Alaska Native Medical Center

ANMC and SCF Protocol for COVID-19 Vaccine Administration to Prevent Coronavirus Disease 2019 (COVID-19) for Persons Age 6 Months and Older.

1. Purpose

To reduce morbidity and mortality from coronavirus disease 2019 (COVID-19) by vaccinating persons who meet the criteria established by the Centers for Disease Control and Prevention's Advisory Committee on Immunization Practices (ACIP).

2. Scope

Eligible healthcare personnel practicing at the Alaska Native Medical Center (ANMC), Southcentral Foundation Anchorage Native Primary Care Center, Southcentral Foundation Benteh Nuutah Valley Native Primary Care Center and Southcentral Foundation Rural Clinics.

3. Policy

Where allowed by state law, this protocol enables eligible nurses and other healthcare professionals to assess the need for vaccination and to vaccinate age-appropriate persons who meet the criteria below.

EUA INFORMATION TO PROVIDE TO VACCINE RECIPIENTS/CAREGIVERS
As the vaccination provider, you must communicate to the recipient or their caregiver, information consistent with the age-appropriate product-specific Emergency Use Authorization (EUA) *Fact Sheet for Recipients and Caregivers* (and provide a copy or direct the individual to the appropriate website to obtain the Fact Sheet) prior to the individual receiving each dose of COVID-19 vaccine.

3.1. EUA Fact Sheets for COVID-19 vaccines are available on the FDA website: https://www.fda.gov/emergency-preparedness-and-response/coronavirus-disease-2019-covid-19/covid-19-vaccines

4. Procedure

4.1. Assess for Need of Vaccination Against COVID-19

4.1.1. Under the EUAs, the following age groups are authorized to receive COVID-19 vaccination:

4.1.1.1. Pfizer-BioNTech COVID-19 Vaccine:
- 4.1.1.1.1. (Primary) For persons aged 6 months through 4 years (maroon cap).
- 4.1.1.1.2. (Primary and Monovalent Booster) For persons aged 5 years through 11 years (orange cap).
- 4.1.1.1.3. (Primary) For persons aged 12 years and older (gray cap).
- 4.1.1.1.4. (Bivalent Booster) For persons aged 12 years and older (gray cap).

4.1.1.2. Moderna COVID-19 Vaccine:
- 4.1.1.2.1. (Primary) For persons aged 6 months through 5 years (blue cap with magenta border).
- 4.1.1.2.2. (Primary) For persons aged 6 years through 11 years (blue cap with purple border).
- 4.1.1.2.3. (Primary) For persons aged 12 years and older (red cap with blue border).
- 4.1.1.2.4. (Bivalent Booster) For persons aged 18 years and older (blue cap with gray border).

4.1.1.3. Novavax (COVID-19 Vaccine: (Primary) For persons aged 12 years and older (blue cap).

4.1.2. **See section 4.2 below** for the age-appropriate product-specific EUA *Fact Sheet for Healthcare Providers Administering Vaccine*).

4.1.3. Utilize the Alaska Immunization Information System VacTrAK to determine the vaccination status of the patient and what COVID-19 vaccine product they may have been given previously.

4.1.4. NOTE: Use these standing orders in conjunction with the **Interim COVID-19 Immunization Schedule for Persons 6 Months and Older**, found here: https://www.cdc.gov/vaccines/covid-19/downloads/COVID-19-immunization-schedule-ages-6months-older.pdf

4.1.5. **For Pfizer-BioNTech COVID-19 Vaccine: 6 months through 4 years of age (Monovalent)**

4.1.5.1. Assess children 6 months through 4 years of age for vaccination with Pfizer BioNTech COVID-19 Vaccine based on the following criteria (**see section 4.1.13** for additional clinical considerations):

4.1.5.2. Children who **ARE NOT** moderately or severely immunocompromised

4.1.5.2.1. If the recipient has never received a COVID-19 vaccine, administer 1 dose of Pfizer-BioNTech COVID-19 Vaccine.

4.1.5.2.2. If the recipient has received 1 previous dose of Pfizer-BioNTech COVID-19 Vaccine, administer the second dose at least 3–8 weeks after Dose 1.

4.1.5.2.3. If the recipient has received 2 previous doses of Pfizer-BioNTech Vaccine, administer the third dose at least 8 weeks after Dose 2. Primary series completed.

4.1.5.3. Children who **ARE** moderately or severely immunocompromised

4.1.5.3.1. Healthcare personnel will notify medical provider; the medical provider is best positioned to determine the degree of immune compromise and appropriate timing of vaccination (for list of conditions, **see section 4.1.13.4**).

4.1.5.3.2. If the recipient has never received a COVID-19 vaccine, administer 1 dose of Pfizer-BioNTech COVID-19 Vaccine.

4.1.5.3.3. If the recipient has received 1 previous dose of Pfizer-BioNTech COVID-19 Vaccine, administer the second dose at least 3 weeks after Dose 1.

4.1.5.3.4. If the recipient has received 2 previous doses of Pfizer-BioNTech Vaccine, administer the third dose at least 8 weeks after Dose 2. Primary series completed.

4.1.5.4. Children with a history of myocarditis or pericarditis (**see section 4.1.13.2**)

4.1.6. **For Pfizer-BioNTech COVID-19 Vaccine: 5 years through 11 years of age (Monovalent)**

4.1.6.1. Assess children 5 years through 11 years of age for vaccination with Pfizer BioNTech COVID-19 Vaccine based on the following criteria (**see section 4.1.13** for additional clinical considerations):

4.1.6.2. Children who **ARE NOT** moderately or severely immunocompromised

4.1.6.2.1. If the recipient has never received a COVID-19 vaccine, administer 1 dose of Pfizer-BioNTech COVID-19 Vaccine.

4.1.6.2.2. If the recipient has received 1 previous dose of Pfizer-BioNTech COVID-19 Vaccine, administer the second dose at least 3–8 weeks after Dose 1. Primary series completed.

4.1.6.2.3. If the recipient has received 2 previous doses of Pfizer-BioNTech Vaccine, administer a booster dose of monovalent Pfizer-BioNTech Vaccine at least 5 months after Dose 2.

4.1.6.2.3.1. **Children 5 years through 11 years**: The monovalent Pfizer-BioNTech booster dose is authorized for children in this age group.

4.1.6.3. Children who **ARE** moderately or severely immunocompromised

4.1.6.3.1. Healthcare personnel will notify medical provider; the medical provider is best positioned to determine the degree of immune compromise and appropriate timing of vaccination (for list of conditions, **see section 4.1.13.4**).

4.1.6.3.2. If the recipient has never received a COVID-19 vaccine, administer 1 dose of Pfizer-BioNTech COVID-19 Vaccine.

4.1.6.3.3. If the recipient has received 1 previous dose of Pfizer-BioNTech COVID-19 Vaccine, administer the second dose at least 3 weeks after Dose 1.

4.1.6.3.4. If the recipient has received 2 previous doses of Pfizer-BioNTech Vaccine, administer the third dose at least 4 weeks after Dose 2.

4.1.6.3.5. If the recipient has received 3 previous doses of Pfizer COVID-19 Vaccine, administer a booster dose of monovalent Pfizer-BioNTech Vaccine at least 3 months after dose 3.

4.1.6.3.5.1. **Children 5 years through 11 years**: The monovalent Pfizer-BioNTech booster dose is authorized for children in this age group.

4.1.6.4. Children with a history of myocarditis or pericarditis (**see section 4.1.13.2**)

4.1.7. **For Pfizer-BioNTech COVID-19 Vaccine: 12 years of age and older (Monovalent and Bivalent)**

4.1.7.1. Assess persons 12 years of age and older for vaccination with Pfizer-BioNTech COVID-19 Vaccine based on the following criteria (**see section 4.1.13** for additional clinical considerations):

4.1.7.2. Persons who **ARE NOT** moderately or severely immunocompromised

4.1.7.2.1. If the recipient has never received a COVID-19 vaccine, administer 1 dose of an age-appropriate monovalent Pfizer-BioNTech COVID-19 vaccine.

