MEMORANDUM OF AGREEMENT Between THE STATE OF FLORIDA DEPARTMENT OF HEALTH And PINELLAS COUNTY EMS AUTHORITY

I. Purpose

This Memorandum of Agreement (MOA) is entered into between the State of Florida Department of Health, (DOH or Department), and Pinellas County EMS Authority (CHEMPACK Cache Location), for the purpose of effectively responding to acts of chemical terrorism and other chemical emergencies posing a public health crisis. The Centers for Disease Control and Prevention (CDC) agrees to pre-position sustainable repositories of nerve agent antidotes (CHEMPACKs) in locations in Florida. This MOA establishes the terms, conditions, and responsibilities between the parties for deployment, management, and maintenance of this federally owned asset. This MOA is subject to the provisions of all applicable Federal and State laws, regulations, policies and standards.

II. Parties

The Parties to this MOA are the Department and the CHEMPACK Cache Location. The Department will carry out the responsibilities in this MOA on behalf of the State of Florida through its participation in the Strategic National Stockpile Program (SNS Program), implemented by the CDC.

The Coordinator/State Project Manager for DOH:

Jennifer Thompson 104-2 Hamilton Park Drive Tallahassee, FL 32304 850-922-9036 ext 3012

The Point of Contact (POC) for the CHEMPACK Cache Location:

Craig A. Hare, EMS Division Manager Pinellas County Public Safety Services – EMS Division 12490 Ulmerton Road, Suite 134 Largo, FL 33774 727-582-5752

III. Definitions

For purposes of this MOA, the terms shall be defined as follows:

CHEMPACK-The sustainable repository of nerve agent antidotes and other necessary and supporting equipment to care for individuals exposed to nerve agents, auto-injectors, bulk symptomatic treatment supplies, and self-monitoring storage containers. CHEMPACK is a component of the SNS Program. This CHEMPACK Project provides two types of containers. The EMS container is designed for use by emergency responders; asset(s) packaged primarily in auto-injectors. The Hospital container is designed for hospital dispensing; asset(s) packaged primarily in multidose vials, for precision dosing and long-term care.

Shelf Life Extension Program (SLEP) -The Food and Drug Administration's (FDA) SLEP is designed to maintain the readiness and effectiveness of pharmaceuticals over extended periods of time. The SLEP defers costs by extending the expiration date of stored pharmaceuticals rather than replacing stocks that have reached a set expiration date. Through centrally located automated monitoring devices, the SNS Program staff is able to ensure that conditions of CHEMPACK asset(s) comply with SLEP guidelines, thus enabling CHEMPACK to provide the State a long-term capability.

Strategic National Stockpile Program (SNS Program) - Implemented by the CDC.

SNS Program Personnel, SNS Program POC, SNS Program CHEMPACK Logistics Team, SNS Program CHEMPACK Fielding Team - Individuals or teams working under the direction of the SNS Program and the CDC.

State Point of Contact (State POC) and Alternate State Point of Contact (Alternate State POC) - The Florida DOH Statewide point of contact and the Florida DOH Alternate Statewide point of contact.

Cache Location POC (Cache Location POC) and Cache Location Alternate POC (Alternate Cache Location POC) - The designated point of contacts specific to the Cache Location.

IV. Department Responsibilities

The Department agrees to the following:

- 1. Provide authority or delegate authority for breaking the CHEMPACK container (Appendix 1, page 9, attached to this MOU) seal and use of the packaged products.
- 2. Designate a State POC and an Alternate State POC for the CHEMPACK Project. Provide corresponding contact information and notification of any changes in contacts.
- 3. Determine the quantity and type of CHEMPACK containers, required to meet state and local needs for first responders to respond to a nerve agent event (within stipulated budget constraints).
- **4.** Develop a CHEMPACK Operational Plan for deployment, surveillance and maintenance operations as an addendum to Florida *Comprehensive Emergency Management Plan* (FL CEMP) and the DOH Emergency Operations Plan (EOP).
- **5.** Provide addresses of all cache storage location sites and ensure pre-coordinated access for SNS Program Personnel.
- **6.** The cache storage locations meet size, environmental, and security conditions for storage of pharmaceuticals based upon the DEA, FDA, and SNS Program Storage Criterion.
- 7. The proper disposal in accordance with applicable federal, state, and local regulations of expired CHEMPACK medical asset(s) and copies of the destruction documentation to the SNS Program.

