Appendix III

MEMORANDUM OF AGREEMENT BETWEEN
THE
UNITED STATES DEPARTMENT OF HEALTH AND HUMAN SERVICES, ASSISTANT SECRETARY OF PREPAREDNESS AND RESPONSE
AND
FLORIDA DEPARTMENT OF HEALTH

I. PURPOSE

To effectively respond to a Public Health nerve agent poisoning event(s), the Secretary of Health and Human Services (HHS) Office of the Assistant Secretary of Preparedness and Response (ASPR) agrees to pre-position CHEMPACK Assets in *Project Area* ("RECIPIENT"). ASPR and the RECIPIENT (collectively, the "parties") agree to the terms, conditions, and responsibilities contained in this Memorandum of Agreement ("MOA"). This MOA is independent of, and supplements, any agreement between ASPR and RECIPIENT concerning the Strategic National Stockpile (SNS), but supersedes any previous agreements concerning CHEMPACK Assets.

II. DEFINITIONS

Cache Location – a facility that stores CHEMPACK Containers.

CHEMPACK Assets – items listed in Appendix I or their approved pharmaceutical alternatives and/or therapeutic equivalents. Appendix I product content are subject to change, however a written revision to MOA will not be required and an update to Appendix I will be provided.

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.

Drop Ship – Shipping of CHEMPACK products from SNS repositories directly to a CHEMPACK cache site and return shipment via mail using a contracted transportation carrier. This involves CHEMPACK cache site personnel or other RECIPIENT representative(s) coordinating the delivery, receipt, replacement, return shipment of product(s) and completion of all required documentation. The cost to implement Drop Ship will be the responsibility of ASPR.

Extended Not Relabeled (ENR) – Product that has been tested through the Shelf Life Extension Program and extended by Food and Drug Administration (FDA) for use beyond the manufacturer's original expiration date; however, product labeling will not reflect the new extension date.

III. RESPONSIBILITIES

A. Prior to receipt of CHEMPACK Containers and CHEMPACK Assets, RECIPIENT will develop and provide to DSNS an operational plan for storage, 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 DSNS, RECIPIENT will provide DSNS the name, title/position, office phone number, cell phone number, and e-mail address(es), for: a primary and alternate statewide point of contact and a primary and alternate point of contact for each cache location. In addition, RECIPIENT will provide CHEMPACK Program 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 CHEMPACK of any changes in the plan or personnel and will provide updated plan and contact information within 48 hours of the change. Upon receiving ASPR's approval of RECIPIENT's operational plan, the RECIPIENT will coordinate with

DSNS for the transportation and delivery of CHEMPACK Container. The cache site/project area will be responsible for all costs associated with the storage of CHEMPACK container(s).

B. RECIPIENT will maintain CHEMPACK Containers as described in Appendix II. RECIPIENT will contact CHEMPACK Program 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 CHEMPACK Program 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 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.

C. 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 ASPR within 24 to 48 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. Cache site will reseal the container following an inventory coordinated by the RECIPIENT.

D. 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.

E. RECIPIENT may temporarily transport CHEMPACK Containers for federally designated special events (i.e., 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:

1. RECIPIENT assumes responsibility for all costs associated with transport of CHEMPACK Containers not specifically directed by the CHEMPACK Program;
2. RECIPIENT must notify CHEMPACK Program at least 48 hours prior to any movement;
3. RECIPIENT must notify CHEMPACK Program 30 days prior to non-emergency internal container moves to new cache storage area;
4. RECIPIENT's notification must be made via phone or email to the designated CHEMPACK Regional Coordinator, CHEMPACK Operations Manager, or the CHEMPACK Section Lead;
5. RECIPIENT will notify the DEA registrant of temporary or permanent container moves;
6. RECIPIENT must complete documentation provided by CHEMPACK for special events/temporary CHEMPACK Container moves;
7. 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 Cache location 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 a 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.

F. Any movement of CHEMPACK Containers not described above in section III (E) must be approved by ASPR.

G. Upon request from CHEMPACK, RECIPIENT will provide access to RECIPIENT's Cache Location to allow CHEMPACK to perform:

1. Routine review of facilities holding CHEMPACK Assets and to inventory, restock, and remove expiring/expired CHEMPACK Assets; and

2. Periodic audits, including quality assurance and quality control inspections, to verify that the RECIPIENT is complying with the terms and conditions of this MOA.