4.1.7.2.2. If the recipient has received 1 previous dose of:

4.1.7.2.2.1. Monovalent Pfizer-BioNTech COVID-19 vaccine, administer the second primary dose of monovalent Pfizer-BioNTech COVID-19 vaccine at least 3 to 8 weeks after the first dose. Primary series completed.

4.1.7.2.2.2. If the first-dose vaccine product cannot be determined, is no longer available, or contraindicated, administer monovalent Pfizer-BioNTech COVID-19 vaccine at least 4 to 8 weeks after the first dose. Primary series completed.

4.1.7.2.3. If the recipient has received 2 primary series doses of:

4.1.7.2.3.1.1. Monovalent COVID-19 Vaccine (Moderna, Novavax or Pfizer-BioNTech), regardless of the number of monovalent booster doses, administer an age-appropriate bivalent mRNA booster dose at least 8 weeks (2 months) after the previous dose.

4.1.7.2.3.1.2. **Adolescents 12 years through 17 years of age**: The bivalent Pfizer-BioNTech booster dose is authorized for adolescents in this age group.

4.1.7.2.3.1.3. **Adults 18 years of age and older**: A bivalent mRNA booster dose (Moderna or Pfizer-BioNTech) is authorized for adults in this adult group.

4.1.7.3. Persons who **ARE** moderately to severely immunocompromised

4.1.7.3.1. Healthcare personnel will notify medical provider; the medical provider is best positioned to determine the degree of immune compromise and appropriate timing of vaccination (for list of conditions, **see section 4.1.13.4**).

4.1.7.3.2. If the recipient has never received a COVID-19 vaccine, administer 1 dose of monovalent Pfizer-BioNTech COVID-19 vaccine.

4.1.7.3.3. If the recipient has received 1 previous dose of:

4.1.7.3.3.1. Monovalent Pfizer-BioNTech COVID-19 vaccine, administer the second primary dose of monovalent Pfizer-BioNTech COVID-19 vaccine at least 3 weeks (21 days) after the first dose.

4.1.7.3.3.2. If the first-dose vaccine product cannot be determined, is no longer available, or contraindicated, administer monovalent Pfizer-BioNTech COVID-19 vaccine at least 4 weeks (28 days) after the first dose.

4.1.7.3.4. If the recipient has received 2 doses of:

4.1.7.3.4.1. Monovalent Pfizer-BioNTech vaccine, administer a third dose of monovalent Pfizer-BioNTech vaccine at least 28 days (4 weeks) after dose 2. Primary series completed.

4.1.7.3.4.2. Monovalent Novavax COVID-19 Vaccine (**see section 4.1.12** for bivalent mRNA booster dose criteria).

4.1.7.3.4.3. If the previous vaccine products cannot be determined, are no longer available, or contraindicated, administer monovalent Pfizer-BioNTech COVID-19 Vaccine at least 4 weeks (28 days) after the second dose. Primary series completed.

4.1.7.3.5. If the recipient has received 3 or more doses of:

4.1.7.3.5.1. Any monovalent COVID-19 Vaccine, administer an age-appropriate bivalent mRNA booster dose at least 8 weeks (2 months) after the previous dose. This includes 3 or more doses of the same monovalent product, or a mix of monovalent products.

4.1.7.3.5.1.1. **Adolescents 12 years through 17 years of age**: The bivalent Pfizer-BioNTech booster dose is authorized for adolescents in this age group.

4.1.7.3.5.1.2. **Adults 18 years of age and older**: A bivalent mRNA booster dose (Moderna or Pfizer-BioNTech) is authorized for adults in this adult group.

4.1.7.4. For bivalent mRNA booster dose guidance in persons who received Janssen COVID-19 vaccine (**see section 4.1.13.8**).

4.1.7.5. Persons with a history of myocarditis or pericarditis (**see section 4.1.13.2**)

4.1.8. **For Moderna COVID-19 Vaccine: 6 months through 5 years of age (Monovalent)**

4.1.8.1. Assess children 6 months through 5 years of age for vaccination with Moderna COVID-19 Vaccine based on the following criteria (**see section 4.1.13** for additional clinical considerations):

4.1.8.2. Children who **ARE NOT** moderately or severely immunocompromised

4.1.8.2.1. If the recipient has never received a COVID-19 vaccine, administer 1 dose of Moderna COVID-19 Vaccine.

4.1.8.2.2. If the recipient has received 1 previous dose of Moderna COVID-19 Vaccine, administer the second dose at least 4–8 weeks after Dose 1. Primary series completed.

4.1.8.3. Children who **ARE** moderately or severely immunocompromised

4.1.8.3.1. Healthcare personnel will notify medical provider; the medical provider is best positioned to determine the degree of immune compromise and appropriate timing of vaccination (for list of conditions, **see section 4.1.13.4**).

4.1.8.3.2. If the recipient has never received a COVID-19 vaccine, administer 1 dose of Moderna COVID-19 Vaccine.

4.1.8.3.3. If the recipient has received 1 previous dose of Moderna COVID-19 Vaccine, administer the second dose at least 4 weeks after Dose 1.

4.1.8.3.4. If the recipient has received 2 previous doses of Moderna Vaccine, administer the third dose at least 4 weeks after Dose 2. Primary series completed.

4.1.8.4. Children with a history of myocarditis or pericarditis (**see section 4.1.13.2**)

4.1.9. **For Moderna COVID-19 Vaccine: 6 years through 11 years of age (Monovalent)**

4.1.9.1. Assess children 6 through 11 years of age for vaccination with Moderna COVID-19 Vaccine based on the following criteria (**see section 4.1.13** for additional clinical considerations):

4.1.9.2. Children who **ARE NOT** moderately or severely immunocompromised

4.1.9.2.1. If the recipient has never received a COVID-19 vaccine, administer 1 dose of Moderna COVID-19 Vaccine.

4.1.9.2.2. If the recipient has received 1 previous dose of Moderna COVID-19 Vaccine, administer the second dose at least 4–8 weeks after Dose 1. Primary series completed.

4.1.9.3. Children who **ARE** moderately or severely immunocompromised

4.1.9.3.1. Healthcare personnel will notify medical provider; the medical provider is best positioned to determine the degree of immune compromise and appropriate timing of vaccination (for list of conditions, **see section 4.1.13.4**).

4.1.9.3.2. If the recipient has never received a COVID-19 vaccine, administer 1 dose of Moderna COVID-19 Vaccine.

4.1.9.3.3. If the recipient has received 1 previous dose of Moderna COVID-19 Vaccine, administer the second dose at least 4 weeks after Dose 1.

4.1.9.3.4. If the recipient has received 2 previous doses of Moderna Vaccine, administer the third dose at least 4 weeks after Dose 2. Primary series completed.

4.1.9.4. Children with a history of myocarditis or pericarditis (**see section 4.1.13.2**)

4.1.10. **For Moderna COVID-19 Vaccine: 12 years through 17 years of age (Monovalent)**

4.1.10.1. Assess persons 12 years through 17 years of age for vaccination with Moderna COVID-19 Vaccine based on the following criteria (**see section 4.1.13** for additional clinical considerations):

4.1.10.2. Persons who **ARE NOT** moderately or severely immunocompromised

4.1.10.2.1. If the recipient has never received a COVID-19 vaccine, administer 1 dose of monovalent Moderna COVID-19 vaccine.

4.1.10.2.2. If the recipient has received 1 previous dose of:

4.1.10.2.2.1. Monovalent Moderna COVID-19 Vaccine, administer the second primary dose of monovalent Moderna COVID-19 Vaccine at least 4 to 8 weeks after the first dose. Primary series completed.

