Purpose
This document is intended to ensure that health care/vaccination providers are aware of requirements issued by the State of Delaware for those who have enrolled to administer COVID-19 vaccinations.

A note about Vaccine Wastage
While not a requirement, providers follow clinical best practice for vaccination as well as best practices when managing inventory to maximize vaccination and minimize dose wastage. Providers should not miss any opportunities to vaccinate every eligible person who presents at a vaccination site, even if it means puncturing a multidose vial to administer vaccine without having enough people available to receive each dose. See this link for best practices: https://www.cdc.gov/vaccines/pubs/pinkbook/strat.html

Summary of Requirements
1. Reporting Vaccination Administrations – Health care providers or other vaccinating providers who administer immunizations shall report information about the immunization and the person to whom it was given, to DelVAX within 24 hours of administering the dose. Information reported must include the vaccinated person’s date of birth, address, phone number, race, ethnicity, date of vaccination, lot number and manufacturer of the vaccine administered, and other information as specified in the Delaware Immunization Information System. (Note: The Division of Public Health emphasizes the importance of recording race and ethnicity in order to evaluate efforts to vaccinate underserved populations. Race and ethnicity need to be complete and accurate. Continued provision of additional vaccine will be contingent upon compliance with data reporting requirements.)

2. Reporting Vaccine Inventory - The health care/vaccination provider must report daily vaccine inventory in VaccineFinder (https://vaccinefinder.org/covid-provider-resources/)

3. Reporting unused Vaccine – The health care/vaccination provider must report the number of doses of COVID-19 vaccine and adjuvants that were unused, spoiled, expired, or wasted. (Note: The Division of Public Health suggests that providers should have plans in place for how to handle unused vaccine.)

4. Requirements for Reporting Adverse Events – Health care/vaccination providers must report any adverse events following vaccination to the Vaccine Adverse Event Reporting System (VAERS) (1-800-822-7967 or http://vaers.hhs.gov/contact.html).
5. **Administering Vaccine to Priority Populations** - Vaccinations shall be made available only to persons who meet current criteria for [https://coronavirus.delaware.gov/vaccine/](https://coronavirus.delaware.gov/vaccine/).

6. **Equitable Access and Ability to Pay** – Health care/vaccination providers are prohibited from denying administration of a COVID-19 vaccination for reasons of race, color, gender, ethnicity, disability, national origin, age, or any other protected status. Further, health care/vaccination providers must make vaccinations available regardless of a person’s ability to pay, type of health insurance, administration fees, or participation in a particular provider or network. While providers may seek reimbursement from a health insurance plan, they may not seek any out-of-pocket costs from the vaccine recipient.

**Complaints**
Complaints regarding conformity to these requirements can be emailed to hspcontact@delaware.gov.

**Penalties**

**Emergency Declaration**
- Failure to comply with the data reporting requirements in the Declaration of a State of Emergency or any modification to a Declaration of the State of Emergency may result in a fine as authorized by 16 Del. C. § 107(a) and/or the cessation of vaccine distribution to the noncompliant provider.
- Any failure to comply with the provisions contained in a Declaration of a State of Emergency or any modification to a Declaration of the State of Emergency may constitute a criminal offense. 20 Del. C. §§ 3115 (b); 3116 (9); 3122; 3125. State and local law enforcement agencies are authorized to enforce the provisions of any Declaration of a State of Emergency.

**DHSS Order**
- Failure to comply with any order of the Department of Health and Social Services may result in a fine as authorized by 16 Del. C. 107(a). Repeated failure to comply with such an order may result in the cessation of vaccine distribution to the noncompliant provider.
- In practice, fines imposed are $100-$1000 per violation per day.

**Original Source Documents**
The requirements listed in this summary can be found in the following documents.
- Governor Carney’s Twenty-Ninth Modification: State of Emergency Declaration, Chapter P Vaccine Administration [https://governor.delaware.gov/health].
soe/twenty-ninth-modification-state-of-emergency-declaration). Designated below as ED.

- DelVAX Delaware Immunization Information System (IIS) User Agreement
  (https://delvax.dhss.delaware.gov/delvax/UserRegistration/NewRegistration/ShowPdf/73921) Designated below as DelVAX.

- CDC Vaccination Program Provider Agreement
  (https://www.cdc.gov/vaccines/covid-19/vaccination-provider-support.html). Designated below as CDC

- Order of the Department of Health and Social Services issued March 15, 2021
  Designated below as DHSS 2-25.
Unabridged Requirements

Reporting Vaccination Administrations

1. Physicians and other health care providers who give immunizations shall report information about the immunization and the person to whom it was given for addition to the immunization registry in a manner prescribed by the Division Director or designee. DelVAX

2. I [the health care provider] will provide immunization data to DelVAX in a timely and accurate manner. DelVAX

3. Within 24 hours of administering a dose of COVID-19 vaccine and adjuvant (if applicable), Organization must record in the vaccine recipient’s record and report required information to the relevant state, local, or territorial public health authority. Details of required information (collectively, Vaccine Administration Data) for reporting can be found on CDC’s website. CDC

4. Organization must submit Vaccine Administration Data through either (1) the immunization information system (IIS) of the state and local or territorial jurisdiction or (2) another system designated by CDC according to CDC documentation and data requirements. CDC

5. All health care providers, facilities, and entities administering COVID-19 vaccination in Delaware must report the vaccination within 24 hours to the Division of Public Health through the Delaware Immunization Information System (DelVAX or its derivative). Health care providers, facilities, and entities administering COVID-19 vaccination in Delaware must request and, when provided, report the vaccinated person’s date of birth, address, phone number, race, ethnicity, date of vaccination, lot number and manufacturer of the vaccine administered, and other information as specified in the Delaware Immunization Information System. ED

Reporting Vaccine Inventory

6. All healthcare providers administering COVID-19 vaccination in Delaware must report daily vaccine inventory in VaccineFinder. DHSS 2-25

Reporting Unused Vaccine

7. Organization must report the number of doses of COVID-19 vaccine and adjuvants that were unused, spoiled, expired, or wasted as required by the relevant jurisdiction. CDC

Reporting Adverse events
8. Organization must report any adverse events following vaccination to the Vaccine Adverse Event Reporting System (VAERS) (1-800-822-7967 or http://vaers.hhs.gov/contact.html). CDC

Administering Vaccine to Priority Populations

9. All COVID-19 vaccinations shall be made available only to persons who meet current criteria for inoculation as determined by DPH. The phases, criteria, or target population will be established and modified over time by DPH in the form of the State of Delaware’s COVID-19 Vaccination Guidance (“Vaccination Guidance”) and may be accessed at the following website: https://coronavirus.delaware.gov/vaccine/ ED

Equitable Access and Ability to Pay

10. The Department of Health and Social Services hereby prohibits healthcare providers from denying administration of a COVID-19 vaccination for reasons of race, color, gender, ethnicity, disability, national origin, age, or any other protected status. DHSS 3-15

11. Organization must administer COVID-19 vaccine regardless of the vaccine recipient’s ability to pay COVID-19 vaccine administration fees or coverage status. Organization may seek appropriate reimbursement from a program or plan that covers COVID-19 Vaccine administration fees for the vaccine recipient. Organization may not seek any reimbursement, including through balance billing, from the vaccine recipient. CDC

12. All health care providers, facilities and entities that decide to offer vaccinations shall make those vaccinations available to any person meeting the vaccination criteria without regard to that person’s ability to pay, type of health insurance, or participation in any particular provider network. ED

13. All health care providers, facilities and entities that offer vaccinations shall provide vaccinations at no out-of-pocket cost to individuals. ED