- 8. Conduct joint inventories with the CHEMPACK Fielding Team upon initial placement and approximately every twelve to twenty four (12-24) months thereafter.
- **9.** Quality control checks are conducted for environmental limits at cache locations and ensure the submission of a quarterly CHEMPACK Project Quality Assurance Survey.
- **10.** Adequate transportation of CHEMPACK asset(s) in an emergency, to include coordinating with state, local officials and emergency planning members for use of vehicles, freeway routes, and airfields.
- 11. Storage facilities have the capability to rapidly move CHEMPACK asset(s) as required. This may include hydraulic lifts, forklifts, loading docks, or ramps.
- 12. Provide a list of personnel with access to the CHEMPACK containers at each cache location to the SNS Program POC at the time of fielding and update as changes occur.
- **13.** Cache storage locations are correct non-compliant environmental and security conditions identified by SNS Program POC in a timely manner.
- 14. Coordinate with SNS Program Personnel to ensure security and environmental conditions are met for CHEMPACK asset(s) during any non-emergency movement (i.e., special events).
- **15.** Notify the SNS Program within twenty four (24) hours of an emergency deployment. The deployment report should identify the amount of CHEMPACK expended and the amount of asset(s) returned to the container.
- 16. In the event of a non-emergency use or compromise of CHEMPACK asset(s); the State will report the loss to the SNS Program as soon as possible following discovery. Within forty eight (48) hours of the discovery of the loss, the State must submit a report documenting the circumstances resulting in the loss and providing an inventory of asset(s) lost or destroyed.

V. CHEMPACK Cache Location Responsibilities

The CHEMPACK Cache Location agrees to the following:

- Authorize breaking the CHEMPACK container seal and use of the packaged products when an accidental or intentional nerve agent release has threatened the medical security of the community; has multiple lives at risk; is beyond local emergency response capabilities; is beyond local pharmaceuticals' supplies; and the asset(s) is/are medically necessary to save lives.
- 2. Designate a Cache Location POC and a Cache Location Alternate POC position for CHEMPACK and provide contact numbers for normal business hours and after hours to the Department. Notify the Department at (850) 245-4444, extension 2089 or 245-4444, extension 3705 and/or via email to the Department Contract Manager of any changes in contact personnel within one business day of assignment of a new Cache Location POC.

- 3. Ensure each cache site is assigned a separate DEA registration license number, not a practitioner license. Identify a pharmaceutical or medical professional with a Drug Enforcement Agency (DEA) registration for the Cache Storage Location that will sign for and accept custody of the Schedule IV controlled substances and other pharmaceuticals in CHEMPACK containers. That person will be responsible for the storage and safeguarding of the DEA compliant container in the facility and ensure compliance with applicable local, state and federal regulatory guidelines. Provide the custodian's name, license number, and contact information to DOH at the time of scheduled delivery to a cache location. Notify the Department of any changes in contact personnel within one business day of assignment of a replacement with DEA registration.
- 4. Develop a plan for CHEMPACK deployment, surveillance and maintenance operations. The plan may be an annex to the facility all-hazards plan. The plan should address: asset placement; distribution; coverage areas; procedures for control, authorization and use of CHEMPACK assets; access coordination procedures to include how asset(s) could be shared with health care facilities within the coverage area; and submission of reports that may be required. Provide copies of this plan to the DOH State POC, the Regional Emergency Advisors (RERAs), and the county Emergency Managers within 4 months of receiving CHEMPACK asset(s).
- **5.** Provide adequate transportation of CHEMPACK asset(s) in an emergency, to include coordinating with state, local officials and emergency planning members for use of vehicles, freeway routes, and airfields.
- 6. Storage facilities have the capability to rapidly move CHEMPACK asset(s) as required. This may include, but is not limited to, hydraulic lifts, forklifts, loading docks, or ramps.
- 7. The cache storage locations are of a suitable size; designed to provide adequate lighting, ventilation, temperature control that results in a mean kinetic temperature calculated to be no more that 77°F, provide sanitation, space and security conditions for storage of pharmaceuticals; and conform to the CHEMPACK storage standards listed in the CHEMPACK Quarterly Quality Assurance Survey.
- 8. Conduct proper disposal in accordance with applicable federal, state, and local regulations of expired CHEMPACK medical asset(s) and provide copies of the destruction documentation to the SNS Program. Coordinate with State POC and SNS Program Personnel prior to disposal. Such disposal will not be at the Cache Site's expense.
- 9. Authorize access for joint inventories with the CHEMPACK Fielding Team upon initial placement and approximately every 12 to 24 months thereafter. Authorize access for monitoring or monthly security checks to visually inspect SNS Program seals on the CHEMPACK containers (in accordance with applicable federal and state regulations for the person signing for custody as duly registered with the DEA).
- 10. Authorize access for quality control checks at each CHEMPACK Cache Location to ensure the facility's climate is within acceptable environmental limits and submit a quarterly CHEMPACK Quality Assurance Survey to document storage conditions at the cache location to SNS Program.

- 11. Allow CHEMPACK asset(s) to be shared with other requesting facilities according to the criteria set forth in this document. Unless arranged otherwise, the cost for transportation shall be reimbursed as agreed between the parties in a "Letter of Agreement" or "Mutual Aid Agreement."
- 12. Provide proper security of CHEMPACK containers. Establish a list of personnel with access to the CHEMPACK containers at the CHEMPACK Cache Location, disclose the list with the State POC, and update the list as necessary.
- 13. Provide cache storage locations correct non-complying environmental and security conditions identified by SNS Program POC in a timely manner (usually within one hour). When conditions cannot be corrected within 12 hours, the SNS Program CHEMPACK Logistics Team will coordinate with the State POC to move CHEMPACK container(s) to an acceptable location to safeguard the quality or security of the asset(s).
- 14. Notify State POC and the SNS Program CHEMPACK Logistics Team within two hours if a CHEMPACK cache storage location loses climate control. Any reports of material stored outside of the accepted storage range will be handled on a case-by-case basis. Outcomes could range from having the asset(s) remain in the SLEP to removing the material from the SLEP program and the State forfeiting the long-term sustainability of the resource.
- 15. In the event of a non-emergency use, or compromise of CHEMPACK asset(s); the facility will report the loss to the State POC as soon as possible following discovery. The facility must submit a report documenting the circumstances resulting in the loss and providing an inventory of CHEMPACK asset(s) lost or destroyed within 24 hours of discovery or next business day.
- 16. In the event the CHEMPACK must be deployed for emergency use, notify the Coordinator/State POC immediately by telephone and provide a written report within a reasonable timeframe for DOH to meet Chempack obligations.

VI. Financial Considerations

Except where otherwise detailed in this MOA, each party is responsible for its own costs. Any assistance provided by the State of Florida under this MOA and any assistance provided by the CDC is subject to the availability of appropriations. The SNS Program is not currently funded to replace any CHEMPACK asset(s) used in response to an actual nerve agent incident. If such an event occurs, however, the SNS Program will cooperate with the State in attempting to secure federal funding to replenish/replace expended CHEMPACK asset(s). Replacement of CHEMPACK asset(s) due to circumstances beyond the control of the parties, such as accident and natural disasters, will be negotiated between the State and the SNS program on a case-by-case basis.

VII. Ownership

The CDC shall at all times retain ownership of CHEMPACK asset(s) in storage. Subject to the terms of an MOA between the CDC and the State of Florida, the CDC has granted the State, and CHEMPACK Cache Storage Locations approved by CDC, permission to use CHEMPACK asset(s) in the event of an accidental or

intentional nerve agent release that threatens the medical security of the community, puts multiple lives at risk, and is beyond local emergency response capabilities.

VIII. Storage

State and local agencies and CHEMPACK Cache Locations may only store the asset(s) provided as part of the CHEMPACK Project in the SNS-provided containers. State-owned and SNS Program-owned nerve agent antidotes may not be co-mingled in storage containers since co-mingled storage will compromise the SNS Program's ability to maintain the CHEMPACK asset(s) under the SLEP.

IX. Movement for Special Events

The CDC has authorized the State to move CHEMPACK for State-designated special events (e. g., National Special Security Events, Super Bowl, World Series. major political conventions, state fair, a major concert, and key summits) on a temporary basis. The temporary movement of CHEMPACK asset(s) is subject to the following conditions: (1) the State POC or Alternate State POC must notify the SNS Program at least 30 days prior to the preemptive movement of CHEMPACK containers; (2) state CHEMPACK staff will provide all information outlined on the Request Form for Temporary Container Movement in writing to the Regional CDC Contact (3) the State shall ensure that environmental and security requirements outlined in the MOA with CDC are maintained throughout transport and preemptive deployment; (4) only locations hosting more than one container shall participate; and (5) any movement of CHEMPACK asset(s) not specifically directed by the SNS Program shall be funded by the State. If the CHEMPACK Cache Location wishes to move CHEMPACK asset(s), it must request permission from the State POC or Alternate State POC who will, in turn, notify the SNS Program in the manner described above.

X. Compliance with U.S. Drug Enforcement Agency Requirements

The State agrees to comply with all applicable federal, state, and local requirements regarding storage, use, and handling of controlled substances. A non-exclusive list of federal requirements regarding the storage, use, and handling of these substances may be found at Title 21 Code of Federal Regulations Part 1301. In addition, the CHEMPACK Cache Location agrees to designate a pharmaceutical or medical professional with a DEA registration who will sign for and accept custody for controlled substances and other pharmaceuticals in CHEMPACK containers at each cache storage location. The CHEMPACK Cache Location designee will be responsible for the storage and safeguarding of controlled substances within the CHEMPACK container and ensure compliance with federal, state, and local requirements. The State POC must provide the custodian's name, license number and contact information two (2) weeks prior to the scheduled delivery of a cache location.

