

STATE OF FLORIDA
DEPARTMENT OF HEALTH
AMENDMENT # A1

This amendment entered into between the State of Florida, Department of Health, hereinafter referred to as "the Department" and Pinellas County, amends the Memorandum of Agreement.

The Department and Pinellas County amend this Memorandum of Agreement to update the terms and to add attachments. Accordingly, the Memorandum of Agreement is amended as follows:

1. Pages 1 through 8, Memorandum of Agreement, are deleted in their entirety, and replaced with the revised Memorandum of Agreement attached hereto.
2. Page 9, Appendix I, is deleted in its entirety and replaced with the revised Appendix I attached hereto.
3. Appendix II, Recipient Storage and Maintenance Requirements, attached hereto, is added to this Memorandum of Agreement.
4. Appendix III, Memorandum of Agreement between the United States Department of Health and Human Services, Administration for Secretary of Preparedness and Response and Florida Department of Health, attached hereto, is added to this Memorandum of Agreement.
5. This amendment will begin on April 11, 2023, or the date on which this amendment has been signed by both Parties, whichever is later.

All provisions in the Memorandum of Agreement and any attachments thereto in conflict with this amendment are hereby changed to conform with this amendment.

All provisions not in conflict with this amendment are still in effect and are to be performed at the level specified in the Memorandum of Agreement.

This amendment and all its attachments are hereby made a part of the Memorandum of Agreement.

IN WITNESS THEREOF, the parties hereto have caused this twenty-page amendment to be executed by their officials thereunto duly authorized.

PINELLAS COUNTY

STATE OF FLORIDA
DEPARTMENT OF HEALTH

SIGNED

SIGNED

BY: _____

BY: _____

NAME: _____

NAME: _____

TITLE: _____

TITLE: _____

DATE: _____

DATE: _____

APPROVED AS TO FORM

By: Jason C. Ester
Office of the County Attorney

MEMORANDUM OF AGREEMENT
Between
STATE OF FLORIDA, DEPARTMENT OF HEALTH
And
PINELLAS COUNTY EMS & FIRE ADMINISTRATION

This Memorandum of Agreement (MOA) is entered into between the State of Florida, Department of Health (DOH) and Pinellas County EMS & Fire Administration (Recipient), each a “Party” and together the “Parties”.

Whereas, DOH has entered into an agreement with the Secretary of Health and Human Services (HHS) Office of the Administration for Secretary of Preparedness of Response (ASPR) to pre-position the Strategic National Stockpile (SNS)’s CHEMPACK Assets and CHEMPACK Containers in Florida, and such agreement is attached hereto as Appendix III and incorporated herein by reference.

Whereas, the Recipient will store and maintain CHEMPACK Assets and CHEMPACK Containers at their Cache Location in accordance with the terms of this MOA.

Accordingly, the Parties agree to the following:

I. PURPOSE

To effectively respond to Public Health nerve agent poisoning event, this MOA establishes the terms, conditions, and responsibilities between the Parties for pre-positioning, deploying, managing, and maintaining CHEMPACK Assets.

II. AUTHORITY

Sections 252.35, 381.0011, and 381.00315, Florida Statutes; and 42 U.S.C. § 243, 247d-6b.

III. DEFINITIONS

- A. Cache Location: A Recipient’s facility that stores CHEMPACK Containers.
- B. CHEMPACK Assets: Items listed in Appendix I or their approval pharmaceutical alternatives and/or therapeutic equivalents.
- C. CHEMPACK Containers: Drug Enforcement Agency (DEA)-approved, self-monitoring, SATCO units containing CHEMPACK Assets, padlock, CHEMPACK-serial-numbered container seal, and a temperature and security monitoring device.
- D. CHEMPACK Program: 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. The CHEMPACK Program is a component of the SNS Program.
- E. DEA Registrant: An employee at Recipient’s Cache Location that is authorized by the DEA to sign and receive controlled substances.
- F. Drop Ship: Shipping of CHEMPACK products from SNS repositories directly to a Cache Location and return shipment via mail using a contracted transportation carrier. This involves Cache Location site personnel or other site representative(s) coordinating the

delivery, receipt, replacement, return shipment of product(s) and completion of all required documentation.

