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# Missouri COVID-19 Vaccinator Newsletter

March 23, 2021

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## Preparing for a new pace

We are encouraged that vaccine supply has continually increased the past several weeks. Last week, our federal partners informed us that we would be seeing a significant increase again in April. The pace is certainly changing, and now is the time to think about what you and your team will need to be successful when the week comes that Missouri vaccinators receive more than double the vaccine that they are seeing now. Will you need more people? More storage capacity? Plan now for what lies ahead so that we can quickly and safely get all willing Missourians vaccinated.

## Insurance Note: Medicare has increased the reimbursement of the COVID-19 vaccine to \$40 per administration.

CMS has released a set of toolkits for providers, states and insurers to help the health care system prepare and assist in swiftly administering these products once they become available. These resources are designed to increase the number of providers that can administer the products and ensure adequate reimbursement for administration in Medicare, while making it clear to private insurers and Medicaid programs their responsibility to cover these products at no charge to beneficiaries. This [webpage](#) provides the payment allowances and other related information for these products. For more information, review the [COVID-19 provider toolkit](#).

## New Standing Orders for vaccine administration

On March 12, 2021, at the direction of President Biden, the Secretary of HHS issued the 7<sup>th</sup> amendment to the declaration issued under the Public Readiness and Emergency Preparedness Act (PREP ACT). The new declaration adds the following, that Missouri has not allowed, to those eligible to give vaccinations: Dentists, Midwives, Optometrists, Respiratory Therapists, and Veterinarians. On its face the PREP Act appears to be only a release from liability for those operating under its authority. However, the US DOJ has issued an [opinion](#), that holds that the PREP Act preempts state and local laws that have to this point prevented those listed above from administering a COVID-19 vaccine.

The Pfizer, Moderna, and Janssen administration [standing orders](#) were rescinded and new orders were issued on March 22. View the [news release here](#) for more details.

# COVID-19 Vaccines Available

Vaccine EUA Date	Pfizer December 11, 2020	Moderna December 18, 2020	Johnson & Johnson February 27, 2021
Doses	2	2	1
Type	mRNA	mRNA	Viral vector
Peak Effectiveness	14 days after the second dose	14 days after the second dose*	28 days after the single dose*
Against Death	100% effective	100% effective	100% effective
Against Severe Infection	75% effective	100% effective	85% effective
Against All Infections	95% effective	94.5% effective	66% effective

\* All three vaccines begin to protect you soon after being administered, including with the first dose. 1

## Statement from CDC on Janssen COVID-19 vaccine dose in combination with mRNA vaccine dose

A single dose of Janssen COVID-19 vaccine may be considered at a minimum interval of 28 days from the mRNA COVID-19 vaccine dose. See [Contraindications and Precautions](#) section for additional information on use of Janssen COVID-19 vaccine and additional precautions in people with a contraindication to mRNA COVID-19 vaccines. Patients who receive Janssen COVID-19 vaccine after a dose of an mRNA COVID-19 vaccine should be considered to have received a valid, single-dose Janssen vaccination—not a mixed vaccination series. For more information visit: <https://www.cdc.gov/vaccines/covid-19/info-by-product/clinical-considerations.html>

## Pfizer-BioNTech sixth dose and low dead-volume syringes

A new set of FAQs released by United States Pharmacopeia (USP) addresses common questions related to low dead-volume (LDV) syringe and needle combinations in the Pfizer-BioNTech ancillary kit and extraction of a sixth dose per vaccine vial. Practice settings have reported success using a combination of 3 LDV syringes and 3 non-LDV syringes for vaccine withdrawal. To ensure success, the CDC is shipping ancillary kits with approximately 80% LDV syringes and 20% non-LDV syringes. This 5:1 ratio should ensure providers are able to obtain all six doses from the Pfizer-BioNTech vial. For additional information, see: [FAQ for Optimizing COVID-19 Vaccine Preparation and Safety \(ashp.org\)](#).

