ILLINOIS STATEWIDE MEDICAL COUNTERMEASURES/STRATEGIC NATIONAL STOCKPILE PHARMACY-LOCAL HEALTH DEPARTMENT

MEMORANDUM OF UNDERSTANDING

This Illinois Statewide Medical Countermeasures/Strategic National Stockpile Pharmacy-Local Health Department Memorandum of Understanding ("MOU") is made and entered into by the signatory Health Department or signatory Health District, or signatory County/ Municipality within the State of Illinois that operates a public health department or division within its government, ("Local Health Department" or "LHD") and each signatory pharmacy entity licensed in the State of Illinois ("Pharmacy"), individually, and with all other signatory LHDs and signatory Pharmacies.

ARTICLE I

PURPOSE

The purpose of this Memorandum of Understanding (MOU) is to expand the capacity to distribute, in a rapid fashion, Medical Countermeasures to citizens of Illinois in response to threats to the public health. To accomplish this important purpose, the parties recognize the need for prior planning, training and coordinated execution of Medical Countermeasures (MCM) distribution. Part of such large scale plans may include the need to utilize existing private Pharmacy infrastructure to assist in rapid distribution and/or administration of MCM to an effected population during a Public Health Incident, Emergency or Disaster ("Incident"), using coordinated and standardized methods statewide, which may be invoked and adjusted on a county by county and ongoing basis as the changing nature of such situations may dictate.

In order to accomplish this important purpose, the parties agree that the Pharmacy signatories may choose to voluntary opt-into to the response efforts, according to the IDPH pre-approved plans developed, adjusted and administered on a real-time basis by the LHD having local geographic jurisdiction and as more fully explained herein.

Participation is entirely voluntary. Pharmacy will not receive any compensation, monetary or otherwise, from IDPH or any LHD for its voluntary participation.

ARTICLE II

DEFINITIONS

Authorized Representative: The person or persons authorized by each LHD and each Pharmacy to coordinate response activities under this MOU with each other and IDPH. Contact information for each LHD and Pharmacy Authorized Representative, or the person who will connect the caller to the Authorized Representative, is found on Appendix 1 to this Agreement.

Local Health Department (LHD): A signatory health department, health district, or county within the State of Illinois that operates a public health department or division within its county government.

Medical Countermeasures (MCM) are medications that are intended to be dispensed and/or administered to members of the public as part of a response to a public health threat.
Pharmacy: A signatory to this MOU who meets the definition of a pharmacy as that term is defined in the Illinois Pharmacy Act and possesses all necessary Federal and State licenses to acquire, distribute, dispense and deliver prescription medications to the public within Illinois.

Plan: a written Operation Plan developed and approved by IDPH pursuant to this MOU.

Public Health Incident, Emergency, or Disaster (“Incident”): Any occurrence, or threat thereof, whether natural or caused by man, in war or in peace, to which an LHD may respond pursuant to its authority under chapter ILCS (add appropriate law here), or other applicable law, and that, in the judgment of the LHD, results or may result in circumstances sufficient to exceed the capabilities of immediate local or regional public health response.

ARTICLE III

ENTIRELY VOLUNTARY PARTICIPATION

Pharmacies have a desire to assist the LHDs in addressing health and medical needs of an affected population during an Incident through the distribution, dispensing and administration of MCMs. Participation is entirely voluntary and without compensation. Under this agreement, Pharmacies have the option to opt-into MCM distribution plans as pre-approved by IDPH and managed by LHDs. Pharmacies have no obligation to opt-into distribution operations. However, if a Pharmacy, acting through its authorized representative, chooses to opt-into distribution operations, then Pharmacy shall do so according to the IDPH Pre-approved plan, as administered by the LHDs having local jurisdiction. It is understood that Pharmacy may have state-wide operations, but that its actions under this agreement shall conform in all respects to the IDPH pre-approved plan, as administered by the LHDs having local geographic jurisdiction. Pharmacy may choose to opt-into one or more such LHD managed plans on a county by county basis. By accepting MCMs allocated by IDPH, Pharmacy signifies its agreement to cooperate with and to distribute such MCMs in strict accordance with the IDPH pre-approved plan, as administered by each such respective LHD.