4.1.10.2.2.2. If the first-dose vaccine product cannot be determined, is no longer available, or contraindicated, administer monovalent Moderna COVID-19 Vaccine at least 4 to 8 weeks after the first dose. Primary series completed.

4.1.10.2.3. If the recipient has received 2 primary series doses of:

4.1.10.2.3.1. Monovalent COVID-19 Vaccine (Moderna, Novavax or Pfizer-BioNTech), regardless of the number of monovalent booster doses, administer an age-appropriate bivalent mRNA booster dose at least 8 weeks (2 months) after the previous dose.

4.1.10.2.3.1.1. **Adolescents 12 years through 17 years of age**: The bivalent Pfizer-BioNTech booster dose is authorized for adolescents in this age group.

4.1.10.3. Persons who **ARE** moderately or severely immunocompromised

4.1.10.3.1. Healthcare personnel will notify medical provider if patient is moderately to severely immunocompromised; the medical provider is best positioned to determine the degree of immune compromise and appropriate timing of vaccination (for list of conditions, **see section 4.1.13.4**).

4.1.10.3.2. If the recipient has never received a COVID-19 vaccine, administer 1 dose of monovalent Moderna COVID-19 vaccine.

4.1.10.3.3. If the recipient has received 1 previous dose of:

4.1.10.3.3.1. Monovalent Moderna COVID-19 Vaccine, administer the second primary dose of monovalent Moderna COVID-19 Vaccine at least 4 weeks (28 days) after the first dose.

4.1.10.3.3.2. If the first-dose vaccine product cannot be determined, is no longer available, or contraindicated, administer monovalent Moderna COVID-19 Vaccine at least 4 weeks (28 days) after the first dose.

4.1.10.3.4. If the recipient has received 2 doses of:

4.1.10.3.4.1. Monovalent Moderna Vaccine, administer a third dose of monovalent Moderna COVID-19 Vaccine at least 28 days (4 weeks) after Dose 2. Primary series completed.

4.1.10.3.4.2. Monovalent Novavax COVID-19 Vaccine (**see section 4.1.12** for bivalent mRNA booster dose criteria).

4.1.10.3.4.3. If the previous vaccine products cannot be determined, are no longer available, or contraindicated, administer monovalent Moderna COVID-19 Vaccine at least 4 weeks (28 days) after the second dose. Primary series completed.

4.1.10.3.5. If the recipient has received 3 or more doses of:

4.1.10.3.5.1. Any monovalent COVID-19 Vaccine, administer an age-appropriate bivalent mRNA booster dose at least 8 weeks (2 months) after the previous dose. This includes 3 or more doses of the same monovalent product, or a mix of monovalent products.

4.1.10.3.5.1.1. **Adolescents 12 years through 17 years of age**: The bivalent Pfizer-BioNTech booster dose is authorized for adolescents in this age group.

4.1.10.4. For bivalent mRNA booster dose guidance in persons who received Janssen COVID-19 vaccine (**see section 4.1.13.8**).

4.1.10.5. Persons with a history of myocarditis or pericarditis (**see section 4.1.13.2**)

4.1.11. **For Moderna COVID-19 Vaccine: 18 years of age and older (Monovalent and Bivalent)**

4.1.11.1. Assess persons 18 years of age and older for vaccination with Moderna COVID-19 Vaccine based on the following criteria (**see section 4.1.13** for additional clinical considerations):

4.1.11.2. Persons who **ARE NOT** moderately or severely immunocompromised

4.1.11.2.1. If the recipient has never received a COVID-19 vaccine, administer 1 dose of monovalent Moderna COVID-19 vaccine.

4.1.11.2.2. If the recipient has received 1 previous dose of:

4.1.11.2.2.1. Monovalent Moderna COVID-19 Vaccine, administer the second primary dose of monovalent Moderna COVID-19 Vaccine at least 4 to 8 weeks after the first dose. Primary series completed.

4.1.11.2.2.2. If the first-dose vaccine product cannot be determined, is no longer available, or contraindicated, administer monovalent Moderna COVID-19 Vaccine at least 4 to 8 weeks after the first dose. Primary series completed.

4.1.11.2.3. If the recipient has received 2 primary series doses of:

4.1.11.2.3.1. Monovalent COVID-19 Vaccine (Moderna, Novavax or Pfizer-BioNTech), regardless of the number of monovalent booster doses, administer an age-appropriate bivalent mRNA booster dose at least 8 weeks (2 months) after the previous dose.

4.1.11.2.3.1.1. **Adults 18 years of age and older**: A bivalent mRNA booster dose (Moderna or Pfizer-BioNTech) is authorized for adults in this adult group.

4.1.11.3. Persons who **ARE** moderately or severely immunocompromised

4.1.11.3.1. Healthcare personnel will notify medical provider if patient is moderately to severely immunocompromised; the medical provider is best positioned to determine the degree of

immune compromise and appropriate timing of vaccination (for list of conditions, **see section 4.1.13.4**).

4.1.11.3.2. If the recipient has never received a COVID-19 vaccine, administer 1 dose of monovalent Moderna COVID-19 vaccine.

4.1.11.3.3. If the recipient has received 1 previous dose of:

4.1.11.3.3.1. Monovalent Moderna COVID-19 Vaccine, administer the second primary dose of monovalent Moderna COVID-19 Vaccine at least 4 weeks (28 days) after the first dose.

4.1.11.3.3.2. If the first-dose vaccine product cannot be determined, is no longer available, or contraindicated, administer monovalent Moderna COVID-19 Vaccine at least 4 weeks (28 days) after the first dose.

4.1.11.3.4. If the recipient has received 2 doses of:

4.1.11.3.4.1. Monovalent Moderna Vaccine, administer a third dose of monovalent Moderna COVID-19 Vaccine at least 28 days (4 weeks) after Dose 2. Primary series completed.

4.1.11.3.4.2. Monovalent Novavax COVID-19 Vaccine (**see section 4.1.12** for bivalent mRNA booster dose criteria).

4.1.11.3.4.3. If the previous vaccine products cannot be determined, are no longer available, or contraindicated, administer monovalent Moderna COVID-19 Vaccine at least 4 weeks (28 days) after the second dose. Primary series completed.

4.1.11.3.5. If the recipient has received 3 or more doses of:

4.1.11.3.5.1. Any monovalent COVID-19 Vaccine, administer an age-appropriate bivalent mRNA booster dose at least 8 weeks (2 months) after the previous dose. This includes 3 or more doses of the same monovalent product, or a mix of monovalent products.

4.1.11.3.5.1.1. **Adults 18 years of age and older**: A bivalent mRNA booster dose (Moderna or Pfizer-BioNTech) is authorized for adults in this adult group.

4.1.11.4. For bivalent mRNA booster dose guidance in persons who received Janssen COVID-19 vaccine (**see section 4.1.13.8**).

4.1.11.5. Persons with a history of myocarditis or pericarditis (**see section 4.1.13.2**)

4.1.12. **For Novavax COVID-19 Vaccine: 12 years of age and older (Monovalent)**

4.1.12.1. Assess persons 12 years of age and older for vaccination with Novavax COVID-19 Vaccine based on the following criteria (**see section 4.1.13** for additional clinical considerations):

4.1.12.2. Persons who **ARE NOT** moderately or severely immunocompromised

4.1.12.2.1. If the recipient has never received a COVID-19 vaccine, administer 1 dose of Novavax COVID-19 Vaccine.

4.1.12.2.2. If the recipient has received 1 previous dose of:

4.1.12.2.2.1. Novavax COVID-19 Vaccine, administer the second dose at least 3-8 weeks after Dose 1. Primary series completed.

4.1.12.2.2.2. A vaccine product that cannot be determined, is no longer available or contraindicated, administer Novavax COVID-19 Vaccine at least 4-8 weeks after the first dose. Primary series completed.