XI. Public Disclosure

Under 42 USC § 247d-6b, no federal agency shall disclose under 5 USC § 552, United States Code, any information identifying the location at which SNS Program asset(s) are stored. To the extent permitted by law, the parties agree that neither will disclose the nature of this effort and the terms of this agreement to any person or entity, except as may be necessary to fulfill its mission and statutory and regulatory

responsibilities. The parties agree to notify one another before releasing asset(s) or information relating to CHEMPACK or this MOA pursuant to federal or state freedom of information act statutes or similar provisions in law. Pursuant to sections 381.95 and 395.1056 Florida Statutes, this document is confidential and exempt from disclosure as a public record under Chapter 119 F.S.

XII. Liability

Each party of this MOA shall be responsible for its own acts and omissions and those of its officers, employees and agents. No party to this agreement shall be responsible for the acts or omissions of entities not a party to this agreement. Neither party to this MOA agrees to release, hold harmless, or indemnify the other party from liability that may arise or relate to this MOA.

XIII. Effect on Procedures and Laws

All assistance provided under this MOA must comply with applicable laws, regulations, and agency policies.

XIV. No Private Right Created

This document is an internal agreement between the Department and the entity with custody or control of a CHEMPACK Cache Location and does not create or confer any right or benefit on any other person or party, private or public. Nothing in this agreement is intended to restrict the authority of either signatory to act as provided by law or regulation, or to restrict any agency from enforcing any laws within its authority or jurisdiction.

XV. Settlement of Disputes

The parties agree to good faith consultation with one another to resolve disagreements that may arise under or relating to this MOA before referring the matter to any other person or entity for settlement.

XVI. Capacity to Enter into Agreement

The persons executing this MOA on behalf of their respective entities hereby represent and warrant that they have the right, power, legal capacity, and appropriate authority to enter into this agreement on behalf of the entity for which they sign.

XVII. Effective Date, Modification, and Termination

This MOU shall become effective upon the signature of both parties and shall remain in effect until otherwise agreed to by the parties. The terms of this agreement may be modified in writing upon the consent and signature agreement of both parties. This agreement may be terminated by either party at any time; however, the terminating party shall provide written notice to the other party at least six months in advance of the effective date of termination unless there is a critical violation of the terms set forth in this MOA. In the event of termination, all SNS Program equipment, related records, and/or other asset(s) generated by or for the CHEMPACK Project in furtherance of this agreement are property of the SNS Program and shall be returned to the SNS Program within six months of the termination date.

IN WITNESS THEREOF, the parties hereto have caused this nine (9) page MOA to be executed by their officials there unto duly authorized.

CHEMPACK CACHE LOCATION	STATE OF FLORIDA DEPARTMENT OF HEALTH	
SIGNED BY: Run Carlo	SIGNED BY:	
NAME: Robert S. LaSala	NAME: Victor Johnson	
TITLE: County Administrator	TITLE: Director, Division of Emergency Preparedness and Community Suppor	
DATE: 912-13	DATE: 10 /2 /2017	

Attorney

FEDERAL ID NUMBER:

APPROVED AS TO FORM OFFICE OF COUNTY AFTORNEY

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Appendix I – CHEMPACK Container Contents, Cubes, and Weights

EMS CHEMPACK Contained	for 454		
Product	UOM	QTY	Case Lbs.
Mark 1 auto-injector with-240 kits	CS	5	39.5
Atropine Sulfate 0.4mg/ml 20ml-100 vials	CS	1	12
Pralidoxime 1gm inj 20ml-276 vials	CS	1	11.5
Atropen .5Mg144 injectors	CS	1	16.8
Atropen 1 Mg144 injectors-	CS	1	16.8
Diazepam 5mg/ml auto-injector-150 injectors	CS	2	20
Diazepam 5mg/ml vial, 10ml-50 vials	CS	1	3.6
Sterile water for injection (SWFI) 20ml-100 vials	cs	2	7.2
Hospital CHEMPACK Containe	er for 1,0	00	
Product	UOM	QTY	Case Lbs.
Mark 1 auto-injector-240 kits	CS	2	39.5
Atropine Sulfate 0.4mg/ml 20ml-100 vials	CS	9	12
Pralidoxime 1gm inj 20ml-276 vials	CS	10	11.5
Atropen .5Mg144 injectors	CS	1	16.8
Atropen 1 Mg144 injectors	CS	1	16.8
Diazepam 5mg/ml auto-injector-150 injectors	CS	1	20
Diazepam 5mg/ml vial, 10ml-50 vials	CS	13	3.6
Sterile water for injection (SWFI) 20ml-100	10 0		- CONTRACTOR