouri COVID Vaccine website as it becomes available. Additional information can be obtained from the CDC at <https://www.hhs.gov/about/news/2020/09/16/trump-administration-releases-covid-19-vaccine-distribution-strategy.html>