### Vaccine Dosages

	Doses/vial	Volume	Ancillary Content
Pfizer	6	0.3 mL	6 doses/vial
Moderna	10	0.5 mL	10 doses/vial
J&J	5	0.5 mL	5 doses/vial
Rules	<ol style="list-style-type: none"> <li>1. Administer only full doses</li> <li>2. Never try to pool vials to make a full dose</li> <li>3. Do not refreeze any COVID vaccines.</li> </ol>		

# Ancillary Kit Contents (Moderna, J&J, Pfizer) & Deficiency Reporting

## Vaccine Ancillary Kit Contents

Moderna/Johnson & Johnson/ other 100 dose products			
Configured for 100 Doses w/ 5% surplus			
Kit Description	Product	Product Description	Qty / Ea
<i>Ancillary Adult</i>	Needles	22-25G x 1"	<b>85</b>
	Needles	22-25G x 1.5"	<b>20</b>
	Syringes	1ml or 3ml	<b>105</b>
	Alcohol Pads	Sterile, individually sealed	<b>210</b>
	Vaccination Card		<b>100</b>
	Needle Info Card		<b>1</b>
	Face Shield		<b>2</b>
	Surgical Mask		<b>4</b>

Pfizer 1170 dose			
Configured for 1175 Doses w/ 5% surplus			
Kit Description	Product	Product Description	Qty / Ea
<i>PMK Adult</i>	Needles	22-25G x 1"	<b>1000</b>
	Needles	22-25G x 1.5"	<b>240</b>
	Syringes	1ml	<b>1240</b>
	Needles, Mixing	21-25G x 1.5"	<b>205</b>
	Syringes, Mixing	3ml or 5ml	<b>205</b>
	Alcohol Pads	Sterile, individually sealed	<b>2900</b>
	Vaccination Card		<b>1200</b>
	Needle Info Card		<b>10</b>
	Face Shield		<b>25</b>
	Surgical Mask		<b>50</b>
	Diluent		<b>200</b>

## Deficiency Reporting

Vaccine providers are encouraged to report any issues with equipment in the ancillary kits that are shipped with their federal vaccine orders. There are four steps to reporting to ensure enough information is gathered so problem trends in packaging and shipping can be identified.

1. Report deficiencies to McKesson directly; the customer service desk is charged with responding to problems and identifying trends.
2. Report deficiencies to the State Department of Health or clinic/hospital leadership who may then contact the Operation Regional LNO. This helps identify trends in problem equipment.
3. If an error or injury occurs during vaccine administration, enter the information into the [Vaccine Adverse Event Reporting System \(VAERS\)](#).
4. Because syringes are a medical device, complete [FDA form 3500](#). Be prepared to provide photos, lot number, order number, date ordered and date received when filing a report for a deficient ancillary kit.

## Moderna COVID-19 vaccine vials

The Moderna COVID-19 Vaccine (aka “COVID-19 Vaccine Moderna”) has traditionally been filled and distributed in clear vials. In order to best meet the vaccine preparation demands of the COVID-19 pandemic, Moderna has engaged multiple vial sources including SiO2 Materials Science. SiO2 Materials Science produces polymer-based vials which may appear thicker and display a slight green tint as a result of the vial sterilization process during manufacturing. This tinting is strictly visual and **has no impact on the vaccine.\*** Over time, vial tinting may fade naturally, resulting in a faint yellow color. Below are images demonstrating a range of vial colors under various lighting conditions that may be encountered in the field.



*\* Typical range of coloration of Cyclic Olefin Polymer (COP) vials, SiO2 Materials Science, 2020*

View full memorandum from Moderna [here](#).

## Using Missouri Vaccine Navigator

One of the benefits of using Vaccine Navigator is its interface with the State’s Immunization Registry, ShowMeVax. That interface ensures that data entered into Vaccine Navigator transfers into ShowMeVax without additional data entry by the vaccinator. To ensure the data transfer occurs timely and to eliminate errors, a Clinic ID, a Facility ID and the ShowMeVax PIN number must be included when scheduling an event in Vaccine Navigator. Most agencies know their PIN number, but the Clinic and Facility ID are not used in most interactions with ShowMeVax.



Before scheduling events in Vaccine Navigator, please reach out to [Susan Thomas](#) to get these three numbers and ensure the accuracy of your scheduling request.

More Vaccine Navigator resources can be found [here](#).

## Inventory adjustments and wastage

### Inventory Adjustments

Covid vaccine adjustments to on-hand inventory are made **only** when the following applies:

1. Extra – additional doses received from vials.
2. Extra – Subtract for duplicate entries.

**Note: An adjustment is not to be used to deduct administered doses. This is completed through the reconciliation process only. Private adjustment reason will not be used.**

### Wastage

Covid vaccine adjustments to on-hand inventory due to wastage are made **only** when the following applies:

1. VTRCKS - Broken vial/syringe.
2. VTRCKS - Vaccine drawn into syringe but not administered.
3. VTRCKS - Open vial but all doses not administered.
4. VTRCKS - Lost or unaccounted for vaccine
5. VTRCKS – Other – **ONLY USED FOR** - Expired vaccines, loss due to temperature excursions.

