ORGANIZATION ATTESTATION FOR TPOXX DISTRIBUTION

The U.S. Department of Health and Human Services (HHS) and its components, the Administration for Strategic Preparedness & Response (ASPR), Strategic National Stockpile (SNS), and Centers for Disease Control and Prevention (CDC) greatly appreciate your participation in the HHS Monkeypox TPOXX Treatment Program. While the US government is making TPOXX (tecovirimat) treatment available at no cost to patients and providers, any person, provider, public agency, or institution (all referred to as "Organization" herein) ordering, accessing, or administering this treatment is subject to compliance with the terms below. Furthermore, if you are an Organization ordering this treatment to distribute to another Organization that will administer this treatment, you are responsible for ensuring that the recipient Organization is in compliance with the terms below. This TPOXX treatment remains property of the United States government and subject to the terms of this Agreement until the doses are administered to the recipient.

1. HHS reserves the right to update these requirements at any time. Any Organization ordering, accessing, or administering TPOXX must review the requirements and comply with any such posted updates. Any questions about these requirements can be directed to mpx.ordering@hhs.gov .

2. Organization must administer TPOXX consistent with the Food and Drug Administration's (FDA's) Investigational New Drug (IND) regulations as applicable to the expanded access IND protocol (IND 116,039/CDC IRB# 6402).

3. Organization must administer TPOXX in accordance with the recommendations of CDC (including those in the CDC Considerations for Monkeypox Treatment and the Clinical Guidance for Tecovirimat (TPOXX) Use, as they may be revised from time to time) and must:
    a. Obtain informed consent, from each recipient, the adult caregiver accompanying the recipient, or other legal representative. https://www.cdc.gov/poxvirus/monkeypox/pdf/Attachment-1-Informed-Consent.pdf
    b. Ensure all required regulatory submissions for TPOXX administration are made in accordance with the Expanded Access Investigational New Drug (EA IND) protocol. Obtaining and Using TPOXX (Tecovirimat)
    c. Report adverse events following TPOXX administration by completing a PDF MedWatch form and returning it to CDC via email (regaffairs@cdc.gov) or uploading to ShareFile within 72 hours of awareness or sooner.
    d. Provide a timely response to any inquiries from HHS or its components including the CDC and FDA related to Organization's ordering, accessing, or administering TPOXX.

4. Organization must record the following TPOXX data elements at least weekly through the Health Partner Ordering Portal (HPOP):
    a. Inventory number (in bottles) on hand at depot and at each site
    b. Number of bottles administered to patients

5. Organization is prohibited from selling or seeking reimbursement for TPOXX and any other supplies that the US government provides without cost to Organization.

6. Organization must provide TPOXX regardless of the recipient's ability to pay administration fees. Organization may seek appropriate reimbursement from a program or plan that covers any TPOXX administration fees for the recipient, such as:
    - Recipient's private insurance company
    - Medicare/Medicaid reimbursement

7. Organization must preserve all records related to TPOXX management and administration and make records related to participation in the HHS Monkeypox TPOXX Treatment Program available for immediate inspection by HHS, its relevant component agencies, and relevant state, tribal, territorial, or local public health authorities for a minimum of 3 years.

8. Organization must comply with manufacturer's specifications for shipping and storage.

9. Organization's TPOXX treatment services must be conducted in compliance with all applicable local, state, and federal laws.