**COVID-19 Vaccination**

**Draft Plan**

**12.17.2020**

**COVID-19 Vaccination**

**Overview and General Information**

Below is a Draft General COVID-19 Vaccination Plan Implementation Checklist designed for leaders to use as a guide as they prepare for the COVID-19 vaccination process. IN coordination with your partner pharmacy, leaders will need to work with their team to align processes and training related to current guidance.

*\*\*Important to Note – As the vaccine process continues to evolve, this Plan and Checklist will need to be modified to align with updated guidance.*

| **Vaccination Plan Area** | **Responsible** | **Completed** |
| --- | --- | --- |
| * Initial QAA Committee Meeting to begin planning, to include (at a minimum):
	+ Administrator
	+ DON
	+ Medical Director
	+ Infection Preventionist
	+ Pharmacy Consultant
 |  |  |
| * Coordinate with partner pharmacy for COVID-19 vaccination program
	+ Document requirements for:
		- Contact
		- Setting up vaccination schedules
		- Documentation required
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| * Contact legal counsel regarding any mandatory directives for employees related to vaccines.
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| * Collaboration with State and Local Public Health
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| * Assign Authority (i.e., Infection Preventionist) plus back up to oversee the COVID-19 Vaccination Program
 |  |  |
| * Obtain EUA Fact Sheet that will include:
	+ “COVID-19 disease description
	+ Dosage and administration information
	+ Storage and handling instructions
	+ Dose preparation and administration information
	+ Requirements for use of vaccine under EUA
	+ Risks and benefits, including common adverse events (AEs)
	+ Any approved available alternatives for preventing COVID-19
	+ Reporting requirements, including reporting AEs to VAERS
	+ Additional resources”1
 |  |  |
| * Watch for V-safe information sheet from CDC (smart-phone based active surveillance program)
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| * Ongoing Resident/Resident Representative and Employee Education:
	+ Benefits: <https://www.cdc.gov/coronavirus/2019-ncov/vaccines/vaccine-benefits.html>
	+ Types: <https://www.cdc.gov/coronavirus/2019-ncov/vaccines/different-vaccines.html>
	+ Side Effects
 |  |  |
| * Collaboration with pharmacy on process following initial vaccine administration completion
	+ New Admissions
	+ New Employees
	+ Residents/Employees who previously refused and now decide to consent for vaccine
 |  |  |
| * Gather Information About Vaccine for Planning
	+ Policy and Procedure
	+ Employee Education
	+ Which vaccine will be delivered?
	+ Develop Standard Operation Procedures
	+ Consent Form
	+ Documentation
	+ Preparation planning
	+ Administration Priority
	+ Pre-plan for 2nd dose
 |  |  |
| Employee education for facilities that will administer vaccine* Type of vaccine (i.e. Pfizer, Moderna, AstraZenica, Janssen, Novavax)
	+ How the vaccine works, manufacturers information (EAU Fact Sheet for each vaccine to be administered)
* Education prior to vaccine administration
	+ Meets the requirements of the Americans with Disabilities Act, the Rehabilitation Act, the Patient Protection and Affordable Care Act, the Plain Language Act, and other applicable disability rights laws for accessibility
* Pharmacy involvement
* Storage and handling
	+ Manufacturer’s recommendations
		- Pfizer
		- Moderna
		- AstraZenica
		- Janssen
		- Novavax
	+ Receipt and storage
	+ How vaccine is to be organized
	+ Temperature monitoring devices
	+ Checking and recording temperatures
	+ How and why stock is rotated
	+ How to respond to out-of-range temperatures
	+ Removing expired vaccine
		- Expired or compromised vaccine: unopened and even potentially compromised vaccines may be able to be returned for credit
		- Open, broken vials and syringes, pre-drawn, etc. cannot be returned and should be discarded in accordance with state requirements
		- Empty vaccine vials do not typically require disposal in biomedical waste container. Must comply with state requirements for disposal
	+ Power outages or disasters
 |  |  |
| * Supplies needed
	+ PPE
	+ Sharps containers
	+ Process to pick up medical waste
 |  |  |
| * Injection – preparation, administration and safety2
	+ Do not use partial doses from 2 or more vials
		- Only the maximum number of doses should be withdrawn from multidose vials even if there is residual vaccine still in the vial
		- Single-dose vials should be used one time for one resident
			* Open only when ready to use
		- Manufacturer-filled syringes-activate only when ready to use
			* Once seal is broken, must be used or discarded by end of the workday
		- Reconstitution
			* Follow the manufacturer’s recommendation-may vary between manufacturers’
			* ONLY use diluent supplied with the vaccine-never use stock supplies
				+ If inadvertently reconstituted with incorrect diluent, discard-do not administer
			* Draw up vaccines only at time of administration
			* Do not transfer pre-drawn vaccine back into a vial for storage
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| * Assessment prior to administration
 |  |  |
| * Vaccine administration errors
 |  |  |
| * Resident/employee monitoring post-administration
	+ Steps for management of anaphylaxis reaction following vaccine administration <https://www.cdc.gov/vaccines/covid-19/info-by-product/pfizer/anaphylaxis-management.html>
	+ Definition of “adverse event (AE) following immunization”
 |  |  |
| * Required documentation
 |  |  |
| * Follow-up
 |  |  |
| * Refusals
	+ Residents
	+ Employee
 |  |  |
| * Physician Orders
 |  |  |
| * Employee Competency
	+ Vaccine process
		- Education and Informed Consent documentation
		- Vaccine preparation
		- PPE
		- Supplies
	+ Administration
	+ Monitoring
	+ Documentation
	+ 2nd dose scheduling (for vaccines that require 2nd dose)
	+ Follow up
	+ Reporting
 |  |  |
| * Documentation3
	+ Documentation promptly (within 24 hours in the medical record) following administration:
		- Date of first dose
		- Vaccine manufacturer
		- Lot number
		- Vaccination site and route
		- Name and title of person administering
		- Due Date of second dose
		- Date of second dose administration
			* Vaccine manufacturer
			* Lot number
			* Vaccination site and route
			* Name and title of person administering
	+ Facility must maintain the vaccine administration record for at least 3 years unless State/Federal requirements require a longer period
	+ Each resident (resident representative) and employee must be provided a COVID-19 vaccination record card
 |  |  |
| * Reporting
	+ NHSN
	+ State required
	+ Vaccine administration errors
	+ Clinically significant adverse event following the COVID-19 vaccination to VAERS even if not sure that the vaccination caused the event
		- <https://vaers.hhs.gov/>
		- <https://open.fda.gov/data/faers/>
 |  |  |
| * Billing
	+ Pharmacy will bill directly for administration by pharmacy
		- Facility to provide billing/insurance information
 |  |  |
| * Follow-up/QAPI Process
 |  |  |