Any Pharmacy may limit its opt-in participation to one or more LHDs as Pharmacy may choose. However, once a Pharmacy opts-in to one or more IDPH pre-approved LHD’s plan(s), Pharmacy shall be bound by that plan(s).

ARTICLE IV

HOW TO INVOKE ASSISTANCE

The Authorized Representative of an LHD may request assistance of a Pharmacy by contacting the Authorized Representative of any particular Pharmacy. The provisions of this MOU shall only apply to requests for assistance made by and to Authorized Representatives of the parties and will typically be in writing. However, if such a request is verbal, then the request shall be confirmed in writing as soon as practicable. Once requested, Pharmacy shall have the choice to opt-in to MCM responses of one or more LHDs or to decline to participate entirely.

CONDITIONS PRECEDENT

LHDs intend to activate community-wide mass vaccination and/or dispensing plans, to include delivery of medications by Pharmacies that voluntarily opt-into LHD managed response plans, only after: 1) a declaration of “Public Health Emergency” made by the Secretary of the Department of Health and Human Services under the Public Readiness and Emergency Preparedness Act (PREP Act), 42 U.S.C.A. §247d-6d; or (2) a gubernatorial proclamation of a disaster.
No Pharmacy may opt-into any distribution plan unless and until after it completes all required ongoing training and all other requirements as specified in Exhibit “A” which is attached hereto and incorporated herein.

ARTICLE V

EFFECT OF DECLARATION OF EMERGENCY

The LHDs and Pharmacies recognize that state or federal declarations of emergency or orders related thereto, may supersede the arrangements made or actions taken pursuant to this MOU. Nothing in this MOU should be construed as independent of or bypassing established emergency management procedures, the provisions of a state proclamation of emergencies, or any conditions for the distribution and dispensing of the Strategic National Stockpile (SNS) or administration of vaccines established by the federal and/or Illinois governments. All distribution is subordinate to and must fully conform with all applicable Federal and Illinois State law.

ARTICLE VI

RESPONSIBILITIES OF LOCAL HEALTH DEPARTMENTS (LHDs)

Local Health Departments shall:

- Coordinate with IDPH and signatory pharmacies to ensure statewide consistency with screening forms, tracking, training and other Pharmacy requirements
- Provide planning and technical assistance to Pharmacy, including but not limited to, supply lists, fact sheets, dispensing algorithms, and applicable requirements.
- Provide medical screening forms to Pharmacy as a guidance for implementing dispensing operations.
- Activate community-wide mass vaccination and dispensing plans as pre-approved by IDPH within its geographic jurisdiction.
- Notify Pharmacy that IDPH-preapproved community dispensing plans should be implemented.
- Request appropriate amounts and types of medication or vaccine, and available supplies, from IDPH.
- Facilitate ongoing discussions with Pharmacy regarding the most appropriate locations for distribution.
- Request IDPH to deliver, or coordinate pick up or delivery of MCMs to specific addresses as requested by pharmacy according to allocation plans pre-approved by IDPH.
- Provide Pharmacy with medical protocols regarding the Pharmacy’s response including, but not limited to, dosing and follow-up procedures.
- Provide Pharmacy with releasable information regarding the public health emergency situation.
- Manage public information activities with regard to the overall health and medical response across the LHD’s jurisdiction.
- Provide educational materials, if appropriate and available, to Pharmacy for the purposes of distributing to all persons in MCM emergencies.
- Make arrangements to tract, retrieve and lawfully dispose of any unused medications from Pharmacy facilities and collect documentation forms.
- Provide guidance and criteria to Pharmacy for tracking levels of activity, supplies and inventory, as applicable to the response and consistent across signatory LHD jurisdiction.