IV. RESPONSIBILITIES OF THE PARTIES:

A. Recipient must conduct the following:

1. Prior to receipt of CHEMPACK Containers and CHEMPACK Assets, Recipient will develop and provide to DOH an operational plan for storage, maintenance, monitoring, deployment, use, and administration of CHEMPACK Assets, which will address asset placement, distribution, coverage areas, and security. As part of Recipient's plan, or in another format approved by DOH, Recipient will provide DOH the name, title/position, office phone number, cell phone number, and e-mail address(es), for: (1) a primary and alternate point of contact and (2) a primary and alternate point of contact for each Cache Location. In addition, Recipient will provide DOH with a list of all personnel, including name, title/position, primary phone number, and alternate phone number, who have access to CHEMPACK Containers and CHEMPACK Assets. Recipient will notify DOH of any changes in the plan or personnel and will provide an updated plan and contact information within twenty-four hours of the change. Recipient will be responsible for all costs associated with the transportation and storage of the CHEMPACK Container(s).
2. Recipient will maintain CHEMPACK Containers as described in Appendix II. Recipient will contact DOH as soon as possible after detecting any non-compliant condition but no later than one hour after detecting a non-compliant deviation of climate control. Recipient will begin to correct any non-compliant condition immediately upon discovery, and for any condition that cannot be corrected within 12 hours, Recipient will coordinate with DOH to move affected CHEMPACK Containers to a mutually acceptable location. Recipient will report any loss or compromise of Cache Locations, CHEMPACK Containers, or CHEMPACK Assets immediately upon discovery, and will report to DOH within 48 hours the circumstances resulting in the loss or compromise, the nature of the loss or compromise, and the types and amounts of any CHEMPACK Containers or assets lost, compromised, or destroyed.
3. Recipient will maintain the integrity of the CHEMPACK Container seal until authorized state or local officials determine that deployment to respond to a nerve agent release is warranted **OR** to prevent the potential loss of life. Recipient may deploy CHEMPACK Assets in response to actual or suspected nerve agent events that: (1) threaten the medical security of the community; (2) put multiple lives at risk; and (3) are beyond local emergency response capabilities. Recipient will notify DOH within 24 to 36 hours of a deployment and report the type(s) and amount of CHEMPACK Assets: (1) used in the deployment; and (2) remaining in the CHEMPACK Container. Recipient will reseal the CHEMPACK Container following an inventory coordinated by Recipient.
4. Recipient will maintain the integrity of product cases and manufacturer labels for CHEMPACK products stored in CHEMPACK Containers. Labels will not be defaced or covered. Products will remain in their original manufacturer packaging/cases.

5. Recipient may temporarily transport CHEMPACK Containers to federally designated special events (e.g., National Special Security events, Super Bowl, World Series, major political conventions, state fair, and large scale or high-risk public event, etc.) for the purpose of strategically pre-positioning CHEMPACK Containers, subject to the following conditions:
 - a. Recipient assumes responsibility for all costs associated with transport of CHEMPACK Containers not specifically directed by DOH;
 - b. Recipient must notify DOH at least 48 hours prior to such movement;
 - c. Recipient must notify DOH 30 days prior to non-emergency internal container moves to a new Cache Location;
 - d. Recipient's notification must be made via phone or email to DOH's CHEMPACK Coordinator;
 - e. Recipient must notify their DEA Registrant of temporary or permanent CHEMPACK Container moves. Document the date and time Recipient notified their DEA Registrant, the address of the new location, and if the move is temporary or permanent, and submit the documentation to DOH within 48 hours of the notification;
 - f. Recipient must complete documentation provided by DOH for special events/temporary CHEMPACK Container moves;
 - g. Recipient must maintain CHEMPACK Container(s) and Assets during transport/storage to include the following:
 - i. Secure temporary location by controlled access to include daily security checks. Each CHEMPACK Container should contain a lock with an ASPR-provided padlock and key access that is limited to personnel authorized by Recipient's DEA Registrant and/or the Recipient's pharmacy director.
 - ii. Monitor and Control temperature at (68°F - 77°F) (20°C - 25°C) to ensure temperatures are maintained during transport and at temporary location. Documentation required if temperature is not being monitored by a temperature monitoring device/system or disruption in system.
 - iii. Ensure the integrity of the CHEMPACK Container(s) and CHEMPACK Assets are maintained according to regulation 21 CFR (i.e. sanitation, pest control, etc.).
 - iv. Maintain fire detection and alarm systems, and fire suppression systems as required by federal, state, and local pharmaceutical regulations and fire codes.
 - v. Store only ASPR-provided CHEMPACK Assets in CHEMPACK Container(s); storage of non-ASPR-provided assets in CHEMPACK Container(s), including state-owned nerve agent antidotes, is not permitted. Ensure no items are placed or stored on top of CHEMPACK Container(s) that exceed 100 pounds.
6. Any movement of CHEMPACK Containers not described above in section III.A.5. must be approved by DOH.