4.1.12.2.3. If the recipient has received 2 primary series doses of:
4.1.12.2.3.1. Monovalent Novavax COVID-19 Vaccine, administer an age-appropriate bivalent mRNA booster dose at least 8 weeks (2 months) after the previous dose.
4.1.12.2.3.1.1. **Adolescents 12 years through 17 years of age**: The bivalent Pfizer-BioNTech booster dose is authorized for adolescents in this age group.
4.1.12.2.3.1.2. **Adults 18 years of age and older**: A bivalent mRNA booster dose (Moderna or Pfizer-BioNTech) is authorized for adults in this adult group.

4.1.12.3. Persons who **ARE** moderately or severely immunocompromised

4.1.12.3.1. Healthcare personnel will notify medical provider; the medical provider is best positioned to determine the degree of immune compromise and appropriate timing of vaccination (for list of conditions, **see section 4.1.13.4**).

4.1.12.3.2. If the recipient has never received a COVID-19 vaccine, administer 1 dose of Novavax COVID-19 Vaccine.

4.1.12.3.3. If the recipient has received 1 previous dose of:
4.1.12.3.3.1. Novavax COVID-19 Vaccine, administer the second dose at least 3 weeks (21 day) after Dose 1. Primary series completed.
4.1.12.3.3.2. A vaccine product that cannot be determined, is no longer available or contraindicated, administer Novavax COVID-19 Vaccine at least 4 weeks after the first dose. Primary series completed.

4.1.12.3.4. If the recipient has received 2 primary series doses of:
4.1.12.3.4.1. Monovalent Novavax COVID-19 Vaccine, administer an age-appropriate bivalent mRNA booster dose at least 8 weeks (2 months) after the previous dose.
4.1.12.3.4.1.1. **Adolescents 12 years through 17 years of age**: The bivalent Pfizer-BioNTech booster dose is authorized for adolescents in this age group.
4.1.12.3.4.1.2. **Adults 18 years of age and older**: A bivalent mRNA booster dose (Moderna or Pfizer-BioNTech) is authorized for adults in this adult group.

4.1.12.4. For bivalent mRNA booster dose guidance in persons who received Janssen COVID-19 vaccine (**see section 4.1.13.8**).

4.1.13. Additional Clinical Considerations
4.1.13.1. Inform recipients, especially males 12 through 39 years of age and their parents/legal representative (when relevant) of the possibility of myocarditis or pericarditis following receipt of mRNA COVID-19 vaccines and the need to seek care if symptoms of mycarditis or pericarditis develop after vaccination. Educational materials on myocarditis/pericarditis are available at https://www.cdc.gov/coronavirus/2019-ncov/vaccines/safety/myocarditis.html

4.1.13.2. Persons with a history of myocarditis or pericarditis:
4.1.13.2.1. If history is prior to COVID-19 vaccination, may receive age-appropriate COVID-19 vaccine product (monovalent or bivalent) after the episode of myocarditis or pericarditis has completely resolved.
4.1.13.2.2. If myocarditis or pericarditis occurred after the first dose of an mRNA or Novavax COVID-19 vaccine, experts advise no additional doses of any COVID-19 vaccine. If, after a risk assessment, a decision is made to administer a subsequent dose of COVID-19 vaccine,

vaccine should not be administered until the myocarditis or pericarditis has completely resolved.

4.1.13.2.3. Healthcare personnel will notify medical provider; the medical provider is best positioned to complete a risk assessment and determine appropriate timing of vaccination.

4.1.13.2.4. Considerations for medical providers are available at CDC Interim Clinical Considerations for Use of COVID-19 Vaccines Currently Approved or Authorized in the United States: https://www.cdc.gov/vaccines/covid-19/clinical-considerations/interim-considerations-us.html#myocarditis-pericarditis

4.1.13.2.5. Educational materials on myocarditis/pericarditis are available at https://www.cdc.gov/coronavirus/2019-ncov/vaccines/safety/myocarditis.html

4.1.13.3. Persons who have received HCT or CAR-T-cell therapy

4.1.13.3.1. Revaccinate persons who received doses of COVID-19 vaccine prior to or during HCT or CAR-t-cell therapy with a primary series using monovalent COVID-19 vaccine and up to 1 booster dose of bivalent COVID-19 vaccine. Revaccination should start at least 3 months (12 weeks) after transplant or CAR-T-cell therapy

4.1.13.3.2. Healthcare personnel will notify medical provider; the medical provider is best positioned to determine the degree of immune compromise and appropriate timing of vaccination.

4.1.13.4. A list of conditions associated with moderate to severe immune compromise and additional considerations for medical providers is available at CDC Interim Clinical Considerations for Use of COVID-19 Vaccines Currently Approved or Authorized in the United States: https://www.cdc.gov/vaccines/covid-19/clinical-considerations/covid-19-vaccines-us.html

4.1.13.5. An 8-week interval between the first and second primary series doses of Moderna, Novavax, and Pfizer-BioNTech COVID-19 vaccines may be optimal for some people ages 6 months–64 years, especially for males ages 12–39 years, as it may reduce the small risk of myocarditis and pericarditis associated with these vaccines. A shorter interval (4 weeks for Moderna) between the first and second doses remains the recommended interval for people who are moderately or severely immunocompromised; adults ages 65 years and older; and in situations in which there is increased concern about COVID-19 community levels or an individual's higher risk of severe disease.

4.1.13.6. Persons with a recent SARS-CoV-2 infection may consider delaying a primary series or booster dose by 3 months from symptom onset or positive test (if infection asymptomatic).

4.1.13.7. See clinical guidance for COVID-19 vaccination and SARS-CoV-2 infection, including recommendations after receiving passive antibody products, at CDC Interim Clinical Considerations for Use of COVID-19 Vaccines Currently Approved or Authorized in the United States: https://www.cdc.gov/vaccines/covid-19/clinical-considerations/covid-19-vaccines-us.html

4.1.13.8. Previous vaccination with Janssen COVID-19 vaccine

4.1.13.8.1. People 18 years of age and older who received the monovalent Janssen COVID-19 Vaccine are recommended to receive an age-appropriate bivalent mRNA booster dose. Considerations for medical providers regarding criteria are available at CDC Interim Clinical Considerations for Use of COVID-19 Vaccines Currently Approved or Authorized in the United States, Appendix A: https://www.cdc.gov/vaccines/covid-19/clinical-considerations/interim-considerations-us-appendix.html#appendix-a

4.1.13.8.1.1. EUA Fact Sheets for Janssen (Johnson & Johnson) COVID-19 Vaccine are available on the FDA website: https://www.fda.gov/emergency-preparedness-and-response/coronavirus-disease-2019-covid-19/covid-19-vaccines

4.1.13.9. Monovalent or bivalent COVID-19 vaccine may be coadministered with other vaccines without regard to timing, including simultaneous administration of a COVID-19 vaccine and other vaccines on the same day.

4.1.13.10. For persons who received a COVID-19 vaccine:
4.1.13.10.1. Outside of the United States.
4.1.13.10.2. Not currently authorized/approved in the United States.
4.1.13.10.3. See CDC Interim Clinical Considerations for Use of COVID-19 Vaccines Currently Approved or Authorized in the United States, including booster dose recommendations, at: https://www.cdc.gov/vaccines/covid-19/clinical-considerations/covid-19-vaccines-us.html

4.2. Refer to the Emergency Use Authorization Fact Sheet for Healthcare Providers Administering Vaccine

4.2.1. Full prescribing information and mandatory requirements for COVID-19 vaccine administration is described in the product-specific EUA *Fact Sheet for Healthcare Providers Administering Vaccine*, available on the FDA website: https://www.fda.gov/emergency-preparedness-and-response/coronavirus-disease-2019-covid-19/covid-19-vaccines

4.2.1.1. Available EUA ***Fact Sheet for Healthcare Providers Administering Vaccine***:
4.2.1.1.1. Pfizer-BioNTech COVID-19 Vaccine:
4.2.1.1.1.1. Age 6 months through 4 years (Primary): https://www.fda.gov/media/159312/download
4.2.1.1.1.2. Age 5 years through 11 years (Primary and Monovalent Booster): https://www.fda.gov/media/153714/download
4.2.1.1.1.3. Age 12 years and older (Primary): https://www.fda.gov/media/153715/download
4.2.1.1.1.4. Age 12 years and older (Bivalent Booster): https://www.fda.gov/media/161327/download

4.2.1.1.2. Moderna COVID-19 Vaccine:
4.2.1.1.2.1. Age 6 months through 5 years (Primary): https://www.fda.gov/media/159307/download
4.2.1.1.2.2. Age 6 years through 11 years (Primary): https://www.fda.gov/media/159308/download
4.2.1.1.2.3. Age 12 years and older (Primary): https://www.fda.gov/media/157233/download
4.2.1.1.2.4. Age 18 years and older (Bivalent Booster): https://www.fda.gov/media/161318/download

4.2.1.1.3. Novavax COVID-19 Vaccine:
4.2.1.1.3.1. Age 12 years and older (Primary): https://www.fda.gov/media/159897/download

4.3. Screen for Contraindications and Precautions

4.3.1. Utilize the most current **CDC Pre-vaccination Checklist for COVID-19 Vaccines** to screen for contraindications, precautions and other clinical considerations: https://www.cdc.gov/vaccines/covid-19/downloads/pre-vaccination-screening-form.pdf

4.3.1.1. CDC Prevaccination checklist and guidelines are available here: https://www.cdc.gov/vaccines/covid-19/info-by-product/index.html)

4.3.1.2. If any doubt regarding a contraindication or precaution or other clinical consideration, healthcare personnel will consult a medical provider before administering vaccines.

4.3.2. For the purpose of this guidance, an immediate allergic reaction is defined as any hypersensitivity-related signs or symptoms such as urticaria, angioedema, respiratory distress (e.g.,wheezing, stridor), or anaphylaxis that occur within 4 hours following exposure to a vaccine or medication.

4.3.3. Contraindications

4.3.3.1. History of a severe allergic reaction (e.g., anaphylaxis) after a previous dose or to a component of the COVID-19 vaccine (**see section 4.3.3.4**).

4.3.3.2. History of a known diagnosed allergy to a component of the COVID-19 vaccine (**see section 4.3.3.4**).

4.3.3.3. For Janssen COVID-19 vaccine, TTS (thrombosis with thrombocytopenia syndrome) following receipt of a previous Janssen COVID-19 vaccine (or other COVID-19 vaccines not currently authorized in the United States that are based on adenovirus vectors e.g., AstraZeneca)

4.3.3.4. A list of COVID-19 vaccine components is available in the product-specific EUA *Fact Sheet for Healthcare Providers Administering Vaccine*, available on the FDA website: https://www.fda.gov/emergency-preparedness-and-response/coronavirus-disease-2019-covid-19/covid-19-vaccines

4.3.4. Precautions

4.3.4.1. 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”]).

4.3.4.2. History of non-severe, immediate (onset less than 4 hours) allergic reaction after a dose of one type of COVID-19 vaccine have a precaution to the same type of COVID-19 vaccine.

4.3.4.3. History of an allergy-related contraindication to one type of COVID-19 vaccine is a precaution to the other types of COVID-19 vaccines (**see section 4.3.4.8**).

4.3.4.4. History of moderate to severe acute illness, with or without fever.

4.3.4.5. History of multisystem inflammatory syndrome in children (MIS-C) or multisystem inflammatory syndrome in adults (MIS-A)

4.3.4.6. History of myocarditis or pericarditis after a dose of an mRNA or Novavax COVID-19 vaccine.

4.3.4.7. For Janssen COVID-19 vaccine, a history of Guillian-Barre syndrome (GBS).

4.3.4.8. Consider consultation with an allergist-immunologist to help determine if the patient can safely receive vaccination. Medical providers may request a consultation from the Clinical Immunization Safety Assessment COVIDvax Project (find weblink in References section below). Vaccination of

these individuals should only be done in an appropriate setting under the supervision of a healthcare provider experienced in the management of severe allergic reactions.

4.3.4.8.1. People with a known allergy to polysorbate have a contraindication to both Novavax and Janssen COVID-19 vaccines and a precaution to mRNA COVID-19 vaccines.

4.3.4.8.2. In all other cases, an allergy-related contraindication to one type of COVID-19 vaccine is a precaution to the other types.

4.3.5. Additional information about contraindications and precautions to COVID-19 vaccines and other clinical considerations for medical providers is available at CDC Interim Clinical Considerations for Use of COVID-19 Vaccines Currently Approved or Authorized in the United States: https://www.cdc.gov/vaccines/covid-19/clinical-considerations/covid-19-vaccines-us.html

4.4. Provide EUA Fact Sheet for Recipients and Caregivers

4.4.1. Provide all patients (or legal representative) with a copy of the current federal EUA *Fact Sheet for Recipients and Caregivers* for the age-appropriate COVID-19 vaccine product selected for administration, available on the FDA website: https://www.fda.gov/emergency-preparedness-and-response/coronavirus-disease-2019-covid-19/covid-19-vaccines

4.4.1.1. Available EUA ***Fact Sheet for Recipients and Caregivers*:**

4.4.1.1.1. Pfizer-BioNTech COVID-19 Vaccine:

4.4.1.1.1.1. Age 6 months through 4 years (Primary): https://www.fda.gov/media/159313/download

4.4.1.1.1.2. Age 5 years through 11 years (Primary and Monovalent Booster): https://www.fda.gov/media/153717/download

4.4.1.1.1.3. Age 12 years and older (Primary and Bivalent Booster): https://www.fda.gov/media/153716/download

4.4.1.1.2. Moderna COVID-19 Vaccine:

4.4.1.1.2.1. Age 6 months through 5 years (Primary): https://www.fda.gov/media/159309/download

4.4.1.1.2.2. Age 6 years through 11 years (Primary): https://www.fda.gov/media/159310/download

4.4.1.1.2.3. Age 12 years and older (Primary) and 18 years and older (Bivalent Booster): https://www.fda.gov/media/144638/download

4.4.1.1.3. Novavax COVID-19 Vaccine:

4.4.1.1.3.1. Age 12 years and older (Primary): https://www.fda.gov/media/159898/download

4.5. Prepare to Administer Vaccine

4.5.1. NOTE: Use these standing orders in conjunction with the **Interim COVID-19 Immunization Schedule for Persons 6 Months and Older,** found here: https://www.cdc.gov/vaccines/covid-19/downloads/COVID-19-immunization-schedule-ages-6months-older.pdf

4.5.2. Prepare to administer the vaccine. Choose the correct formulation, injection site, needle gauge and needle length (**see Chart 1 below**).

4.5.3. **For Pfizer-BioNTech COVID-19 Vaccine: 6 months through 4 years of age (Monovalent)**

4.5.3.1. Mix Pfizer-BioNTech COVID-19 vaccine formulation following the manufacturer's directions using **2.2 mL of 0.9% sodium chloride** (normal saline, preservative-free) diluent.

4.5.3.2. Administer 0.2 mL of Pfizer-BioNTech COVID-19 vaccine formulation for children 6 months through 4 years of age (maroon cap with maroon-bordered label) by intramuscular (IM) injection.

4.5.4. **For Pfizer-BioNTech COVID-19 Vaccine: 5 years through 11 years of age (Monovalent)**

4.5.4.1. Mix Pfizer-BioNTech COVID-19 vaccine formulation following the manufacturer's directions using **1.3 mL of 0.9% sodium chloride** (normal saline, preservative-free) diluent.

4.5.4.2. Administer 0.2 mL of Pfizer-BioNTech COVID-19 vaccine formulation for children 5 years through 11 years of age (orange cap and orange-bordered label) by intramuscular (IM) injection.

