COVID-19 Vaccine Provider Guidance
Summary Updates
Updated November 12, 2021

Our goal continues to be to vaccinate as many people as easily, quickly and fairly as possible everywhere in North Carolina against COVID-19. The COVID-19 vaccines available in the United States continue to be remarkably effective in reducing risk of severe disease, hospitalization, and death, even against the widely circulating Delta variant.

Key Updates:

**Individuals 5 Years and Older Are Eligible for COVID-19 Vaccine:** On October 29, 2021, the US FDA amended the EUA for the Pfizer-BioNTech vaccine to allow for use of a specific Pfizer-BioNTech COVID-19 vaccine formulation (with a dose of 10 micrograms which is different than for adolescents and adults) for a 2-dose primary vaccination series at least 21 days apart in individuals 5-11 years of age. On November 2, 2021, CDC provided detailed and updated recommendations for use of Pfizer products. *(See Sections 11, 13 and 14)*

- Clinical trials with more than 3,000 children found the vaccines work and are safe.
- Temporary side effects for the COVID-19 vaccine for kids 5 to 11 were similar to side effects seen in adults.
- Children should receive the age-appropriate vaccine formulation regardless of their size or weight.

**Three Pfizer-BioNTech Vaccine Products Are Now Available:** There are three vaccine formulations now available that come in vials with different color caps, labels and borders: purple, gray and orange. The three products have different preparation and storage guidelines. There are now three EUA Fact Sheets for Health Care Providers for each formulation and two EUA Fact Sheets for Recipients and Caregivers based on the age of the recipients. All Pfizer-BioNTech Fact sheets and the most current FDA Letter of Authorization with details about the authorized changes and information about the specific formulations can be found at the FDA site. There is also information about ingredients in each of the products in the CDC guidance. *(See Sections 13 and 14 for more information about storage, handling, ingredients, and administration for each product.)*

**Expiration Date for 5 Through 11 Years of Age Pfizer Vaccine:** The Pfizer Vaccine for use in individuals 5-11 years of age has no expiration date printed on the box or vial. The date on these vials and boxes is the manufacturer date. Providers need to use the Pfizer Ages 5-11 Years EUA Fact Sheet for Health Care Providers or the Pfizer website and the manufacturer date printed on the box in order to determine the expiration date. *(See Section 13.5)*

**COVID-19 Vaccine Documentation and Reporting:** NC DHHS is now offering providers the ability to use the NC Immunization Registry (NCIR) for COVID-19 vaccine management to help streamline the experience for those currently using NCIR for other vaccines. Your organization may request a preferred system for documenting COVID-19 vaccine administrations, managing inventory, and querying COVID-19 immunization status, among other system-dependent functionalities. Organizations should review
the considerations detailed in the System Selection Information, which provides an overview of the implications of choosing either system. (See Section 7.0)

- For information about CVMS which includes support services and resources please go here.
- For information on NCIR, please go here.
- For information about NCIR interoperability with electronic health records, please go here.

Statewide Standing Orders for Pfizer Vaccines: There are now two separate statewide standing orders for administration of the available Pfizer-BioNTech COVID-19 vaccine formulations to be used in eligible patients:

- NC State Health Director’s Statewide Standing Order for COMIRNATY/Pfizer-BioNTech mRNA COVID-19 Vaccine Administration in Patients Ages 12 Years and Older
- NC State Health Director’s Statewide Standing Order for Pfizer-BioNTech mRNA COVID-19 Vaccine Administration in Patients Ages 5-11 Years

All of the statewide standing orders for COVID-19 can be found here. (See Section 12)