H. CHEMPACK and/or RECIPIENT will inventory CHEMPACK Containers approximately every 12 to 24 months or as required by CHEMPACK.

I. RECIPIENT agrees to provide CHEMPACK Assets to patient(s) free-of-charge.

J. Drop Ship of CHEMPACK Assets, RECIPIENT and CHEMPACK cache site personnel or their authorized representatives will accept the arranged delivery, conduct and verify product replacement, sign applicable documentation, and return such assets and records as outlined in the "CHEMPACK Drop Ship: Receive and Return Instructions" included in each shipment.

K. Expiring product from a Drop Ship will be returned to a DSNS warehouse within 10 business days of receipt of replacement product. If, unable to return expiring product within recommended window contact CHEMPACK Regional Coordinator for guidance.

IV. COSTS

Except where otherwise described in this MOA, each party is responsible for its own costs. ASPR's responsibilities are subject to the availability of appropriated funds. ASPR is generally not funded to replace CHEMPACK Assets and CHEMPACK Containers lost, compromised, or destroyed, but may replenish or replace, or assist RECIPIENT 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 reasonable control of the parties, i.e., natural disasters.

V. OWNERSHIP

HHS retains ownership of all CHEMPACK Assets and CHEMPACK Containers, including after such Assets and Containers have been delivered to RECIPIENT and RECIPIENT has assumed custody.

Appendix I product content are subject to change, however a revision to MOA will not be required and an update to Appendix I will be provided.

VI. COMPLIANCE WITH US 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 pharmaceutical or medical professional with a DEA-registration 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 CHEMPACK Cache Site possesses a valid, separate DEA registration.

D. RECIPIENT will ensure a valid 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 DSNS's schedule delivery of any CHEMPACK Assets. RECIPIENT will ensure that the DEA registrant or their designated representative will be present for all ASPR visits.

VII. REQUESTS FOR INFORMATION

Under 42 USC § 247d-6b, federal agencies are prohibited from disclosing under the Freedom of Information Act (5 USC § 552) any information identifying the location at which CHEMPACK Assets are stored. To the extent permitted by law, the parties agree that neither will disclose the nature of this effort or the terms of this MOA to any person or entity, except as may be necessary to fulfill their respective missions and statutory and regulatory responsibilities. The parties agree to notify one another before making any such disclosure.

VIII. LIABILITY

Each party to 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.

IX. NO PRIVATE RIGHT CREATED

This document is an internal MOA between the parties and does not create or confer any right or benefit on any other person(s) or party, private or public. Nothing in this MOA 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.

X. 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.

XI. AUTHORITY, EFFECTIVE DATE, MODIFICATION, AND TERMINATION

A. This MOA is made under the authority of section 319F-2 of the Public Health Service Act, as amended (42 USC § 247d-6b).

B. This MOA 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 MOA may be modified upon written agreement by both parties. Either party may terminate this MOA at any time upon 180 days advance written notice unless there is a critical failure to perform. In the event of termination, all CHEMPACK Assets and Containers shall be returned to the ASPR within 180 days of termination. If ASPR terminates this MOA for a reason other than RECIPIENT'S critical failure to perform, ASPR will, at its own cost, arrange for the return of the CHEMPACK Assets and Containers. The terms and conditions of this MOA will remain in effect until all CHEMPACK Assets and CHEMPACK Containers are returned.

XII. CAPACITY TO ENTER 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 MOA on behalf of the entity for which they sign.

Director, Strategic National Stockpile

Steven A. Adams -S — Digitally signed by Steven A. Adams -S Date: 2021.03.22 14:24:03 -04'00'

Date signed

Project Area Representative

for DW 6/24/2021

Date Signed

APPENDIX I
CHEMPACK Container Contents

EMS CHEMPACK Container for 454 Treatments			
	Unit Pack	**Cases**	**QTY**
Mark 1 auto-injector*	240	5	1200
ATNAAs**	200	6	1200
Pralidoxime 300mg auto-injector***	240	5	1200
Atropine Sulfate 0.4mg/ml 20ml	100	1	100
Pralidoxime 1gm inj 20ml	276	1	276
Atropen 0.5 mg	144	1	144
Atropen 1.0 mg	144	1	144
Atropen 2.0mg***	136	9	1224
Diazepam 5mg/ml auto-injector	150	2	300
Seizalam (Midazolam) 5mg/ml vial, 10ml	50	1	50
Sterile water for injection (SWFI) 20cc Vials****	100	1	100
Security Temperature Monitoring System			1
SATCO C DEA Container			1

