ADPH Mpox Vaccination Program Provider Agreement

ALABAMA PUBLIC HEALTH

Please complete Sections A and B of this form as follows:

The Alabama Department of Public Health (ADPH) greatly appreciates your site's participation in the Mpox (JYNNEOS/ACAM2000) Vaccination Program. Your site's chief medical officer (or equivalent) must complete and sign the ADPH Mpox Vaccination Program Provider Requirements and Legal Agreement (Section A). ADPH Mpox Vaccination Program Provider Profile Information (Section B) must be completed.

Section A. Mpox Vaccination Program Provider Requirements and Legal Agreement

AGREEMENT REQUIREMENTS

I understand this is an agreement between _____(Provider Name) and ADPH. This program is a part of collaboration under the relevant state, local, or territorial immunization's cooperative agreement with CDC. To receive one or more of the publicly funded Mpox vaccines (Mpox Vaccine) at no cost, Site agrees that it will adhere to the following requirements:

1. Site/Organization must administer JYNNEOS or ACAM2000 in accordance with all requirements and recommendations of CDC, CDC's Advisory Committee on Immunization Practices (ACIP) (including those in the CDC Interim Clinical Considerations for Mpox Vaccination and any CDC Emergency Use Instructions as they may be revised from time to time), and consistent with the scope of the Food and Drug Administration's (FDA's) approval, authorization, and/or any applicable expanded access requirements per FDA's protocol.
2. This Agreement expressly incorporates all information included in web links in this Agreement as they may be revised from time to time. HHS reserves the right to update this Agreement at any time by posting updates on the HHS Mpox Vaccination Program Provider Agreement update webpage at: https://www.cdc.gov/poxvirus/monkeypox/provider-agreement.html. Organization must monitor this website for updates and comply with any such posted updates.
3. Organization must record the following Vaccine Administration Data elements in each vaccine recipient's record:
    - **a.** Administration address (including Company)*
    - **b.** Recipient name and ID*
    - **c.** Recipient date of birth*
    - **d.** Recipient sex*
    - **e.** Recipient address*
    - **f.** Administration date*
    - **g.** CVX (product)*
    - **h.** Dose number*
    - **i.** Lot number (Unit of Use [UoU] or Unit of Sale [UoS])*
    - **j.** MVX (manufacturer)*
    - **k.** Vaccine administering provider's name and suffix*
    - **l.** Administering provider's address, if different than the administration address*
    - **m.** Vaccine administration site (on the body)*
    - **n.** Vaccine expiration date*
    - **o.** Vaccine route of administration*
4. Organization must submit the following Vaccine Administration Data at least weekly through either (1) the Immunization Information System (IIS) of the state, local, or territorial jurisdiction or (2) another system designated by CDC according to CDC documentation as may be posted on the Provider Agreement update webpage:
    - **a.** Administered at location/facility name/ID
    - **b.** Administered at location type
    - **c.** Administration address (including Company)*
    - **d.** Recipient name and ID*
    - **e.** Recipient date of birth*

f. Recipien tsex*
g. Recipient race
h. Recipient ethnicity
i. Recipient address*
j. Administration date*
k. CVX (product)*
l. NDC (national drug code)
m. Dose number*
n. Lot number (Unit of Use [UoU] or Unit of Sale [UoS])*
o. MVX (manufacturer)*
p. Sending organization (name of the entity submitting the report)
q. Vaccine administering provider's name and suffix*
r. Administering provider's address, if different than the administration address*
s. Vaccine administration site (on the body)*
t. Vaccine expiration date*
u. Vaccine route of administration*
v. Vaccine series.

5 Organization is prohibited from selling or seeking reimbursement for JYNNEOS or ACAM2000 vaccine doses and any other supplies that the federal government provides without cost to Organization.

6 Organization must administer JYNNEOS or ACAM2000 vaccine at no cost to the recipient and regardless of the vaccine recipient's ability to pay administration fees. Organization may seek appropriate reimbursement from a program or plan that covers JYNNEOS or ACAM2000 vaccine administration fees for the vaccine recipient, such as:

» vaccine recipient's private insurance company
» Medicare/Medicaid reimbursement

7 Before administering JYNNEOS vaccine, Organization must provide a CDC Vaccine Information Statement (VIS) (https://www.cdc.gov/vaccines/hcp/vis/vis-statements/smallpox-monkeypox.html), or FDA Emergency Use Authorization (EUA) Fact Sheet (https://www.fda.gov/media/160773/download) for persons receiving JYNNEOS vaccine under EUA, as applicable, to each vaccine recipient, the adult caregiver accompanying the recipient, or other legal representative. Before administering ACAM2000 vaccine, Organization must provide an FDA Medication Guide (https://www.fda.gov/media/75800/download) to each vaccine recipient, the adult caregiver accompanying the recipient, or other legal representative.

8 Organization must report weekly the number of doses of JYNNEOS/ACAM2000 vaccine that were administered, remain in inventory, or were spoiled, expired, or wasted during the previous week. These reports of inventory count and aggregate doses administered must be submitted by the Organization through the IIS. Future allotments of this vaccine are dependent upon Organization reporting of Vaccine Administration Data and reporting required under this paragraph.

9 Organization must make records related to participation in the HHS Mpox Vaccination Program available for immediate inspection upon request by HHS, its relevant component agencies, and relevant state, tribal, territorial, or local public health authorities.

10 Organization must comply with CDC requirements for JYNNEOS/ACAM2000 vaccine management

a. Organization must store and handle JYNNEOS/ACAM2000 vaccine under proper conditions, including maintaining cold chain conditions and chain of custody at all times in accordance with CDC guidance regarding monkeypox vaccines in the CDC Vaccine Storage and Handling Toolkit Addendum (https://www.cdc.gov/vaccines/hcp/admin/storage/toolkit/storage-handling-toolkit.pdf) and in CDC's Monkeypox Vaccine Storage and Handling Summary (https://www.cdc.gov/poxvirus/monkeypox/pdf/Storage-and-Handling-Summary.pdf)

b. Organization must monitor vaccine storage unit temperatures at all times using equipment and practices that comply with guidance located in CDC's Mpox Vaccine Storage and Handling Summary

c. Organization must comply with CDC's Mpox Vaccine Storage and Handling Summary guidance for dealing with temperature excursions

d. Organization must monitor and comply with JYNNEOS and ACAM2000 vaccine expiration dates and beyond-use date timeframes as noted in CDC's Mpox Vaccine Storage and Handling Summary guidance

e. Organization must preserve all records related to JYNNEOS and ACAM2000 vaccine management and administration for a minimum of 3 years, or longer if required by state, local, or territorial law.

11 Organization must report all SERIOUS ADVERSE EVENTS (AEs) following administration of JYNNEOS or ACAM2000 vaccine and VACCINE ADMINISTRATION ERRORS to the Vaccine Adverse Event Reporting System (VAERS) at https://vaers.hhs.gov/reportevent.html:

The vaccination provider is responsible for MANDATORY reporting of the following listed events following JYNNEOS or ACAM2000 vaccination to VAERS:

- »Vaccine administration errors whether or not associated with an adverse event
- »Serious adverse events* (irrespective of attribution to vaccination)
- »Cases of cardiac events including myocarditis and pericarditis
- »Cases of thromboembolic events and neurovascular events

*Serious adverse events are defined as:

- »Death
- »A life-threatening adverse event
- »Inpatient hospitalization or prolongation of existing hospitalization
- »A persistent or significant incapacity or substantial disruption of the ability to conduct normal life functions
- »A congenital anomaly/birth defect
- »An important medical event that based on appropriate medical judgement may jeopardize the individual and may require medical or surgical intervention to prevent one of the outcomes listed above

Providers are encouraged to also report to VAERS any additional clinically significant AEs following vaccination, even if they are not sure if vaccination caused the event.

12 Organization's JYNNEOS and ACAM2000 vaccination services must be conducted in compliance with:

- **a.** All applicable local, state, and federal vaccination laws
- **b.** CDC's guidance on vaccine administration, available at: https://www.cdc.gov/vaccines/hcp/admin/admin-protocols.html
- **c.** CDC's General Best Practice Guidelines for Immunization, available at: https://www.cdc.gov/vaccines/hcp/acip-recs/general-recs/index.html

13 Organization is prohibited from transferring JYNNEOS and ACAM2000 vaccine doses to another provider unless authorized by HHS or the relevant public health jurisdiction.