Please click [HERE](#) for steps to complete an inventory adjustment.

Additional resources can be found in ShowMeVax through Reports, then Missouri Forms and Documents for user guides and ShowMeVax Training Videos. The training videos link will take you to our YouTube page where you will find short videos on the different processes in ShowMeVax.

Please contact the helpdesk at [vfc-smvsupport@health.mo.gov](mailto:vfc-smvsupport@health.mo.gov) for assistance or if unsure on the process and include your Covid/VFC PIN in the subject line.

## Avoiding vaccine wastage at vaccination events

### Before the Event

1. Order enough doses for all appointment slots, assuming everyone will show up for the event. Do not register for the event until the order is made and the number of doses is confirmed to avoid over-booking of an event if a full order requested is not approved. **NOTE: Doses for MONG mass vaccine events are allocated by the state. Communicate with the state RIT coordination team regarding possible over- or under-allocation of doses as soon as possible before the event to determine how to adjust as appropriate.**
2. When ordering vaccine for smaller events, consider ordering vaccine that comes in smaller tray sizes and/or smaller dose vials. Four doses left from a 5-dose vial is easier to manage than 9 doses left from a 10-dose vial. Here is a comparison of the current COVID-19 vaccine tray sizes and doses:

Vaccine	Minimum Ordering Quantity	Number of Doses per Vial
Pfizer	1170 doses (195 vials per tray)	6 doses
Moderna	100 doses (10 vials per tray)	10 doses
Johnson & Johnson (J&J)	100 doses (10 vials x 2 cartons)	5 doses

3. If the vaccine will be provided at an offsite event, verify that there is a cold chain plan for safely transporting vaccine to the site, storing the vaccine at the site, and potentially transporting the vaccine

back to the storage site and/or a redistribution partner site if there are extra, unopened vials. **NOTE: For MONG mass vaccination events, coordinate with the state RIT coordination team on necessary redistributions of doses from these events.** For guidance on the safe transport of vaccine, refer to page 21 in CDC’s Vaccine Storage and Handling Toolkit.

4. Look at data from previous events to estimate the number of no-shows. Have a waitlist of people with AT LEAST the number of anticipated no-shows who are eligible to receive the vaccine but are not registered for the event. They should be available to come to the event within 30 minutes of being notified that a dose is available for them.
5. Plan for a worst-case scenario for vaccine storage and/or redistribution in case the event needs to be cancelled after your vaccine has been delivered. In order for one COVID-19 vaccine provider to redistribute vaccine to another provider, both must be approved COVID-19 vaccinators, and a Vaccine Redistribution Agreement must be in place, and a COVID-19 Vaccine Redistribution Form must be completed.

## During the Event

1. Identify one or more “Vaccine Champions” who are responsible for monitoring vaccine temperatures and preventing vaccine wastage. Everyone who handles vaccine should be reminded of the following:
  - Only thaw the amount of vaccine needed. Thawed vaccine cannot be refrozen!
  - Vaccine may be thawed in a refrigerator (between 2°C and 8°C or 36°F and 46°F) or at room temperature (between 15°C and 25°C or 59°F and 77°F).
    - Refrigerator: 25 to 195 vials may take 2 to 3 hours to thaw in the refrigerator. Fewer number of vials will take less time.
    - Room temperature: Thawing will take between 30 minutes and 2 hours.
  - When you open and puncture a vial, write the date and time on the vial.