**References and Resources**

Centers for Disease Control and Prevention. COVID-19 Vaccination Training Programs and Reference Materials for Healthcare Professionals. 11.24.20 : <https://www.cdc.gov/vaccines/covid-19/downloads/COVID-19-Clinical-Training-and-Resources-for-HCPs.pdf>

1Centers for Disease Control and Prevention. COVID-19 Vaccine Training Module. November 19, 2020: <https://www2.cdc.gov/vaccines/ed/covid19/>

2Centers for Disease Control and Prevention. Vaccine Storage and Handling Toolkit, November 2020: <https://www.cdc.gov/vaccines/hcp/admin/storage/toolkit/storage-handling-toolkit.pdf>

3Centers for Disease Control and Prevention. COVID-19 Vaccination Program Interim Playbook for Jurisdiction Operations. October 29, 2020: <https://www.cdc.gov/vaccines/imz-managers/downloads/COVID-19-Vaccination-Program-Interim_Playbook.pdf>

Centers for Disease Control and Prevention. Interim Considerations: Preparing for the Potential Management of Anaphylaxis at COVID-19 Vaccination Sites: <https://www.cdc.gov/vaccines/covid-19/info-by-product/pfizer/anaphylaxis-management.html>

Centers for Medicare & Medicaid Services. COVID-19 Vaccine Policies & Guidance. <https://www.cms.gov/covidvax>

Centers for Medicare & Medicaid Services. COVID-19: <https://www.cms.gov/covidvax-provider>