

Governor

JAMES V. McDONALD, M.D., M.P.H. Acting Commissioner MEGAN E. BALDWIN
Acting Executive Deputy Commissioner

## MPOX OUTBREAK VACCINE PROVIDER AGREEMENT FOR VACCINE DURING EMERGENCIES UPDATED MAY 10, 2023

The New York State Department of Health (NYSDOH) Bureau of Immunization (BI) is committed to utilizing publicly purchased vaccines for vaccine-preventable disease (VPD) control efforts and public health emergency response and preparedness activities. Outbreak vaccines are not typically ordered in the New York State Immunization Information System (NYSIIS). The NYSDOH BI Vaccine Program will place an order for vaccine using the appropriate funding source based on available supply or facilitate redistribution of vaccine from current supply to the outbreak provider.

Vaccines sent to providers under this outbreak agreement, may be administered to eligible individuals regardless of insurance status during public health emergency response activities including outbreak response, post-exposure prophylaxis (PEP), disaster relief efforts, or mass vaccination campaigns or exercises for public health preparedness approved by the NYSDOH BI Vaccine Program.

Completion of the Outbreak Agreement is required for all providers receiving, storing, or administering Mpox vaccines. Providers participating in any of the existing Vaccine Programs (Vaccines for Children, Vaccines for Adults, or COVID-19 Vaccine Program) will continue to use the existing NYSIIS account and unique provider PIN. Providers that have not previously participated in any of the Vaccine Programs will be set up with a NYSIIS account, if necessary, and be assigned a unique PIN for reporting.

Providers receiving Mpox vaccine must utilize the NYSIIS to maintain inventory of outbreak doses received and administered. In accordance with NYS Public Health Law Section 2168, health care providers who administer Mpox vaccines to persons younger than 19 years of age are required to report such vaccinations to the New York State Immunization Information System (NYSIIS) or to the New York City Immunization Registry (CIR). Health care providers who administer Mpox vaccines to persons 19 years of age and older must obtain patient consent to report such vaccinations to the New York State Immunization Information System (NYSIIS) or to the New York City Immunization Registry (CIR). Providers enrolling for Mpox vaccine are encouraged to sign up for the CDC's vaccine finder tool once vaccine is received to maximize accessibility and ensure community members know where to find a nearby vaccine. Providers can sign up by following this link and creating/amending your NPIN profile: Submit your organization.

The primary and backup contacts to be listed in the agreement are responsible for receiving vaccine deliveries, monitoring vaccine temperatures, managing physical inventory of vaccine, and ensuring the reporting of inventory, wastage and doses administered are done in NYSIIS. Staff will need to complete the Standard User and Administrative User trainings located at

https://www.health.ny.gov/prevention/immunization/information\_system/status.htm to access the required NYSIIS modules if they do not currently have access.

Additional resources can be found at <a href="https://www.health.ny.gov/diseases/communicable/zoonoses/mpox/">https://www.health.ny.gov/diseases/communicable/zoonoses/mpox/</a>, including the <a href="https://www.health.ny.gov/diseases/communicable/zoonoses/mpox/">JYNNEOS™ Vaccine Guidance for Health Care Providers and Vaccine Administrators</a>. Check these sites regularly for updates.

New York State Department of Health Bureau of Immunization - Vaccine Program

Email to: <a href="mailto:nyvfc@health.ny.gov">nyvfc@health.ny.gov</a> Attn: Vaccine Program Manager

Phone: (800) 543-7468 Fax: (518) 449-6912

Date Received				
Date Approved				
or Expedited Review				

2023 MPOX VACCINE (JYNNEOS) OUTBREAK APPLICATION						
OUTBREAK RESPONSE	INFOR	MATION				
Briefly describe your						
role in the outbreak						
and need for vaccine	2					
	ORMATION (Responsible for vaccine deliveries, temperature monitoring, inventory, and reporting)					
Primary Contact	Name:					
	Phone:		Email:			
Backup Contact	Name:					
	Phon	e:	Email:			
Does staff above have	access	to:				
Health Commerce Syst	em 🗆	l No □ Yes If yes, HCS ID:				
New York State Immun	ization	Information System (NYSIIS)	□ No □ Yes NY	SIIS org ID or PIN (if known):		
		, , ,		515 Org 12 Or 111 (11 Kilowii).		
PROVIDER/FACILITY IN						
Provider Location/Facili	ity Nar	ne:				
Address (where vaccine will be delivered to):						
City:		County:	State:	Zip:		
•		-				
Phone:		Fax:				
Please provide your specific vaccine delivery days/hours. Someone must be onsite to accept deliveries during these						
times:						
What type of storage unit(s) will store outbreak vaccines? (check all that apply)						
☐ Refrigerator	Refrigerator   Standard Freezer   Ultra-cold freezer					
What is the Grade/Sty	le of st	orage unit that will store outk	oreak vaccine?			
☐ Pharmaceutical-Grade Stand-alone ☐ Pharmaceutical-Grade Combination						
☐ Household/Commercial Stand-alone ☐ Household/Commercial Combination						
Digital Data Logger Use	ed					
Brand:	Calibration Expiration Date:					
טומווע.	Campi ation Expiration Date:					