14 Upon request by HHS or the relevant public health jurisdiction, Organization must return all JYNNEOS and ACAM2000 vaccine doses not yet used.

15 Effective August 15, 2022, vaccine allocation decisions by HHS will be made based on the expectation that vaccine will be administered to individuals over 18 years of age via intradermal injections at 0.1mL per injection. This route of administration is authorized by the FDA through Emergency Use Authorization since, as a two-dose intradermal regimen, it safely provides a similar immune response against mpox as the approved two-dose subcutaneous regimen. While a subcutaneous route of administration utilizing 0.5 mL per injection is still permitted (per original FDA approval), it should only be utilized for those who have a contraindication to intradermal injection (e.g., those with a history of keloid formation or those unable to tolerate intradermal injections). For individuals under 18 years of age, subcutaneous administration utilizing 0.5 mL per injection is also authorized.

Non-compliance with the terms of Agreement may result in suspension or termination from the HHS Monkeypox Vaccination Program and imposition of criminal and civil penalties under federal law, including but not limited to the False Claims Act, 31 U.S.C. § 3729 et seq., and other related federal laws, 18 U.S.C. §§ 1001, 1035, 1347, 1349.

Site Information

RESPONSIBLE OFFICERS

For the purposes of this agreement, in addition to Site, Responsible Officers named below will also be accountable for compliance with the conditions specified in this agreement. The individuals listed below must provide their signature after reviewing the agreement requirements.

Please print clearly.

Site Name: _____

Specialty Type: _____

Public or Private: _____

Site Address: _____

Unit#: _____

Street Address 2: _____

City: _____

State: _____

Zip: _____

County: _____

Country: United States of America

Telephone: _____

Signature: _____

Email: _____

Email must be monitored and will serve as dedicated contact method for the ADPH Mpox Vaccination Program

For official use only:

Section B. ADPH Mpox Vaccination Program Provider Profile Information

Please complete and sign this form for your Site location. If you are enrolling on behalf of one or more other affiliated Site vaccination locations, complete and sign this form for each location. Each individual Site vaccination location must adhere to the requirements listed in Section A.

CONTACT INFORMATION FOR SITE'S PRIMARY MPOX VACCINE COORDINATOR

Please print clearly.

*Name (Last Name, First Name, Middle Initial): _____

*Email: _____

*Address (Street Name): _____

*City,State, Zip: _____

*Signature: _____

*Date: _____

SITE ADDRESS FOR RECEIPT OF MPOX VACCINE SHIPMENTS

Please print clearly.

*Site Name:_____

*Shipping Address: _____

*Unit #: _____

*Street Address 2 (optional) **No P.O Box:**_____

*City: _____

*State:_____

*Zip Code:_____

*County:_____

*Country: **United States of America**

*Phone:_____

DAYS AND TIMES VACCINE COORDINATORS ARE AVAILABLE FOR RECEIPT OF MPOX VACCINE SHIPMENTS:
At least two days timing is required, and morning hours should not overlap with the afternoon hours

_____

Special Instructions:_____

PROVIDER TYPE FOR THIS LOCATION:_____

SETTING(S) FOR THIS LOCATION: (e.g., local health department, hospital, provider office):

_____

REFRIGERATED INSTRUCTIONS:

For Refrigerator:

1. Standalonerefrigeratorisapreferred.
2. Household refrigerator with separate compartments for refrigerator and freezer with separate exterior doors (**refrigerator portion is the only section that may be used.**) Commercial refrigerator with separate compartments for refrigerator and freezer with separate exterior doors(**refrigerator portion is the only section that may be used.**)

I understand that non-acceptable units include:

- Dormitory-style units, and
- Units that do not meet temperature criteria.

For freezer:

1. Stand alone freezer (e.g., chest freezer, frost-free freezer, manual defrost freezer)

PROVIDERS PRACTICING AT THIS FACILITY

I attest that each storage unit will maintain the appropriate temperature range: (please sign and date)

* Medical/pharmacy director or location's vaccine coordinator:_____

*Date:_____

Please add below the list of vaccinating providers for this site.

FULL NAME	LICENSE #	LICENSE TYPE