7. Upon request from DOH or ASPR, Recipient will provide access to their Cache Location to allow ASPR fielding team to perform:
 - a. Routine review of facilities holding CHEMPACK Assets and to inventory, restock, and remove expiring/expired CHEMPACK Assets; and
 - b. Periodic audits, including quality assurance and quality control inspections, to verify that the Cache Location is complying with the terms and conditions of this MOA.
 8. ASPR and/or DOH will inventory CHEMPACK Containers approximately every 12 to 24 months or as required by the CHEMPACK Program. Recipient will Drop Ship CHEMPACK Assets as directed by DOH.
 9. Recipient will provide CHEMPACK Assets to patient(s) free-of-charge.
- B. DOH's Responsibility: DOH will coordinate with ASPR for the transportation and delivery of CHEMPACK Container upon receiving ASPR's approval of the Recipient's operational plan.

V. COSTS

Except where otherwise described in this MOA, each Party is responsible for its own costs. Subject to the terms of the agreement between ASPR and DOH, the cost to implement Drop Ship will be the responsibility of ASPR.

VI. EQUIPMENT

Subject to the terms of the agreement between ASPR and DOH, ASPR is generally not funded to replace CHEMPACK Assets and CHEMPACK Containers lost, compromised, or destroyed, but may replenish or replace, or assist DOH in identifying and/or paying for potential mechanisms to replenish or replace, CHEMPACK Assets used in response to a nerve agent incident or as a result of circumstances beyond the control of the Parties, e.g., natural disasters.

VII. OWNERSHIP

ASPR retains ownership of CHEMPACK Asset(s) and CHEMPACK Containers, including after such CHEMPACK Asset(s) and CHEMPACK Containers have been delivered to Recipient and Recipient has assumed custody. Subject to the terms of the agreement between ASPR and DOH, ASPR has granted DOH and Recipient's Cache Location approved by ASPR, 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. CONTACT

DOH CHEMPACK Coordinator:

Name: Manyvone LLaque
Address: 4052 Bald Cypress Way, Bin A23
City, State, Zip Code: Tallahassee, FL 32399
Phone Number: 850-617-1538

The Point of Contact (POC) for Recipient:

Name: David Hudak
Cache Location: Pinellas County EMS & Fire Administration
Address: 12490 Ulmerton Road
City, State, Zip Code: Largo, FL 33774
Phone Number: 727-582-5756

IX. COMPLIANCE WITH U.S. DRUG ENFORCEMENT AGENCY REQUIREMENTS

- A. Recipient agrees to comply with all applicable federal, state, and local requirements regarding storage, use, and handling of controlled substances, including, but not limited to, those described in 21 CFR Parts 1301 and 1304. (This also applies to the handling of controlled substances during temporary CHEMPACK Container moves).
- B. Recipient must designate a DEA Registrant who will sign for and accept custody for CHEMPACK Assets and who will be responsible for ensuring compliance with the terms and conditions of this MOA including Appendix II.
- C. Recipient will ensure that each Cache Location possesses a valid, separate DEA registration.
- D. Recipient will ensure their DEA Registrant assumes custody of CHEMPACK controlled substances: Distributor, Hospital/Clinic, Emergency Medical Services and Retail Pharmacy. Practitioner registrations are not approved for use in the CHEMPACK Program.
- E. Recipient must provide the DEA Registrant's contact information (name, license number, primary and alternate phone number) four weeks prior to ASPR's schedule delivery of any CHEMPACK Assets to the DOH CHEMPACK Coordinator. Recipient will ensure that the DEA Registrant or their designated representative will be present for all ASPR visits.

