**COVID-19 Vaccine**

**Employees**

**Policy & Procedure**

**COVID-19 Vaccine Policy & Procedure**

**Facility Employees**

Policy

It is the policy of this facility that all staff are fully vaccinated for COVID-19, unless medically contraindicated, have been granted an exemption or vaccination is temporarily delayed due to clinical precautions and considerations. Staff not fully vaccinated must have received at least a single-dose, or the first dose of a multi-dose COVID-19 series, prior to providing any care, treatment, or other services for the facility and/or its residents.

Definitions:

The Advisory Committee on Immunization Practices (ACIP): “is a group of medical and public health experts that develops recommendations on how to use vaccines to control diseases in the United States.”1

* “The Centers for Disease Control and Prevention (CDC) sets the U.S. adult and childhood immunization schedules based on recommendations from the Advisory Committee on Immunization Practices (ACIP).
* Before recommending any vaccine, ACIP considers many factors, including the safety and effectiveness of the vaccine.
* Candidates for ACIP membership are screened carefully prior to being selected to join the committee.
* ACIP develops vaccine recommendations for children and adults. The recommendations include the age(s) when the vaccine should be given, the number of doses needed, the amount of time between doses, and precautions and contraindications.”1

“Booster” per Centers for Disease Control and Prevention (CDC), refers to a dose of vaccine administered when the initial sufficient immune response to the primary vaccination series is likely to have waned over time.”2

“Clinical contraindications” refer to conditions or risks that preclude the administration of a treatment or intervention. With regard to recognized clinical contraindications to receiving a COVID19 vaccine, facilities should refer to the CDC informational document, Summary Document for Interim Clinical Considerations for Use of COVID-19 Vaccines Currently Authorized in the United States, accessed at https://www.cdc.gov/vaccines/covid-19/downloads/summary-interim-clinicalconsiderations.pdf. For COVID-19 vaccines, according to CDC, a vaccine is clinically contraindicated if an individual has a severe allergic reaction (e.g., anaphylaxis) after a previous dose or to a component of the COVID-19 vaccine or an immediate (within 4 hours of exposure) allergic reaction of any severity to a previous dose or known (diagnosed) allergy to a component of the vaccine.”2

“Emergency Use Authorization (EUA)” is a mechanism to facilitate the availability and use of medical countermeasures, including vaccines, during public health emergencies, such as the current COVID-19 pandemic. The EUA process is a way to ensure safety while still expediting approval in emergent situations.3

“Fully vaccinated” refers to staff for whom it has been 2 weeks or more since completion of their primary vaccination series for COVID-19.”2

“Primary Vaccination Series” refers to staff who have received a single-dose vaccine or all required doses of a multi-dose vaccine for COVID-19.”2

“Staff” refers to individuals who provide any care, treatment, or other services for the facility and/or its residents, including employees; licensed practitioners; adult students, trainees, and volunteers; and individuals who provide care, treatment, or other services for the facility and/or its residents, under contract or by other arrangements. This also includes individuals under contract or by arrangement with the facility, including hospice and dialysis staff, physical therapists, occupational therapists, mental health professionals, licensed practitioners, or adult students, trainees, or volunteers.”2

“Temporarily delayed vaccination” refers to vaccination that must be temporarily deferred, as recommended by CDC, due to clinical considerations, including known COVID-19 infection until recovery from the acute illness (if symptoms were present) and criteria to discontinue isolation have been met.”2

Up to Date: “You are up to date with your COVID-19 vaccines if you have completed a COVID-19 vaccine primary series and received the most recent booster dose recommended for you by CDC.”4

Procedure

* 1. The facility’s Medical Director will review and approve the Employee/Staff COVID-19 Vaccination Policy and Procedure
	2. An initial review of all facility staff COVID-19 vaccination status will be completed by the infection preventionist to identify all staff compliance to include:
		+ 1. Staff who are fully vaccinated,
				- Specific vaccine received
				- Dates of each dose received
			2. Staff who have requested an exemption in review
			3. Staff with documented granted exemption,
			4. Staff who have temporary delays in vaccination, including date for review,
			5. Staff who are partially vaccinated for a COVID-19
				- Specific vaccine received
				- Date of vaccine administration
				- Date of next scheduled dose of a multi-dose vaccine
			6. Staff not vaccinated without exemption or delay
			7. Staff who have received booster dose(s)
				- Specific vaccine received
				- Date of vaccine administration
	3. The Infection Preventionist will keep the “COVID-19 Staff Vaccination Status for Providers Matrix (CMS)” up to date.
	4. Prior to administration of all doses of primary or booster COVID-19 vaccination doses:
1. Education on the COVID-19 vaccination will be conducted

Current EAU Fact Sheet for COVID-19 Vaccine being administered

1. Written Consent obtained from employee
2. Physician order (Standing Medical Director Order if applicable)
3. Screening
	1. The employee will be interviewed to identify any medical precautions or contraindications to determine if employee is an appropriate candidate for vaccination
	2. An inquiry with employee will be completed to determine employee’s COVID-19 vaccination status. (Documentation of evidence of COVID-19 vaccination must be provided, such as a copy of the COVID-19 vaccination card)
	3. If employee is not fully vaccinated with COVID-19 vaccination, review physician order, education will be provided, and employee will be offered the appropriate COVID-19 vaccination unless contraindicated or delayed.
		1. If COVID-19 vaccination was delayed, schedule COVID-19 vaccine at soonest opportunity
	4. If an employee refuses to complete the primary COVID-19 vaccine to become fully vaccinated, document education on the benefits, risks and side effects provided (EAU Fact sheet) and employee refusal.
* Refer employee to Human Resources. Employee will not be able to provide any care, treatment, or other services for the facility and/or its residents.
* Employees requesting medical or non-medical exemptions, see below.
	1. Assess employee for fever or signs/symptoms of illness. Delay administration if employee is not well.
	2. Administer COVID-19 vaccine following manufacturer’s recommendations.
		+ 1. CDC does not recommend mixing products for the primary series doses
			2. The flu vaccine and COVID-19 vaccine can be administered at the same visit

“COVID-19 vaccines may be administered without regard to timing of other vaccines. This includes simultaneous administration of COVID-19 vaccine and other vaccines on the same day. However, there are additional considerations if administering an orthopoxvirus vaccine.”5

* 1. Documentation for employee COVID-19 vaccination should include:
		+ 1. Education provided to the employee on the benefits and potential side effects of the COVID-19 vaccines
			2. Document administration:
				1. Type and details of vaccine
				2. Location of administration
				3. Date and time
				4. Employee response
				5. Side effects or adverse consequences
	2. Employees with active COVID-19 infection:
		+ - 1. Vaccination should be deferred until employee has recovered from acute illness and the employee has met the criteria to return to work
	3. Employees who have received antibody products: “People who previously received antibody products (anti-SARS-CoV-2 monoclonal antibodies or convalescent plasma) as part of COVID-19 treatment, post-exposure prophylaxis, or pre-exposure prophylaxis can be vaccinated at any time; COVID-19 vaccination does not need to be delayed following receipt of monoclonal antibodies or convalescent plasma.”5
		+ - 1. “**Special situation**: administration of tixagevimab/cilgavimab (EVUSHELD™) for pre-exposure prophylaxis should be deferred for at least two weeks after receipt of a dose of COVID-19 vaccine, per the product EUA.”5
	4. Contraindications and Precautions: The COVID-19 vaccine should not be administered to an employee who has had a severe reaction or allergy to a prior dose of COVID-19 vaccine or any of its components. Employee should be directed to consult with physician for evaluation and documentation.
		+ 1. Contraindications- do not vaccinate include:
				1. “History of a severe reaction (e.g., anaphylaxis) after a previous dose or to a component of the COVID-19 vaccine”5
				2. “History of a known diagnosed allergy to a component of the COVID-19 vaccine”5
			2. **Precautions:** Discuss with practitioner
				1. “History of anaphylaxis after any vaccine other than COVID-19 vaccine or after any injectable therapy (i.e., intramuscular, intravenous, or subcutaneous vaccines or therapies [excluding subcutaneous immunotherapy for allergies, i.e., “allergy shots”])\*5
				2. “People with an allergy-related contraindication to one type of COVID-19 vaccine have a precaution to the other types of COVID-19 vaccines.