* If Mark 1 auto-injector is included in the container the ATNAAs, Pralidoxime 300mg and Atropen 2.0mg will not be included

**If ATNAA is included in the container Mark 1 auto-injector, Pralidoxime 300mg, and Atropen 2.0mg will not be included

***If the Pralidoxime 300mg and Atropen 2.0mg are included in the container Mark 1 auto-injectors and ATNAA will not be included

****EMS containers stored at non-medical treatment facilities will receive 2 cases of Sterile Water.

APPENDIX I
CHEMPACK Container Contents
(Continued)

Hospital CHEMPACK Container for 1,000 Treatments			
	Unit Pack	**Cases**	**QTY**
Pralidoxime 300mg auto-injector**	240	2	480
Atropine Sulfate 0.4mg/ml 20ml	100	11	900
Pralidoxime 1gm inj 20ml	276	10	2760
Atropen 0.5 mg	144	1	144
Atropen 1.0 mg	144	1	144
Atropen 2.0 mg**	136	4	544
Diazepam 5mg/ml auto-injector	150	1	150
Seizalam (Midazolam) 5mg/ml vial, 10ml	50	10	500
Diazepam 5mg/ml vial, 10ml	50	3	150
Sterile water for injection (SWFI) 20cc Vials***	100	1	100
Security Temperature Monitoring System			1
SATCO C DEA Container			1

*If Mark 1 auto-injector is included in the container the Pralidoxime 300mg and Atropen 2.0mg will not be included

**If the Pralidoxime 300mg and Atropen 2.0mg are included in the container Mark 1 auto-injectors will not be included

***Hospital containers stored at non-medical treatment facilities will receive 28 cases of Sterile Water.

APPENDIX I
CHEMPACK Contents

(Guam)

Hospital CHEMPACK Container for 1,000 Treatments			
	Unit Pack	**Cases**	**QTY**
Mark 1 auto-injector*	240	2	480
Pralidoxime 300mg auto-injector**	240	2	480
Atropine Sulfate 0.4mg/ml 20ml	100	9	900
Pralidoxime 1gm inj 20ml	276	10	2760
Atropen 0.5 mg	144	1	144
Atropen 1.0 mg	144	1	144
Atropen 2.0 mg**	136	4	544
Diazepam 5mg/ml auto-injector	150	1	150
Seizalam (Midazolam) 5mg/ml vial, 10ml	50	10	500
Diazepam 5mg/ml vial, 10ml	50	3	150
Sterile water for injection (SWFI) 20cc Vials***	100	28	100
SATCO C DEA Container			1

*If Mark 1 auto-injector is included in the container the Pralidoxime 300mg and Atropen 2.0mg will not be included

**If the Pralidoxime 300mg and Atropen 2.0mg are included in the container Mark 1 auto-injectors will not be included

***Hospital containers stored at non-medical treatment facilities will receive 28 cases of Sterile Water.

APPENDIX I
CHEMPACK Contents

American Samoa			
	Unit Pack	**Cases**	**QTY**
Mark 1 auto-injector*	240	2	480
Atropen 0.5 mg	144	1	144
Atropen 1.0 mg	144	1	144
Diazepam 5mg/ml auto-injector	150	1	150

Mariana Island			
	Unit Pack	**Cases**	**QTY**
Mark 1 auto-injector*	240	2	480
Atropen 0.5 mg	144	1	144
Atropen 1.0 mg	144	1	144
Diazepam 5mg/ml auto-injector	150	1	150

Micronesia			
	Unit Pack	**Cases**	**QTY**
Mark 1 auto-injector*	240	2	480
Atropen 0.5 mg	144	1	144
Atropen 1.0 mg	144	1	144
Diazepam 5mg/ml auto-injector	150	1	150

Palau			
	Unit Pack	**Cases**	**QTY**
Mark 1 auto-injector*	240	2	480
Atropen 0.5 mg	144	1	144
Atropen 1.0 mg	144	1	144
Diazepam 5mg/ml auto-injector	150	1	150

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 (≤77°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 or 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.