X. PUBLIC DISCLOSURE

Under 42 USC § 247d-6b, federal agencies are prohibited from disclosing under the Freedom of Information Act (under 5 USC § 552) any information identifying the location at which CHEMPACK Assets and CHEMPACK Containers 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 MOA 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 CHEMPACK Asset(s) or information relating to CHEMPACK Program 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.

XI. 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 MOA shall be responsible for the acts or omissions of entities not a party to this MOA. 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

XII. SEVERABILITY

The provisions of this MOA are severable. If any provision of the MOA is found to be invalid by any court, that finding shall not affect the other provisions of this MOA.

XIII. COOPERATION WITH INSPECTORS GENERAL

To the extent applicable, Recipient acknowledges and understands it has a duty to and will cooperate with the inspector general in any investigation, audit, inspection, review, or hearing pursuant to section 20.055(5), Florida Statutes.

XIV. NO PRIVATE RIGHT CREATED

This document is an internal agreement between the Parties and does not create or confer any right or benefit on any other person or party, private or public. Nothing in this MOA is intended to restrict the authority of either Party to act as provided by law or regulation, or to restrict any agency from enforcing any laws within its authority or jurisdiction.

XV. MODIFICATION

The terms of this MOA may be modified upon written agreement signed by both Parties. Appendix I product content are subject to change; however, a modification to this MOA will not be required and an update to Appendix I will be provided by DOH.

XVI. TERM 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. This MOA may be terminated by either Party at any time; however, the terminating party must provide written notice to the other Party at least six months in advance of the effective date of termination unless there is a critical failure to perform or a material breach of this MOA. In the event of termination, all CHEMPACK Assets and CHEMPACK Containers, related records, and other asset(s) generated by or for the CHEMPACK Program in furtherance of this MOA are property of the CHEMPACK Program and shall be returned by Recipient to ASPR within six months of the termination date. The terms and conditions of this MOA will remain in effect until all CHEMPACK Assets and CHEMPACK Containers are returned.

XVII. WAIVER

The failure of either Party, in any respect, to exercise, or delay in exercising any right, power, or privilege provided for hereunder will not be deemed a waiver thereof; nor will any single or partial exercise of any such right, power or privilege preclude any other, or further exercise thereof, or the exercise of any other right, power, or privilege under this MOA, unless that Party has submitted a waiver in writing, and is signed by the Party against whom such waiver is sought. This provision herein does not limit the either Party's right to remedies at law or in equity.

XVIII. ENTIRE AGREEMENT

This MOA contains all the terms and conditions agreed upon by the Parties. No other understandings, oral or otherwise, regarding the subject matter of this MOA shall be deemed to exist or bind any of the Parties hereto.

APPENDIX I
CHEMPACK Container Contents
Update as of 11/13/19

EMS CHEMPACK Container for 454 Treatments			
	Unit Pack	Cases	QTY
ATNAA auto-injector	200	6	1200
Mark 1 auto-injector Mark 1 auto-injector	240	5	1200
Pralidoxime 300mg auto-injector	240	5	1200
Atropine Sulfate 0.4mg/ml 20ml	100	1	100
Pralidoxime 1gm injector 20ml	276	1	276
Atropen 0.5 mg	144	1	144
Atropen 1.0 mg	144	1	144
Atropen 2 Mg. - RAFA	136	9	1224
*Diazepam 10mg auto-injector	150	2	300
*Seizalam (Midazolam) 5mg/ml vial, 10ml	50	1	50
Sterile water for injection (SWFI) 20cc Vials Non-Medical Treatment Facility gets 2 cases	100	1	100
Sensaphone® 2050	1	1	1
SATCO B or C DEA Container	1	1	1
EMS containers can get issued ATNAA, Mark 1s or Pralidoxime 300mg not all three			
Only issued with Pralidoxime 300 mg auto-injector			
*DEA Scheduled IV Controlled Substance			
Hospital CHEMPACK Container for 1,000 Treatments			
	Unit Pack	Cases	QTY
Atropine Sulfate 0.4mg/ml 20ml	100	11	1100
Pralidoxime 1gm injector 20ml	276	12	3312
Atropen 0.5 mg	144	1	144
Atropen 1.0 mg	144	1	144
*Diazepam 5mg/ml auto-injector	150	1	150
*Diazepam 5mg/ml vial, 10ml	50	3	150
*Seizalam (Midazolam) 5mg/ml vial, 10ml	50	10	500
Sterile water for injection (SWFI) 20cc Vials Non-Medical Treatment Facility gets 28 cases	100	1	100
Sensaphone® 2050	1	1	1
SATCO B or C DEA Container	1	1	1
*DEA Scheduled IV Controlled Substance			