Vaccine	Intact vials may be stored ...	If cap is removed and stopper punctured, vaccine must be ...
Pfizer	At room temperature for 2 hours before mixing with diluent	Used within 6 hours after mixing
Moderna	At room temperature for up to 12 hours	Used within 6 hours
Johnson & Johnson (J&J)	In a refrigerator until its expiration date	Refrigerated and used within 6 hours or ( <b>NOT</b> recommended) Stored at room temperature for 2 hours*

*\* If you do not reach the 2-hour time limit at room temperature, you may transfer the punctured vial to a refrigerated storage unit for the remaining time, up to 6 hours total storage time (time vial was held at room temperature plus time vial held in refrigerator). However, it is **STRONGLY** recommended that vaccine be stored in a refrigerated vaccine cooler instead of being stored at room temperature for any period of time.*

2. Only prepare vaccines when you are ready to use them. If possible, keep track of who registered for the event versus who presents. This will require communication between event greeters/screeners and the lead vaccinator.
3. Do not pre-draw more vaccine than there are people immediately available to be vaccinated (1 to 2 vials at a time).
4. If a vaccine dose is within 1 hour of expiration and there are no scheduled appointments, contact the people on the event wait list that can arrive within 30 minutes. If no waitlist individuals can be identified, administer the vaccine to eligible event staff or unregistered people who may have gathered at the event in hopes of leftover vaccine. If no eligible recipients are available (i.e., people on the waiting list developed before the event), administer to other individuals interested in receiving the vaccine regardless of phase eligibility.
5. Be sure that all used and partially used vaccine vials are disposed of in an approved sharps container.

## After the Event

Return all unopened vials to the designated storage facility or redistribute to a facility with which the event sponsor has an agreement. **NOTE: For MONG mass vaccination events, proposed redistributions of left over vaccine from an event need to be coordinated with the RIT, and state RIT coordination team as necessary, to assure doses are used primarily for the MONG mass vaccination events within the region allocated.**

**IMPORTANT:** The individual transporting vaccine back to a storage location or to a redistribution site must be trained in cold chain management and must understand what to do in the event of an emergency.

If absolutely necessary, a partially used vial may be transported to or from an off-site/satellite facility operated by the same provider, as long as the cold chain is properly maintained. However, a partially used vial cannot be transferred from one provider to another or across state lines. Also, vaccine drawn up in syringes may not be transported.

## Quality assurance visits

The CDC will be requiring DHSS to perform quality assurance visits on all COVID-19 vaccine providers enrolled with the state of Missouri. 100% of all enrolled providers will need to be visited by the end of 2022. These on-site visits will consist of a DHSS Bureau of Immunization (BI) staff member who will meet with a designated COVID-19 vaccine coordinator. The first focus will be on providers that vaccinated Tier 1A individuals and high volume providers. Pharmacies that are enrolled in the Federal pharmacy program will NOT be visited. The visits will consist of BI staff completing a CDC documentation that includes:

- Validation of vaccine storage units and validating units;
- Review of storage and vaccine handling;
- Review of vaccine documentation (e.g., wastage reports, temperature logs); and
- Review of patient eligibility screening.

## Need more information?

We continuously update Missouri's [vaccinator resource hub](#) with the latest information on the approved vaccines, guidance, Missouri Vaccine Navigator, vaccinator FAQs and training opportunities.

### DHSS contacts by topic area:

- ShowMeVax enrollment support: [Cathy Kennon](#)
- ShowMeVax troubleshooting: [vfc-smvsupport@health.mo.gov](mailto:vfc-smvsupport@health.mo.gov)
- Reporting Dose Administration assistance: [ImmunizationHL7Onboarding@health.mo.gov](mailto:ImmunizationHL7Onboarding@health.mo.gov)
- Adverse events/clinical assistance: [Lana Hudanick](#)
- Vaccine redistribution: [covidvaccineredistribution@health.mo.gov](mailto:covidvaccineredistribution@health.mo.gov)
- Ordering and supply management support: [covidvaccineorders@health.mo.gov](mailto:covidvaccineorders@health.mo.gov)
- Additional PPE and other equipment: [Jenn Stockman](#)
- Newsletter/webinars: [Lisa Cox](#)
- All other questions: [CovidVaccine@health.mo.gov](mailto:CovidVaccine@health.mo.gov)

### Upcoming Meetings

- Vaccine Call for local public health agencies: every **Tuesday from 4-5 p.m.** Reach out to [Tiffany Bayer](#) for more information.
- Vaccinator webinar: Past webinars can be found [here](#).  
The next webinar will be from **3-4 p.m. on Tuesday, March 23. [Click here to attend.](#)** You can now use this same link to attend each Tuesday! Or join by phone: 1-650-479-3207 | Meeting number (access code): 133 183 7153 Meeting password: AtqpY6fi7F5



Missouri Department of Health & Senior Services

Health.Mo.Gov

COVID-19 Hotline: 877-435-8411