Special situation: People with a known allergy to polysorbate have a contraindication to both Novavax and Janssen COVID-19 vaccines.\*†5

“Moderate to severe acute illness, with or without fever”5

“History of MIS-C or MIS-A”5

“History of myocarditis or pericarditis after a dose of an mRNA or Novavax COVID-19 Vaccine.”5

* 1. Monitoring for Anaphylaxis: Emergency equipment should be available at all times when vaccinations are being administered to include:

Epinephrine (i.e., prefilled syringe, autoinjector)

At least 3 doses at all times

H1 antihistamine (i.e., diphenhydramine, cetirizine)

H2 antihistamine (i.e., famotidine, cimetidine)

Oxygen Bronchodilator (i.e., albuterol)

Blood pressure monitor

Pulse oximeter

CPR Mask

1. All employees will be monitored for at least 15 minutes. Employees will be observed for acute anaphylactic reaction for 30 minutes following administration if they have had :

“Allergy-related contraindication to a different type of COVID-19 vaccine

Non-severe, immediate (onset within 4 hours) allergic reaction after a previous dose of COVID-19 vaccine

Anaphylaxis after non-COVID-19 vaccines or injectable therapies”5

* + - * + Early identification of anaphylaxis:
* “**Respiratory**: sensation of throat closing or tightness, stridor (high-pitched sound while breathing), hoarseness, respiratory distress (such as shortness of breath or wheezing), coughing, trouble swallowing/drooling, nasal congestion, rhinorrhea, sneezing
* **Gastrointestinal**: nausea, vomiting, diarrhea, abdominal pain, or cramps
* **Cardiovascular**: dizziness; fainting; tachycardia (abnormally fast heart rate); hypotension (abnormally low blood pressure); pulse difficult to find or “weak”; cyanosis (bluish discoloration); pallor; flushing
* **Skin/mucosal**: generalized hives; widespread redness; itching; conjunctivitis; or swelling of eyes, lips, tongue, mouth, face, or extremities
* **Neurologic**: agitation; convulsions; acute change in mental status; sense of impending doom (a feeling that something bad is about to happen)
* **Other**: sudden increase in secretions (from eyes, nose, or mouth); urinary incontinence

**\*\*Anaphylaxis should be considered when signs or symptoms are generalized (i.e., if there are generalized hives or more than one body system is involved) or are serious or life-threatening in nature, even if they involve a single body system (e.g., hypotension, respiratory distress, or significant swelling of the tongue or lips.**

“Symptoms of anaphylaxis often occur within 15-30 minutes of vaccination, though it can sometimes take several hours for symptoms to appear. Early signs of anaphylaxis can resemble a mild allergic reaction, and it is often difficult to predict whether initial, mild symptoms will progress to become an anaphylactic reaction. In addition, symptoms of anaphylaxis might be more difficult to recognize in people with communication difficulties, such as long-term care facility residents with cognitive impairment, those with neurologic disease, or those taking medications that can cause sedation. Not all symptoms listed above are necessarily present during anaphylaxis, and not all patients have skin reactions”.6

