

COVID-19 Vaccine Quality Assurance Visits Frequently Asked Questions

The following questions and answers were compiled based information presented during the COVID-19 Vaccine Informational Session on DHSS Quality Assurance Visits webinar on Monday, June 7, 2021. This document was sent to the Missouri Department of Health and Senior Services to ensure accuracy of the answers.

What is the purpose of the COVID-19 vaccine audit?

COVID-19 Vaccine audits are being completed in accordance with requirements and guidelines set forth by the CDC. These audits are meant to validate the information in the [COVID-19 Vaccination Program Provider Agreement](#). Audits also are the conduit for education and information to ensure safe COVID-19 vaccine administration.

When will vaccine audits begin?

Onsite vaccine audits conducted by the Missouri Department of Health Bureau of Immunization will begin July 2021. All audits are required to be completed prior to December 30, 2022.

Who will receive a vaccine audit?

All vaccine providers registered with ShowMeVax will be audited. Facilities performing the largest quantities of vaccination currently will be prioritized. Federal vaccine partners will not be a part of this auditing process and will receive their audit through a different coordinating body.

Will there be notice of these visits?

Yes. DHSS send an email and letter to the primary and back-up COVID-19 vaccine contact with a date range for the audit. They will work with the vaccinator to find a mutually agreeable time within the date range provided. When scheduling the visit, keep in mind that DHSS would like to observe COVID-19 vaccine administration if possible.

How long will the vaccine audit last?

Generally, these visits last 3-4 hours. However, this is an estimate as these visits have not previously been conducted.

Who needs to be present for the COVID-19 vaccine audit?

The primary and backup coordinator need to be available for the entire visit. DHSS encourages the Chief Medical Officer, or designee, and Chief Executive Officer to be available for the last 30 minutes of the visit during which educational improvements and wrap-up of the visit will be discussed.

Are there checklists or guides to help facilities prepare for these visits?

The [COVID-19 Vaccination Program Provider Agreement](#) should be used to prepare for these visits. If your facility participates in the Vaccine For Children Program (VFC), staff should reach out to the VFC coordinator at their facility to discuss the visits DHSS conducts for VFC as these audits are modeled after these visits.

What will the audits include?

- Vaccine administration records – DHSS will review a random sampling of vaccine administration records to make sure the were administered and the correct information is recorded in the record as required by law.
- Consent forms
- Vaccine eligibility documentation – at this time DHSS is only reviewing to ensure vaccination of the appropriate age of vaccine recipients.
- All relevant policies and procedures related to COVID-19 including vaccine handling, storage, reconstitution or preparation, administration, and documentation.
- Waste logs
- Documentation of vaccinator training/staff training certificates
- Refrigerator/temperature logs
- Redistribution paperwork
- Storage and handling documents
- Vaccine tally sheets (if used)
- Digital data loggers certificates
- COVID-19 vaccine billing records – need to be able to talk to billing staff if needed.
- Vaccine adverse event management plan
- Written emergency storage plan (used in case a facility loses power)
- DHSS staff will need access to the vaccine storage area and breaker box

Does documentation need to be in a certain format for the visit?

DHSS will review documentation the documentation in way it is maintained by the vaccinator – this can be scanned in copies, paper copies or electronic records.

A lot of the information covered in these visits is reported by our facility in ShowMeVax. Will the auditor know provider specific information prior to arrival?

Yes, the auditor will review the participants enrollment and documentation in ShowMeVax prior to the onsite visit.

Will other standards from CMS or DHSS be included in site visits?

No, DHSS is only reviewing COVID-19 vaccination.

How will the noncompliance be cited? Are there penalties?

There are no penalties at this time. These visits are designed to be advisory and educational in nature, not punitive. If an issue is noted during your visit, it will be reported in the notes section and discussed at the end of your visit. DHSS may call your facility to check in to ensure the issue is being addressed appropriately a month or two after the visit is conducted.

Does each nurse have to provide the CDC training, or can they do a train the trainer (TtT) model?

The auditors will be primarily review training documentation for individuals who prepare the vaccine and will ensure staff is aware of how to administer correctly. Related training records will be reviewed. Prior to the visit, if the auditor sees multiple VAERS reports related to vaccine administration errors, such as cellulitis, for the facility, the auditor will review training records in more details and will ask to check staff technique to identify any additional technical assistance or resources needed. Follow up communication with DHSS validated train the trainer as an appropriate vaccinator training method.

Will there be a review for stratification of vaccine recipients by phase and tier to ensure eligibility was met?

DHSS will only review current vaccine eligibility. At this time, age is the only eligibility criteria that will be reviewed to ensure you are vaccinating appropriate age.

Waste was documented in ShowMeVax, is that sufficient? Is other documentation required?

Documentation of waste in ShowMeVax is sufficient. During the visit, the auditor will ask to review documentation related to wastage that is kept by your facility if you keep records outside of ShowMeVax.

My facility is no longer administering COVID-19 vaccines, will our facility receive an audit?

If you are enrolled as a COVID-19 vaccinator in ShowMeVax, you will receive an audit visit. Facilities who are no longer vaccinating for COVID-19 may choose to disenroll from the program. However, your facility will not be able to receive future COVID-19 vaccine without reenrolling. For example, if it is determined that booster doses are needed, facilities that disenroll will be required to reenroll into Show Me Vax to receive COVID-19 vaccine.

How does a facility disenroll as a COVID-19 vaccine provider?

Facilities that wish to disenroll should complete the [disenrollment form](#) the [COVID-19 Vaccinator resource page](#).

Can a facility disenroll as a COVID-19 provider but maintain ShowMeVax enrollment?

Yes, using the disenrollment form only removes your facility as a COVID-19 vaccine provider.

Can I disenroll if I have vaccine on hand?

No, facilities must have zero doses of COVID-19 vaccine on hand to disenroll.

I am not sure if I am an enrolled COVID-19 vaccine provider. How do I verify if my facility is enrolled?

The easiest and quickest way to check if you are enrolled is to log into ShowMeVax. Once in the system, click on the clinic tab and select the option to enroll. If it is green you are still enrolled. If you are unable to verify your status this way, please email c19vaxenroll@health.mo.gov.