Agreement requirements

I understand this is an agreement between Organization and CDC. This program is part of a collaboration under the relevant state, local, or territorial immunization program's cooperative agreement with CDC.

To receive one or more of the publicly funded COVID-19 vaccines (COVID-19 vaccine), constituent products, and ancillary supplies at no cost, Organization agrees that it will adhere to the following requirements:

1. Organization must administer COVID-19 vaccine in accordance with all requirements and recommendations of CDC and CDC's Advisory Committee on Immunization Practices (ACIP).[1]

2. 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.[2]
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.[2]
Organization must preserve the record for at least 3 years following vaccination, or longer if required by state, local, or territorial law. Such records must be made available to any federal, state, local, or territorial public health department to the extent authorized by law.

3. Organization must not sell or seek reimbursement for COVID-19 vaccine and any adjuvant, syringes, needles, or other constituent products and ancillary supplies that the federal government provides without cost to Organization.

4. 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.

5. Before administering COVID-19 vaccine, Organization must provide an approved Emergency Use Authorization (EUA) fact sheet or vaccine information statement (VIS), as required, to each vaccine recipient, the adult caregiver accompanying the recipient, or other legal representative.

6. Organization's COVID-19 vaccination services must be conducted in compliance with *CDC's Guidance for Immunization Services During the COVID-19 Pandemic* for safe delivery of vaccines.[3]

7. Organization must comply with CDC requirements for COVID-19 vaccine management. Those requirements include the following:

a) Organization must store and handle COVID-19 vaccine under proper conditions, including maintaining cold chain conditions and chain of custody at all times in accordance with the manufacturer's package insert and CDC guidance in CDC's *Vaccine Storage and Handling Toolkit*, which will be updated to include specific information related to COVID-19 vaccine;

b) Organization must monitor vaccine storage unit temperatures at all times using equipment and practices that comply with guidance in CDC's *Vaccine Storage and Handling Toolkit*[4];

c) Organization must comply with each relevant jurisdiction's immunization program guidance for dealing with temperature excursions;

d) Organization must monitor and comply with COVID-19 vaccine expiration dates; and

e) Organization must preserve all records related to COVID-19 vaccine management for a minimum of 3 years, or longer if required by state, local, or territorial law.

8. 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.

9. Organization must comply with all federal instructions and timelines for disposing of COVID-19 Vaccine and adjuvant, including unused doses.[5]

10. 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).

11. Organization must provide a completed COVID-19 vaccination record card to every COVID-19 vaccine recipient, the adult caregiver accompanying the recipient, or other legal representative. Each COVID-19 vaccine shipment will include COVID-19 vaccination record cards.

12. a) Organization must comply with all applicable requirements as set forth by the U.S. Food and Drug Administration, including but not limited to requirements in any EUA that covers COVID-19 vaccine.

b) Organization must administer COVID-19 vaccine in compliance with all applicable state and territorial vaccination laws.

This agreement expressly incorporates all recommendations, requirements, and other guidance that this agreement specifically identifies. Organization must monitor such identified guidance for updates. Organization must comply with such updates.

[1] www.cdc.gov/vaccines/hcp/acip-recs/index.html
[2] www.cdc.gov/vaccines/programs/iis/index.html
[3] www.cdc.gov/vaccines/pandemic-guidance/index.html
[4] https://www.cdc.gov/vaccines/hcp/admin/storage/toolkit/index.html
[5] The disposal process for remaining unused COVID-19 vaccine and adjuvant may be different from the process for other vaccines; unused vaccines must remain under storage and handling conditions noted in Item 7 until CDC provides disposal instructions; website URL will be made available.
[6] See Pub. L. No. 109-148, Public Health Service Act § 319F-3, 42 U.S.C. § 247d-6d and 42 U.S.C. § 247d-6e; 85 Fed. Reg. 15,198, 15,202 (March 17, 2020).