* + - **Protocol for Management of Anaphylaxis**
			* Facility will follow protocol for Management of anaphylaxis in accordance with State guidance, to include:
				+ Assessment of airway, breathing circulation and mentation rapidly
				+ Call 911
				+ Place individual in a supine position with feet elevated unless upper airway obstruction is present, or individual is vomiting.
				+ Administration of Epinephrine per Medical Director standing order.
			* \*\*For example: “Epinephrine (1 mg/ml aqueous solution [1:1000 dilution]) is the first-line treatment for anaphylaxis and should be administered immediately.
			* In adults, administer a 0.3 mg intramuscular dose using a premeasured or prefilled syringe, or an autoinjector in the mid-outer thigh.
			* The maximum adult dose is 0.5 mg per dose”6.
			* Epinephrine dose may be repeated every 5-15 minutes as needed to control symptoms while waiting for emergency medical services. (Document and report number of doses to EMS)
			* “Because of the acute, life-threatening nature of anaphylaxis, there are no contraindications to epinephrine administration.”6
			* Employees who have been determined to have had a severe allergic reaction to an mRNA COVID-19 vaccine should not receive additional dose(s).
	1. Update employee vaccination card and facility tracking.
	2. Instruct employee to monitor for any side effects or adverse events

All adverse events occurring in an individual following COVID-19 vaccinations under Emergency Use Authorization, including anaphylaxis must be reported to the Vaccine Adverse Event Reporting System (VAERS): <https://vaers.hhs.gov/reportevent.html>

All vaccine administration errors

Serious adverse events (AE)

Death

A life-threatening Adverse Event

Inpatient hospitalization or prolongation of existing hospitalization

Persistent or signification incapacity or substantial disruption in the ability to conduct normal life functions

A congenital anomaly/birth defect

An important medical event that may jeopardize the individual and require medical or surgical interventions to prevent the above outcomes

Cases of myocarditis after a Pfizer-BioNTech, Moderna, or Novavax vaccine

Cases of pericarditis after a Pfizer-BioNTech, Moderna, or Novavax vaccine

Cases of Multisystem Inflammatory Syndrome

Cases of COVID-19 that result in hospitalization or death.

* 1. IP will report the participation of employee COVID-19 vaccinations to the QAA committee.
	2. IP will report employee COVID-19 vaccinations in NHSN and keep an ongoing updated tracking log for all employees
	3. **COVID-19 Vaccines Administered Outside the Facility:**

If the facility is unable to arrange COVID-19 vaccinations in the facility (i.e., unable to obtain product and coordinate vaccine administration in the facility)

The Infection Preventionist will:

* 1. Work with employee to coordinate vaccination program with outside vaccine provider for:
		1. New employees
		2. Employees in need of a second mRNA COVID-19 Vaccination
		3. Employees who did not receive the COVID-19 vaccination (i.e., illness)
		4. Booster dose(s) for employees
	2. Coordinate with local public health department, local pharmacies, or partner health systems.
		1. Document all efforts to access COVID-19 vaccine

**NOTE:** If unable to obtain an appointment for a COVID-19 Vaccine for employees, document all efforts to obtain vaccine. Continue to investigate vaccination opportunities.

* 1. **Exemptions**

Employees may request exemption from COVID-19 vaccination based upon Federal law. Staff will be required to:

Obtain the appropriate exemption form from (Occupational Health or Human Resources) upon hire or prior to when eligible for applicable primary series dose of COVID-19 vaccine

**Medical Exemption Form**

Employee is to complete Section 1 of the Medical Exemption Form and have their medical provider complete Section 2, acting within their respective scope of practice in accordance with all applicable State and local laws. This Form will be returned to (Occupational Health or Human Resources within 7 days)

The individual signing the exemption form cannot be the same individual requesting the exemption

A confidential review of the medical exemption form will be conducted by the (Identify team, i.e., Medical Director, Infection Preventionist, Occupational Health and Human Resources) to approve or deny request for medical exemption.

**Non-Medical Exemptions, Including Religious Exemptions**

Employee is to complete the “Non-Medical Exemptions, Including Religious Exemptions Form” and return to (Occupational Health or Human Resources) within 3 days.

A confidential review of the non-medical exemption form will be conducted by the (Identify team, i.e., Medical Director, Infection Preventionist, Occupational Health and Human Resources) to approve or deny request for exemption.

If exemption is denied, employee will be provided with a deadline to obtain first dose of a multi-dose vaccine. If not met, employee will be replaced on the schedule.