APPENDIX II

RECIPIENT Storage and Maintenance Requirements

Consistent with relevant Drug Enforcement Agency (DEA) and Food and Drug Administration (FDA) requirements, RECIPIENT agrees to:

1. Provide a locked room or cage for storage of CHEMPACK Containers and CHEMPACK Assets for the purpose of controlling access and ensuring compliance with applicable federal, state, and local regulations.
2. Install and monitor on a 24-hour basis an intrusion detection device that alerts RECIPIENT personnel of intrusions or attempted intrusions into the secure storage area
3. Conduct and record monthly security checks to visually inspect and confirm the integrity of CHEMPACK container storage room, CHEMPACK containers, and CHEMPACK container seals. All inspection records completed by the RECIPIENT will be made available to the HHS / ASPR during the annual on-site inspections.
4. Ensure each CHEMPACK Container is locked with an ASPR-provided padlock and key access is limited to personnel authorized by RECIPIENT's DEA-registrant and/or the Cache Location pharmacy director.
5. Maintain minimum aisle widths of 72", door widths of 34", and other clearances to allow easy access to and maneuvering of CHEMPACK Containers.
6. Equip Cache Locations with appropriate equipment and structures (e.g., hydraulic lifts, forklifts, loading docks, ramps) for rapidly accessing, moving, and transporting CHEMPACK Containers.
7. Store CHEMPACK Containers in a thermostatically temperature controlled environment meeting the current United States Pharmacopeia definition of Controlled Room Temperature that encompasses the usual and customary working environment of 20°C to 25°C (68°F to 77°F); that results in a mean kinetic temperature calculated to be not more than 25°C (77°F); and that allows for excursions between 15°C and 30°C (59°F and 86°F) that are experienced in pharmacies, hospitals, and warehouses. Provided the mean kinetic temperature remains in the allowed range ($\leq 77^{\circ}\text{F}$, 15°C), transient spikes up to 40°C (104°F) may be permitted if the manufacturer so instructs. An article for which storage at controlled room temperature is directed may, alternatively, be stored and distributed in a cool place, unless otherwise specified in the individual monograph on the label. Cool Room Temperature is any temperature between 8°C and 15°C (46°F and 59°F). An article for which storage in a cool place is directed may, alternatively, be stored and distributed in a refrigerator, unless otherwise specified by the individual monograph.
8. For use with the temperature and security monitoring device, maintain: (1) dedicated 120VAC, 60HZ, 10W, UL-listed power outlet connected to an existing facility emergency generator or other Uninterrupted Power Supply(UPS) device. The use of (2) one dedicated, unshared Plain Old Telephone Service (POTS) data quality analog phone line until the Sensaphone® 2050 replacement occurs with new hardware which may or may not require functional internet access.
9. Maintain the CHEMPACK Containers and CHEMPACK Assets in buildings and facilities that provide proper design and construction; lighting; ventilation, air filtration, and air heating and

cooling; plumbing; sewage and refuse; hand washing and toilet facilities; sanitation; pest control; and maintenance in accordance with 21 CFR §§211.42 - 211.58.

10. Ensure location is free of pesticides, solvents, petroleum products, and flammable materials. If flammable or hazardous material are present the flammable or hazardous item(s) must be at least 50 feet away from the container or properly stored in an appropriate Hazmat/Flammable Storage Locker.
11. Maintain fire detection and alarm systems, and fire suppression systems as required by federal, state, and local pharmaceutical regulations and fire codes.
12. Store only ASPR-provided CHEMPACK Assets in CHEMPACK Containers; storage of non-ASPR-provided assets in CHEMPACK Containers, including state-owned nerve agent antidotes, is not permitted. Ensure no items are placed or stored on top of the CHEMPACK container that exceed 100 pounds.