## **OUTBREAK VACCINE PROVIDER AGREEMENT**

To receive publicly funded outbreak vaccines at no cost, I agree to the following conditions, on behalf of myself and all the practitioners, nurses, and others associated with the health care facility:

- 1. Mpox is a disease caused by infection with the monkeypox virus (MPXV). In the current outbreak, MPXV is spreading as described on the NYSDOH Mpox Vaccine Information webpage. JYNNEOS vaccine is available to help protect against MPXV infection and is recommend for those who are at risk of becoming infected. I agree to administer JYNNEOS in accordance with the recommendations of CDC and ACIP, and consistent with the scope of the FDA's approval, authorization, and/or any applicable expanded access requirements per FDA's protocol.
- 2. I will ensure availability of staff to receive/accept outbreak vaccine deliveries during the hours listed on the application.
- **3.** For the vaccines identified and agreed upon, I will use my New York State Immunization Information System (NYSIIS) account through the Health Commerce System to:
  - a) Maintain accurate vaccine inventory by manually adding outbreak vaccine orders to NYSIIS inventory. NYIIS inventory must be reviewed weekly and verified against physical doses on hand.
  - b) Record doses of outbreak vaccine administered in accordance with Public Health Law. Unless suspended by an executive order or required by CDC, consent is required to report immunizations administered to adults 19 and older to NYSIIS. I will attempt to obtain consent from ALL adult patients for their immunizations to be reported to NYSIIS. Doses administered to children less than 19 years of age or to adults who consent to NYSIIS will be reported to NYSIIS within two weeks of administration, unless timeliness is otherwise defined by executive order or CDC requirement. Doses administered to adults who do not consent will be appropriately decremented from the vaccine inventory in NYSIIS (using reason code "Adult not in NYSIIS").
- 4. I will store outbreak vaccine under <u>proper storage conditions</u> at all times. I understand that the refrigerator must be able to maintain temperature ranges between 36° and 46° Fahrenheit (or 2° and 8° Celsius) and the freezer must maintain temperatures between -13F° and 5° Fahrenheit (or -25° and 15° Celsius).
- 5. I will ensure storage units for vaccines are monitored with a continuous temperature monitoring device (e.g. data logger). I will record the minimum and maximum temperatures on a temperature log each day and report any excursions to <a href="mailto:vaccinetempexcursion@health.ny.gov">vaccinetempexcursion@health.ny.gov</a>.
- 6. I will follow NYS transport guidance for transport of outbreak vaccine, including use of a digital data logger at all times. I will notify NYSDOH of any redistribution to another provider. I will not redistribute to providers outside of my county, unless approved by NYSDOH.
- 7. I will administer JYNNEOS™ regardless of the vaccine recipient's ability to pay vaccine administration fees or coverage status. I may seek appropriate reimbursement from a program or plan that covers JYNNEOS™ vaccine administration fees for the vaccine recipient, but may not seek any reimbursement, including through balance billing, from the vaccine recipient.
- 8. Before administering JYNNEOS™ vaccine, I will 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. I will report any clinically significant adverse events to the Vaccine Adverse Event Reporting System (VAERS).
- 9. With use of the JYNNEOS™ vaccine provided at no cost by the US government, I agreed to comply with the requirements of the HHS Mpox Vaccination Program Provider Agreement, including any updates, located at <a href="https://www.cdc.gov/poxvirus/mpox/clinicians/provider-agreement.html">https://www.cdc.gov/poxvirus/mpox/clinicians/provider-agreement.html</a>.

## **MEDICAL DIRECTOR SIGNATURE**

The health care provider signing the agreement will be held accountable for compliance of the entire organization and/or its authorized providers to administer vaccine with the conditions outlined in the attached outbreak provider agreement.

Name:	Title:
License Number:	NPI Number:
Email:	Phone:
Signature:	Date: