SUMMIT COUNTY PUBLIC HEALTH

CLOSED PODS

Legal Reference

Memorandum of Agreement (MOA)
Regarding Mass Prophylaxis Dispensing
CLOSED Point of Dispensing (POD)

This Memorandum of Agreement is entered into this the ___ day of _____, 20 between the _____ (Provider) and Summit County Public Health.

Definitions:

1. SCPH: Summit County Public Health
2. SNS: Strategic National Stockpile
3. PODS: Point of Dispensing Site
4. Provider: Business/Organization willing to become a CLOSED PODS

Recitals

WHEREAS, the Centers for Disease Control and Prevention (CDC) has established the SNS to assist in the event of a catastrophic biological incident or an incident requiring the use of medical materiel maintained in the SNS; and

WHEREAS, the SCPH has agreed to function as the lead agency in events where SNS assets are deployed or in instances where an incident requires such operation and the use of closed points of dispensing; and

WHEREAS, the CDC, through the Ohio Department of Health and the State of Ohio, will provide the Strategic National Stockpile (SNS), which includes medications and medical supplies, to the SCPH; and

WHEREAS, the SCPH approves the transfer of a pre-determined quantity of the aforementioned medication to (provider name): and

WHEREAS, the SCPH wishes to collaborate with (provider name) to enhance their ability to respond to a catastrophic biological incident, communicable threat, or any incident requiring the use of Closed PODS as outlined herein.

NOW THEREFORE, in consideration of the foregoing, the parties hereto agree as follows:

The Provider Agrees:

a. To request medications according to the number of employees and identified household family members (if applicable).

b. To assume responsibility for the transportation and security of materiel from a location specified by the SCPH to the providers location.

c. To assume responsibility of dispensing medications (mass prophylaxis) to those individuals identified above by the Provider's trained staff, at a site chosen by the Provider and with no liability assumed by the SCPH.

d. To utilize pharmaceuticals in accordance with the policies and procedures outlined in the SCPH Public Health Emergency Operations Plans and Standard Operating Guidelines and the Provider's own Mass Prophylaxis Dispensing Plan and (on file with the SCPH).

e. To dispense medications per established medical protocols/algorithms (provided by SCPH at time of the event) under the supervision of licensed medical personnel.

f. To provide any updates of the Provider's Mass Prophylaxis Dispensing Plan to the SCPH.

g. To provide training and education to all Provider staff that will be utilized in Mass Prophylaxis Dispensing Operations in regards to specifics of the Mass Prophylaxis Dispensing Plan provided by the Provider.

h. To not charge individuals for medications or administration of that have been provided through this agreement, except as permitted by the State of Ohio or by CDC.

i. To participate in any SCPH-sponsored dispensing training/education opportunities.

j. To provide emergency point of contact information to ensure timely notification of the Provider in the event of a public health emergency.

k. To dispense medications and/or supplies in accordance with the guidance provided by the SCPH.

l. To secure any unused medications and return them to the location designated by the SCPH.

m. To compile and file an after-action report with the SCPH, identifying shortfalls and accomplishments of the operation

<u>The SCPH Agrees</u>:

a. To provide Mass Prophylaxis Dispensing specific training/education opportunities to identified staff of the Provider.

b. To provide pre-event planning assistance and technical assistance, including but not limited to supply lists, PODS layouts, fact sheets, dispensing algorithms, etc.

c. To, conditionally, ensure availability of the appropriate amount of medications in a reasonable, timely manner

d. To provide coordination as outlined in the SCPH Emergency Operations Plan(s) related to the dispensing of mass prophylaxis materials to closed PODS locations.

e. To provide the Provider with standing orders and medical protocols regarding Dispensing activities including but not limited to, dosing, follow-up procedures and releasable information regarding the public health emergency situation that accompany the medications or that are received from the Ohio Department of Health, CDC etc.,

f. To provide the Provider with consultation and assistance as needed and available for the given public health emergency or incident.

g. To collect any unused medications as well as copies of all medical documentation returned by the Provider.

h. To provide after-action consultation to the Provider.

It Is Mutually Agreed That:

a. The confidentiality of patients and patient information will be maintained as written and enforced by the Health Insurance Portability and Accountability Act (HIPAA).

b. This Memorandum can be extended by two-year intervals with agreement of both parties either through verbal agreement by making contact which shall be recorded on the attached form titled, " Closed PODS MOA validation and record of changes" attached; or by written communication which shall also be documented on the .

c. This Memorandum can be amended by mutual agreement of both parties at any time and may be terminated by either party upon 60 days notice in writing to the other party.

d. This Memorandum will not supersede any laws, rules or polices of either party.

e. This Memorandum will go into effect only at the request and direction of the SCPH.

f. The Provider would be considered a CLOSED PODS in that it would not Dispense Medications to the "general public" but to identified staff, family members, patients, contacts, and specific groups outlined in the Provider's Mass Prophylaxis Dispensing Plan and the SCPH Emergency Operations Plans.

g. The Provider will follow the dispensing directives of the SCPH during Mass Dispensing Operations.

h. It is understood that the Provider's participation is completely voluntary and may not be available/utilized at the time of the event. If so, the Provider would not be considered a CLOSED PODS and their staff and/or specific groups would be required to attend a Public/OPEN PODS operated by the SCPH and not receive any preferential treatment.

SIGNATURES

The following signatures indicate agreement with the above stated agreements and conditions:

Health Commissioner Summit County Public Health	Date
Witness	Date
(Provider Representative)	Date
Witness	Date

Closed POD MOA Validation
&
Record of Changes

Date of Change/Validation	Type of Validation (Verbal/Written)	Revisions Made	Entered By	Re-distributed Yes/No

Emergency Use Authorization (EUA) and the Public Readiness and Emergency Preparedness (PREP) Act

What is an EUA?

The Food and Drug Administration (FDA) can issue an EUA to allow either the use of an unapproved medical product (e.g., drug, vaccine, or device) or the unapproved use of an approved medical product during certain types of emergencies with specified agents.

Section 564 of the Federal Food, Drug, and Cosmetic (FD&C) Act, as amended by the Project BioShield Act of 2004, permits authorization of such products to diagnose, treat, or prevent serious or life-threatening diseases or conditions caused by biological, chemical, radiological, or nuclear agents, if certain statutory criteria are met. The Secretary of the Department of Health and Human Services (HHS) has delegated the authority to issue an EUA under section 564 of the FD&C Act to the FDA Commissioner.

What is required before FDA issues an EUA?

The FD&C Act requires that, before an emergency use is authorized, the Secretary of HHS must declare an emergency justifying the emergency use based on one of the following grounds:

> (1) The Secretary of the Department of Homeland Security determines that there is a domestic emergency, or a significant potential for a domestic emergency, involving a heightened risk of attack with a specified biological, chemical, radiological, or nuclear agent or agents; or
>
> (2) The Secretary of the Department of Defense determines that there is a military emergency, or a significant potential for a military emergency, involving a heightened risk to United States military forces of attack with a specified biological, chemical, radiological, or nuclear agent or agents; or
>
> (3) The HHS Secretary determines that there is a public health emergency under the Public Health Service (PHS) Act that affects, or has a significant potential to affect, national security, and involves a specified biological, chemical, radiological, or nuclear agent or agents, or a specified disease or condition that may be attributable to such agent or agents.

Are there any limits on the use of an EUA product?

For unapproved products, the law requires the FDA Commissioner (to the extent practicable given the circumstances of the emergency) to establish certain conditions on an EUA that the Commissioner finds necessary or appropriate to protect the public health, and permits the Commissioner to establish other conditions that the Commissioner finds necessary or appropriate to protect the public health. Such conditions may include a requirement to disseminate information to health care professionals or authorized dispensers and to prospective patients and other consumers regarding the EUA, the product's significant known and potential benefits and risks, and the extent to which such benefits and risks are unknown; available alternatives and their benefits and risks; and, for prospective patients and consumers, the option to accept or refuse the product and any consequences of refusal. Other conditions may include adverse event reporting and monitoring, data collection and analysis, and recordkeeping and records access.

For unapproved uses of approved products, certain of these conditions and other conditions may be required in an EUA.

Use of a product under an authorization must be consistent with any conditions imposed on the EUA.

Where can I find additional information about EUAs?

Additional information about FDA's EUA authority, including EUA guidance and EUAs that have been issued, is available at http://www.fda.gov/EmergencyPreparedness/Counterterrorism/ucm182568.htm

What is the PREP Act?

The PREP Act authorizes the HHS Secretary to issue a PREP Act declaration that provides immunity from tort liability (except for willful misconduct) for claims of loss caused by, arising out of, relating to, or resulting from the administration or use of a countermeasure to a disease, threat, or condition determined by the Secretary to constitute a present or credible risk of a future public health emergency to entities and individuals involved in the development, manufacture, testing, distribution, administration, and use of the countermeasure. A PREP Act declaration is specifically for the purpose of providing immunity from tort liability, and is different from, and not dependent on, other emergency declarations.

The PREP Act also authorizes the establishment of an emergency fund in the United States Treasury to provide compensation for injuries directly caused by administration or use of a countermeasure covered by the HHS Secretary's declaration. Compensation may be available under the Countermeasures Injury Compensation Program (CICP), which is administered by the Health Resources and Services Administration (HRSA), for medical benefits, lost wages, and death benefits to individuals for specified injuries.

Countermeasures covered under a PREP Act declaration can include products that are approved, cleared, or licensed under the FD&C Act or the PHS Act, authorized for investigational use under the FD&C Act, or authorized under an EUA. For example, if a person is given a countermeasure that is authorized for emergency use under an EUA in a declaration made by the HHS Secretary, then that person may be eligible under the PREP Act for compensation through the CICP if serious physical injury or death results from use of the countermeasure.

For more information on the PREP Act, visit http://www.phe.gov/Preparedness/legal/prepact/Pages/prepqa.aspx. Additional information on the PREP Act (including PREP Act declarations that have been issued) and on the CICP can be found on http://www.hrsa.gov/gethealthcare/conditions/countermeasurescomp/.

What happens if the drugs that are authorized for emergency use under an EUA (i.e., unapproved drugs or approved drugs for unapproved uses) are distributed outside the scope of, or inconsistent with, the conditions of the EUA once it has been issued?

If the FDA issues an EUA to allow for the lawful distribution or dispensing of products for emergency use under certain circumstances and if stakeholders do not distribute or dispense the countermeasures in accordance with the scope and conditions of the EUA, then liability protections afforded by the PREP Act may be affected.

Who are the *stakeholders* in the EUA?

For the purposes of this EUA, the term *stakeholder* means the public agency or its delegate that has the legal responsibility and authority to respond to an incident, based on political or geographical (e.g., city, county, tribal, State, or Federal boundary lines) or functional (e.g., law enforcement or public health) range or sphere of authority to prescribe, administer, deliver, distribute, or dispense doxycycline in an emergency situation.

What products does this EUA cover?

This EUA covers oral formulations of doxycycline products that have been approved by the FDA for PEP to reduce the incidence or progression of disease, including inhalational anthrax, following exposure to aerosolized *B. anthracis*. For purposes of illustration, such products include capsule, tablet, and liquid formulations of doxycycline, including:

- Doxycycline hyclate 100 mg oral tablets, supplied in a unit-of-use (UoU) bottle containing 120 tablets for a 60-day treatment or containing 20 tablets for an initial 10-day supply
- Doxycycline monohydrate 100 mg oral capsules, supplied in a UoU bottle containing 120 capsules for a 60-day treatment or containing 20 capsules for an initial 10-day supply
- Doxycycline 25 mg/5 mL suspension, supplied as dry powder in a 60 mL bottle
- Doxycycline (Vibramycin) 50 mg/5 mL syrup in a 473 mL bottle

During an emergency, this authorization would permit dispensing of FDA-approved drugs that are not supplied in a UoU container, if necessary.

Is FDA planning to issue additional EUAs for preparedness purposes (e.g., for ciprofloxacin)?

While FDA does not independently initiate EUA requests, FDA works closely with its federal government partners (e.g., CDC) to provide technical assistance and regulatory feedback on preparedness issues related to EUAs and would favorably consider a request from CDC for a ciprofloxacin EUA. Although FDA currently has no plans to issue additional EUAs within a specific timeframe, the same legal preparedness issues apply to ciprofloxacin that apply to doxycycline. In other words, an EUA would also be needed for ciprofloxacin to facilitate preparedness and response activities for an anthrax emergency.

Does this EUA preempt state law?

As stated in FDA's EUA Guidance found at:
http://www.fda.gov/RegulatoryInformation/Guidances/ucm125127.htm The FDA believes that the terms and conditions of an EUA issued under section 564 of the Act preempt State laws (i.e., legislative requirements and common-law duties) that impose different or additional requirements on the medical product for which the EUA was issued in the context of the emergency declared under section 564. However, questions about whether specific State laws would be preempted by an EUA would need to be addressed on a case-by-case basis.

Are volunteers and other non-health care professionals (e.g., certain public health officials) dispensing doxycycline at a POD the same as *health care professionals* under the EUA?

The EUA's Conditions of Authorization require that recipients and health care professionals administering the doxycycline product be informed of the minimum elements of information (as exemplified in the fact sheets for recipients and health care professionals). A non-health care professional volunteer or responder handing out doxycycline product is not considered to be a health care professional under the EUA.

However, depending on stakeholders' applicable mass dispensing plans and state and local law, the EUA acknowledges that non-health care professionals might be involved in dispensing doxycycline to the public at PODs. Regardless of the dispensing modality, including the use of responders and volunteers who are not health care professionals to dispense doxycycline, it is expected that a health care professional will be available on-site at a POD or that information will be made available at a POD about how to reach a health care professional to respond to questions from recipients of doxycycline product. Additionally, stakeholders may choose to provide, for reference purposes, the health care professional and recipient fact sheets to their non-health care professional dispensers.

Will the PREP Act cover doxycycline products under the EUA?

A PREP Act declaration for multiple types of anthrax countermeasures, http://edocket.access.gpo.gov/2008/E8-23547.htm, was issued on October 1, 2008, and extends through December 15, 2015. Because this PREP Act declaration is in effect for anthrax countermeasures, including antimicrobials such as doxycycline, and because the PREP Act covers countermeasures authorized for emergency use under an EUA, the PREP Act covers doxycycline products authorized for emergency use under this EUA if the terms and conditions of the EUA and the PREP Act declaration are met.