4.5.5. **For Pfizer-BioNTech COVID-19 Vaccine: 12 years of age and older (Monovalent)**

4.5.5.1. Do NOT dilute.

4.5.5.2. Administer 0.3 mL Pfizer-BioNTech COVID-19 vaccine (monovalent) for persons 12 years of age and older (gray cap and gray-bordered label) by intramuscular (IM) injection.

4.5.6. **For Pfizer-BioNTech COVID-19 Vaccine: 12 years of age and older (Bivalent)**

4.5.6.1. Do NOT dilute.

4.5.6.2. Administer 0.3 mL Pfizer-BioNTech COVID-19 vaccine (bivalent) for persons 12 years of age and older (gray cap and gray-bordered label) by intramuscular (IM) injection.

4.5.7. **For Moderna COVID-19 Vaccine: 6 months through 5 years of age (Monovalent)**

4.5.7.1. Administer 0.25 mL of Moderna COVID-19 Vaccine for children 6 months through 5 years of age (blue cap with magenta-bordered label) by intramuscular (IM) injection.

4.5.8. **For Moderna COVID-19 Vaccine: 6 years through 11 years of age (Monovalent)**

4.5.8.1. Administer 0.5 mL of Moderna COVID-19 Vaccine for children 6 through 11 years of age (blue cap with purple-bordered label) by intramuscular (IM) injection.

4.5.9. **For Moderna COVID-19 Vaccine: 12 years of age and older (Monovalent)**

4.5.9.1. Administer 0.5 mL of Moderna COVID-19 Vaccine (monovalent) for persons 12 years of age and older (red cap with blue-bordered label) by intramuscular (IM) injection.

4.5.10. **For Moderna COVID-19 Vaccine: 18 years of age and older (Bivalent)**

4.5.10.1. Administer 0.5 mL Moderna COVID-19 vaccine (bivalent) for persons 18 years of age and older (blue cap with gray-bordered label) by intramuscular (IM) injection.

4.5.11. **For Novavax COVID-19 Vaccine: 12 years of age and older (Monovalent)**

4.5.11.1. Administer 0.5 mL of Novavax COVID-19 Vaccine for persons 12 years of age and older (blue cap) by intramuscular (IM) injection.

4.5.12. Prior to administering a vaccine, follow the ANMC Medication Administration Procedure 500-19E at http://share.home.anthc.org/cbss/ecs/SitePages/ANMC%20Polices%20and%20Procedures.aspx

4.5.13. Utilize the most current age-appropriate product-specific EUA *Fact Sheet for Healthcare Providers Administering Vaccine* for Dosing Schedule, Dose Preparation and Administration information for the selected COVID-19 vaccine (for Fact Sheets, **see section 4.2**).

4.5.14. Check vaccine name and expiration date per process for COVID-19 vaccine.

4.5.15. Wash hands, prepare and draw up vaccine using aseptic technique.

4.5.16. Label each syringe according to the ANMC Medication Administration Procedure 500-19E at http://share.home.anthc.org/cbss/ecs/SitePages/ANMC%20Polices%20and%20Procedures.aspx

4.5.17. Choose the correct needle gauge, needle length, and injection site for patient (**see Chart 1 below**)

Chart 1: Intramuscular (IM) injection				
Choose the injection site and needle length that is appropriate to the person's age and body mass.				
Children		**Needle gauge**	**Needle length**	**Injection site**
Age 6 months through 2 years		22-25	1'	Vastus lateralis (anterolateral thigh) muscle
Age 3 years through 11 years		22-25	1"	Deltoid muscle of arm preferred (anterolateral thigh muscle can also be used)
Age 12 years through 18 years		22-25	1"	Deltoid muscle of arm
Adults 19 years and older				
Gender & weight:	Less than 130 lbs.	22-25	1"	Deltoid muscle of arm
	130-152 lbs.	22-25	1"	Deltoid muscle of arm
	Female 153-200 lbs.	22-25	1-1 ½"	Deltoid muscle of arm
	Male 153-260 lbs.	22-25	1-1 ½"	Deltoid muscle of arm
	Female 200+ lbs.	22-25	1 ½"	Deltoid muscle of arm
	Male 260+ lbs.	22-25	1 ½"	Deltoid muscle of arm

4.5.18. Vaccines should be stored at recommended temperatures until used.

4.5.19. Follow the manufacturer's guidance for storing/handling punctured vaccine vials.

4.5.20. The information in the most current age-appropriate product-specific EUA *Fact Sheet for Healthcare Providers Administering Vaccine* for COVID-19 vaccine supersedes the information on the vial and carton labels (for Fact Sheets, **see section 4.2**).

4.5.21. ACIP discourages the routine practice of personnel prefilling syringes.

4.5.22. Failure to adhere to recommended specifications for storage and handling of vaccines can reduce or destroy their potency, resulting in inadequate or no immune response in the recipient.

4.6. Administer COVID-19 Vaccine

4.6.1. Utilize the 7 rights of medication administration:
4.6.1.1. Right Patient (using name and date of birth),

4.6.1.2. Right Drug,
4.6.1.3. Right Dose,
4.6.1.4. Right Route,
4.6.1.5. Right Time,
4.6.1.6. Right Documentation, and
4.6.1.7. Right Allergies

4.6.2. Administer selected COVID-19 vaccine immediately to the patient.

4.6.3. Never inject vaccine in the buttock.

4.6.4. Immediately discard used needles, syringes in labeled puncture-proof containers.

4.6.5. The vaccine recipient should remain in clinic for 15 or 30 minutes after injection to be monitored for the occurrence of immediate adverse reactions, including syncope. CDC recommends the following observation periods after COVID-19 vaccination:

4.6.5.1. **30 minutes for persons with**:
4.6.5.1.1. An allergy-related contraindication to a different type of COVID-19 vaccine.
4.6.5.1.2. A history of non-severe, immediate (onset within 4 hours) allergic reaction (**see section 4.3.2**) after a previous dose of COVID-19 vaccine.
4.6.5.1.3. A history of anaphylaxis after non-COVID-19 vaccines or injectable therapies.

4.6.5.2. **15 minutes:** All other persons.

4.6.5.3. Additional information is available at CDC Interim Clinical Considerations for Use of COVID-19 Vaccines Currently Approved or Authorized in the United States, found under Appendices, Triage of people with a history of allergies or allergic reactions: https://www.cdc.gov/vaccines/covid-19/clinical-considerations/covid-19-vaccines-us.html

4.6.6. People should be seated or lying down during vaccination. Have vaccine recipient remain seated during the observation period to reduce the risk of syncope (fainting) and the risk for injury should they faint. If syncope develops, patients should be observed until symptoms resolve.

4.6.6.1. Syncope may occur in association with injectable vaccines, in particular among adolescents. Procedures should be in place to avoid falling injuries and manage syncopal reactions.

4.6.7. Provide a vaccination record card to the recipient or their caregiver with the date of vaccination, product name/manufacturer, lot number, and name of vaccinator or location of the administering clinic.

5. Document Vaccination

5.1. Documentation Process (Outpatient Clinics)

5.1.1. In VacTrAK, the healthcare personnel reviews the forecast. If the patient is “Due Now” or “Past Due” for vaccine and the patient, parent or legal representative agrees to vaccination, the medical provider is verbally notified.
5.1.2. Patient, parent or legal representative receives the age-appropriate product-specific EUA *Fact Sheet for Recipients and Caregivers.*

5.1.3. Screening for contraindications, precautions and other clinical considerations is completed (**see section 4.3**) and the medical provider is notified before vaccine is administered if contraindications or precautions or other clinical considerations are revealed or if there is doubt whether one exists.

5.1.4. In Cerner, the healthcare personnel enters orders in the patient's medical record for the needed vaccine using 'Protocol with Co-Signature'. The medical provider reviews VacTrAK as well as the orders in Cerner and co-signs the order. Vaccine may be given prior to provider co-signature.

5.1.5. Ordered vaccine is documented in Cerner according to workflow.

5.2. Documentation Process (Inpatient, ED and UCC)

5.2.1. In VacTrAK, the healthcare personnel reviews the forecast for patient's immunization status.

5.2.2. Patient, parent or legal representative receives the age-appropriate product-specific EUA *Fact Sheet for Recipients and Caregivers.* If the patient, parent or legal representative agrees to vaccination, the medical provider is notified.

5.2.3. Screening for contraindications, precautions and other clinical considerations is completed (**see section 4.3**) and the medical provider is notified if contraindications or precautions or other clinical considerations are revealed or if there is doubt whether one exists.

5.2.4. A medical provider's order is required in Cerner for COVID-19 vaccine.

5.2.5. Ordered vaccine is documented in Cerner according to workflow.

5.3. Documentation Process (On-Site Pharmacist Mass Clinics)

5.3.1. Patient, parent or legal representative receives the age-appropriate product-specific EUA *Fact Sheet for Recipients and Caregivers.* Screening for contraindications, precautions and other clinical considerations is completed (**see section 4.3**). If contraindications or precautions or other clinical considerations are revealed or if there is doubt whether one exists, the patient will not be vaccinated during the mass clinic and referred to their regular medical provider.

5.3.2. Documentation will be completed per the expectations of the mass clinic coordinator utilizing an appropriate job aide.

5.4. Documentation Process (On-Site Campus Mass Clinics and Off-Site Mass Clinics)

5.4.1. Patient, parent or legal representative receives the age-appropriate product-specific EUA *Fact Sheet for Recipients and Caregivers.* Screening for contraindications, precautions and other clinical considerations is completed (**see section 4.3**). If contraindications or precautions or other clinical considerations are revealed or if there is doubt whether one exists, the patient will not be vaccinated during the mass clinic and referred to their regular medical provider.

5.4.2. Documentation will be completed per the expectations of the mass clinic coordinator utilizing an appropriate job aide.

5.5. Documentation is completed for the administered COVID-19 vaccine.

5.5.1. In the medical record, record the date of vaccine administration; the vaccine name, manufacturer, lot number and manufacturer expiration date; the vaccination site and route; the age-appropriate product-specific EUA *Fact Sheet for Recipients and Caregivers* publication date; vaccine funding source and eligibility; and, name and title of the person administering the vaccine.

5.5.2. The State of Alaska requires vaccine funding source and eligibility documentation on all administered vaccine doses. Document vaccine funding source and eligibility correctly.

5.6. Per requirements of the federal COVID-19 Vaccination Program, healthcare organizations are required to report all administered COVID-19 vaccinations to VacTrAK within 24 hours of vaccine administration.

5.6.1. Vaccines documented in Cerner will transfer to VacTrAK electronically in real time.
5.6.2. COVID-19 vaccination providers should use their best efforts to report administration data to the relevant system (e.g. VacTrAK) as soon as practicable and no later than 72 hours after administration.

5.7. The Cerner Registry Import offers healthcare personnel the capacity to import immunizations from VacTrAK into the Cerner patient medical record to complete the Cerner immunization record.

5.8. If vaccines are not administered (i.e. contraindicated or refused), the medical provider is notified. The medical provider, nurse or other healthcare personnel documents in Cerner.

6. Be Prepared to Manage Medical Emergencies

6.1. An adverse event is an untoward event that occurs after a vaccination that might be caused by the vaccine product or vaccination process. These events range from common, minor, local reactions to rare, severe, allergic reactions (e.g., anaphylaxis).

6.2. Be prepared for management of a medical emergency related to the administration of vaccine by activating the medical emergency processes specific to the department when indicated.

6.3. Appropriate medical treatment used to manage severe allergic reactions must be immediately available.

6.4. For more information, see CDC Interim Considerations: Preparing for the Potential Management of Anaphylaxis after COVID-19 Vaccination: https://www.cdc.gov/vaccines/covid-19/clinical-considerations/managing-anaphylaxis.html

7. Report All Adverse Events to VAERS

7.1. Adverse events that occur in a recipient following COVID-19 vaccination should be reported to VAERS.

7.2. While COVID-19 vaccine is under Emergency Use Authorization (EUA), healthcare professionals are required to report to the Vaccine Adverse Event Reporting System (VAERS):

7.2.1. Vaccine administration errors (whether associated with an adverse event or not)
7.2.2. Serious adverse events (irrespective of attribution to vaccination)
7.2.3. Multisystem Inflammatory Syndrome (MIS) in adults or children
7.2.4. Cases of myocarditis (for mRNA vaccines)
7.2.5. Cases of pericarditis (for mRNA vaccines)
7.2.6. Cases of COVID-19 that result in hospitalization or death
7.2.7. Any additional adverse events and revised safety requirements per the Food and Drug Administration's conditions for use of an authorized vaccine throughout the duration of the EUA.

7.2.8. Refer to the age-appropriate product-specific EUA *Fact Sheet for Healthcare Providers Administering Vaccine* for COVID-19 vaccine for a complete description of the mandatory reporting requirements to VAERS (for Fact Sheets, **see section 4.2**), including the definition of serious adverse events.

7.2.9. Healthcare professionals are encouraged to report to VAERS clinically important adverse events that occur after vaccination, even if it is uncertain whether the vaccine caused the adverse event.

7.3. If an adverse event occurs, notify a medical provider, complete an incident report, and notify the Quality Improvement Pharmacy Manager by completing the following form: http://share.home.anthc.org/anmc/pharmacy/ANMC%20VAERS%20Reporting

7.4. The Quality Improvement Pharmacy Manager will file a report to the federal Vaccine Adverse Event Reporting System (VAERS), if indicated.

7.5. Additional information:

7.5.1. Food and Drug Administration's Emergency Use Authorization: https://www.fda.gov/emergency-preparedness-and-response/mcm-legal-regulatory-and-policy-framework/emergency-use-authorization

7.5.2. Multisystem Inflammatory Syndrome (MIS) in adults or children: https://www.cdc.gov/mis/index.html

8. V-SAFE

8.1. In addition to VAERS, CDC has developed a new, voluntary smartphone-based tool, V-SAFE. This tool uses text messaging and web surveys to provide near real-time health check-ins after patients receive COVID-19 vaccination.

8.1.1. Reports to V-SAFE indicating a medically significant health impact are followed up by the CDC/V-SAFE call center to collect additional information to complete a VAERS report.

9. Protocol Authorization

This protocol, authorized by the signatures below, serves as a pre-authorization order for eligible healthcare personal who have demonstrated competency to administer vaccines according to the protocol criteria.

References:

1. U.S. Food and Drug Administration, Vaccines, Blood, and Biologics: Emergency Use Authorization and Fact Sheets for COVID-19 Vaccines. Available at: https://www.fda.gov/emergency-preparedness-and-response/coronavirus-disease-2019-covid-19/covid-19-vaccines
2. Advisory Committee on Immunization Practice (ACIP) COVID-19 Vaccine Recommendations: https://www.cdc.gov/vaccines/hcp/acip-recs/vacc-specific/covid-19.html
3. Committee on Infectious Diseases. COVID-19 vaccines in children and adolescents. Pediatrics. 2021; doi: 10.1542/peds.2021-052336
4. CDC COVID-19 Vaccinations Clinical & Professional Resources. Available at: https://www.cdc.gov/vaccines/covid-19/index.html
    a. Interim Clinical Considerations for Use of COVID-19 Vaccines Currently Approved or Authorized in the United States: https://www.cdc.gov/vaccines/covid-19/clinical-considerations/covid-19-vaccines-us.html
    b. Interim Considerations: Preparing for the Potential Management of Anaphylaxis after COVID-19 Vaccination: https://www.cdc.gov/vaccines/covid-19/clinical-considerations/managing-anaphylaxis.html
    c. Pfizer-BioNTech COVID-19 Vaccine Standing Orders: https://www.cdc.gov/vaccines/covid-19/info-by-product/pfizer/administration.html

d. Moderna COVID-19 Vaccine Standing Orders: https://www.cdc.gov/vaccines/covid-19/info-by-product/moderna/administration.html
e. Novavax COVID-19 Vaccine Standing Orders: https://www.cdc.gov/vaccines/covid-19/info-by-product/novavax/administration.html
f. Janssen COVID-19 Vaccine (Johnson & Johnson) Standing Orders: https://www.cdc.gov/vaccines/covid-19/info-by-product/janssen/administration.html

5. Immunization Action Coalition Using Standing Orders for Administering Vaccines: What You Should Know. Available at: https://www.immunize.org/catg.d/p3066.pdf
6. Immunization Action Coalition Administering Vaccines: Dose, Route, Site, and Needle Size: https://www.immunize.org/catg.d/p3085.pdf
7. ACIP General Best Practices Guidelines for Immunization. Available at: https://www.cdc.gov/vaccines/hcp/acip-recs/general-recs/index.html
8. Clinical Immunization Safety Assessment (CISA) COVIDvax Project. Available at: https://www.cdc.gov/vaccinesafety/ensuringsafety/monitoring/cisa/index.html
9. VAERS. Available at: https://vaers.hhs.gov/reportevent.html
10. V-SAFE. Available at: https://www.cdc.gov/coronavirus/2019-ncov/vaccines/safety/vsafe.html
11. IHS Pharmacovigilance Program. Available at: https://www.ihs.gov/nptc/pharmacovigilance/

Created Date: 6/23/21 (Replaces previous individual protocols), updated 11/4/21, updated 9/15/22

Standing Orders Authorization

This policy and procedures shall remain in effect for all patients of the Alaska Native Medical Center (ANMC), Southcentral Foundation Anchorage Native Primary Care Center, Southcentral Foundation Benteh Nuutah Valley Native Primary Care Center and Southcentral Foundation Rural Clinics effective upon signatures below until rescinded or until DATE: _____

ANMC President Medical Staff	Name: _____	Signature: _____	Date: _____
ANMC Chief Nursing Officer	Name: _____	Signature: _____	Date: _____
ANMC Director of Pharmacy	Name: _____	Signature: _____	Date: _____
SCF Medical Director	Name: _____	Signature: _____	Date: _____
SCF Nursing Director	Name: _____	Signature: _____	Date: _____

d. Moderna COVID-19 Vaccine Standing Orders: https://www.cdc.gov/vaccines/covid-19/info-by-product/moderna/administration.html
e. Novavax COVID-19 Vaccine Standing Orders: https://www.cdc.gov/vaccines/covid-19/info-by-product/novavax/administration.html
f. Janssen COVID-19 Vaccine (Johnson & Johnson) Standing Orders: https://www.cdc.gov/vaccines/covid-19/info-by-product/janssen/administration.html

5. Immunization Action Coalition Using Standing Orders for Administering Vaccines: What You Should Know. Available at: https://www.immunize.org/catg.d/p3066.pdf
6. Immunization Action Coalition Administering Vaccines: Dose, Route, Site, and Needle Size: https://www.immunize.org/catg.d/p3085.pdf
7. ACIP General Best Practices Guidelines for Immunization. Available at: https://www.cdc.gov/vaccines/hcp/acip-recs/general-recs/index.html
8. Clinical Immunization Safety Assessment (CISA) COVIDvax Project. Available at: https://www.cdc.gov/vaccinesafety/ensuringsafety/monitoring/cisa/index.html
9. VAERS. Available at: https://vaers.hhs.gov/reportevent.html
10. V-SAFE. Available at: https://www.cdc.gov/coronavirus/2019-ncov/vaccines/safety/vsafe.html
11. IHS Pharmacovigilance Program. Available at: https://www.ihs.gov/nptc/pharmacovigilance/

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ANMC President Medical Staff	Name: _____	Signature: _____	Date: _____
ANMC Chief Nursing Officer	Name: _____	Signature: _____	Date: _____
ANMC Director of Pharmacy	Name: _____	Signature: _____	Date: _____
SCF Medical Director	Name: V. ORSECK	Signature: _____	Date: 9-22-22
SCF Nursing Director	Name: RONA JOHNSON	Signature: _____	Date: 09/22/2022

d. Moderna COVID-19 Vaccine Standing Orders: https://www.cdc.gov/vaccines/covid-19/info-by-product/moderna/administration.html
e. Novavax COVID-19 Vaccine Standing Orders: https://www.cdc.gov/vaccines/covid-19/info-by-product/novavax/administration.html
f. Janssen COVID-19 Vaccine (Johnson & Johnson) Standing Orders: https://www.cdc.gov/vaccines/covid-19/info-by-product/janssen/administration.html

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8. Clinical Immunization Safety Assessment (CISA) COVIDvax Project. Available at: https://www.cdc.gov/vaccinesafety/ensuringsafety/monitoring/cisa/index.html
9. VAERS. Available at: https://vaers.hhs.gov/reportevent.html
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ANMC President Medical Staff	Name:	_____	Signature:	_____	Date: _____
ANMC Chief Nursing Officer	Name:	_____	Signature:	_____	Date: _____
ANMC Director of Pharmacy	Name:	Christina Eldridge for Ashley Schaber	Signature:	Cldridge	Date: 9/22/22
SCF Medical Director	Name:	_____	Signature:	_____	Date: _____
SCF Nursing Director	Name:	_____	Signature:	_____	Date: _____

d. Moderna COVID-19 Vaccine Standing Orders: https://www.cdc.gov/vaccines/covid-19/info-by-product/moderna/administration.html
e. Novavax COVID-19 Vaccine Standing Orders: https://www.cdc.gov/vaccines/covid-19/info-by-product/novavax/administration.html
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6. Immunization Action Coalition Administering Vaccines: Dose, Route, Site, and Needle Size: https://www.immunize.org/catg.d/p3085.pdf
7. ACIP General Best Practices Guidelines for Immunization. Available at: https://www.cdc.gov/vaccines/hcp/acip-recs/general-recs/index.html
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9. VAERS. Available at: https://vaers.hhs.gov/reportevent.html
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ANMC President Medical Staff	Name: _____	Signature: _____	Date: _____
ANMC Chief Nursing Officer	Name: Tracy Nunnyan-Mayo	Signature: _____	Date: 9/12/22
ANMC Director of Pharmacy	Name: _____	Signature: _____	Date: _____
SCF Medical Director	Name: _____	Signature: _____	Date: _____
SCF Nursing Director	Name: _____	Signature: _____	Date: _____

d. Moderna COVID-19 Vaccine Standing Orders: https://www.cdc.gov/vaccines/covid-19/info-by-product/moderna/administration.html
e. Novavax COVID-19 Vaccine Standing Orders: https://www.cdc.gov/vaccines/covid-19/info-by-product/novavax/administration.html
f. Janssen COVID-19 Vaccine (Johnson & Johnson) Standing Orders: https://www.cdc.gov/vaccines/covid-19/info-by-product/janssen/administration.html

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7. ACIP General Best Practices Guidelines for Immunization. Available at: https://www.cdc.gov/vaccines/hcp/acip-recs/general-recs/index.html
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10. V-SAFE. Available at: https://www.cdc.gov/coronavirus/2019-ncov/vaccines/safety/vsafe.html
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ANMC President Medical Staff Name: Joshua Tolita Signature:  Date: 9/24/22

ANMC Chief Nursing Officer Name: _____ Signature: _____ Date: _____

ANMC Director of Pharmacy Name: _____ Signature: _____ Date: _____

SCF Medical Director Name: _____ Signature: _____ Date: _____

SCF Nursing Director Name: _____ Signature: _____ Date: _____