* 1. **Temporary Delay**: For employees unable to receive the COVID-19 vaccine due to clinical considerations (i.e., temporary illness, active COVID-19 infection, etc.) the Infection Preventionist will confidentially track and document status, including scheduling employee for COVID-19 vaccine as soon as able.
	2. **Contingency Plans:** For employees who are not fully vaccinated, (granted exemption, temporary delay, new employee after receiving the first dose of a multi-dose vaccine, etc.) the following actions will be required:
		+ 1. Employees will be educated on the core elements of infection prevention and control
			2. Employee(s) will be required to wear source control when in areas that residents are not present (i.e., meeting rooms, break rooms, etc.)
			3. Employee will be required to use a NIOSH-approved N95 or equivalent or higher-level respirator for source control when care for or interacting with residents
			4. Facility specific requirements (list-i.e., testing, etc.)
			5. Employees with temporary delay will be provided with a deadline to receive applicable COVID-19 vaccination

**References and Resources**

**1**Centers for Disease Control and Prevention. Role of the Advisory Committee on Immunization Practices in CDC’s Vaccine Recommendations: <https://www.cdc.gov/vaccines/acip/committee/role-vaccine-recommendations.html>

**2**Centers for Medicare & Medicaid Services. QSO-23-02-ALL, Revised Guidance for Staff Vaccination Requirements. October 26, 2022: <https://www.cms.gov/files/document/qs0-23-02-all.pdf>

3 Centers for Medicare & Medicaid Services. QSO-21-19-NH. Interim Final Rule – COVID-19 Vaccine Immunization Requirements for Residents and Staff. May 11, 2021: <https://www.cms.gov/files/document/qso-21-19-nh.pdf>

**4**Centers for Disease Control and Prevention. Stay Up to Date with COVID-19 Vaccines Including Boosters. Updated Nov. 1, 2022: <https://www.cdc.gov/coronavirus/2019-ncov/vaccines/stay-up-to-date.html>

5Centers for Disease Control and Prevention. Interim Clinical Considerations for Use of COVID-19 Vaccines Currently Approved or Authorized in the United States. Last reviewed Nov. 15, 2022: <https://www.cdc.gov/vaccines/covid-19/clinical-considerations/interim-considerations-us.html>

6Centers for Disease Control and Prevention. Interim Considerations: Preparing for the Potential Management of Anaphylaxis after COVID-19 Vaccination. Page Last Reviewed September 2, 2022: <https://www.cdc.gov/vaccines/covid-19/clinical-considerations/managing-anaphylaxis.html>

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Centers for Disease Control and Prevention. Vaccine Storage and Handling Toolkit, updated April 12, 2022: <https://www.cdc.gov/vaccines/hcp/admin/storage/toolkit/storage-handling-toolkit.pdf>

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Centers for Disease Control and Prevention. Interim Infection Prevention and Control Recommendations for Healthcare Personnel During the Coronavirus Disease 2019 (COVID-19) Pandemic. Updated Sept. 23, 2022: <https://www.cdc.gov/coronavirus/2019-ncov/hcp/infection-control-recommendations.html>

United States Food & Drug Administration. Emergency Use Authorization. Content current as of: 12/05/2022: <https://www.fda.gov/emergency-preparedness-and-response/mcm-legal-regulatory-and-policy-framework/emergency-use-authorization>

Vaccine Adverse Event Reporting System (VAERS) Frequently Asked Questions (FAQs): <https://vaers.hhs.gov/faq.html>

Centers for Disease Control and Prevention. COVID-19 ACIP Vaccine Recommendations. Advisory Committee on Immunization Practices (ACIP): <https://www.cdc.gov/vaccines/hcp/acip-recs/vacc-specific/covid-19.html>

Centers for Disease Control and Prevention. New COVID-19 Vaccination Provider Trainings. 03/24/2021: <https://www.cdc.gov/vaccines/covid-19/downloads/covid19-vaccination-provider-trainings.pdf>