ARTICLE VII

RESPONSIBILITIES OF PHARMACIES

Pharmacies shall:
- Participate in all training and exercise requirements of IDPH when offered. The current training and exercise requirements are contained within Exhibit “A”.
- Coordinate with IDPH and/or signatory LHDs to ensure statewide consistency with screening forms, tracking, training, and other Pharmacy requirements.
- Comply with all lawful pharmacy standards in effect during the Incident.
- Identify the approximate realistic number of medication doses that could be administered by Pharmacy in a specified time period and communicate that information to the LHD.
- Identify Pharmacy sites to receive medication and communicate site locations to the LHD.
- Communicate to LHDs each site location’s scope of pharmacy care regarding affected populations, e.g., convey age or prescriptive authority limitations or extent known.
- Receive, securely store and track medication deliveries, consistent with all federal, state and local government requirements, at Pharmacy-identified facilities during Incidents.
- Ensure that Pharmacy site locations serve the general public.
- At Pharmacy’s discretion, ensure that its own employees, including those employed by its parent company, and their families, are cared for.
- Conduct medical pre-screening of individuals receiving medications, based on guidance pre-approved by IDPH and supplied by LHD, to identify potential indications, contraindications and complications, and assure dispensing and administration consistent with federal, state and local government requirements.
- Prescribe and dispense medications under an appropriate written collaborative agreement with a licensed health care prescriber, a Disaster proclamation or as otherwise required by applicable law.
- Create and maintain accurate records of medications dispensed, administered, and remaining inventory, which shall be shared with IDPH upon request.
- Securely inventory, track and maintain the local, state or federal stock of medications, vaccines and supplies and maintain such materials separately from regular pharmacy stock. The local, state and federal stock shall not be used in place of commercial pharmacy stock for any reason. Identical Pharmacy stock may be used as a substitute for the local, state or federal stock at Pharmacy’s discretion. However, reimbursement, if any, shall depend upon then current state or federal guidance and is not guaranteed.
- Track contact information of individuals receiving medications.
- Communicate information regarding medications dispensed, administered, and contact information to Local Health Department as required by Local Health Department.
- Provide IDPH pre-approved education materials, supplied by LHD to all individuals receiving medications.
- Secure any unused medications until a time when LHD can make arrangements for collection or disposal.
- Participate, as appropriate, in Local Health Department-sponsored planning and mass vaccination or medication dispensing or administration training and exercises.
- All Personal Health Information (PHI) and Personally Identifiable Information (PII) shall be treated as confidential and treated and protected according to applicable Federal and Illinois State law.
- If Pharmacy signs this agreement, Pharmacy agrees to complete all requirements listed in Exhibit “A” in a timely fashion when such trainings are made available.
- All pharmacy personnel will maintain licensure, in good standing, with the Illinois Department of Financial and Professional Regulation.

ARTICLE VIII

COST AND PAYMENT

IDPH and/or Local Health Department shall provide the medications that are to be dispensed or administered by Pharmacy under this Agreement at no cost to Pharmacy. Pharmacy shall dispense and/or administer these
medications to patients or customers at no charge to the patient or customer except for a pre-authorized administrative fee not to exceed the lesser of that reimbursed by the Medicare Part B schedule, or written emergency federal or state current authorization at the time. Pharmacy agrees to waive this fee if required by then current federal or state guidance. Pharmacy may also, in its discretion, waive this fee for patients or customers who demonstrate an inability to pay whom would otherwise be required to pay.

All other costs, expenses, and fees, losses, of every type and description, without limitation, including lost profits or lost opportunities incurred by either LHD and/or Pharmacy that are in any way related to implementation and/or participation of this Agreement shall be fully borne by each respective agency. All parties agree not to seek any such reimbursement from any other party.

ARTICLE IX
ACKNOWLEDGEMENTS

The Parties to this agreement (together with their respective employees, officers, agents, and attorneys) are and shall forever remain under independent control and responsible for their own respective torts, costs, actions, inactions, losses and expenses. The Parties are and shall forever remain independent contractors and not joint venturers. Under no circumstances shall any party be liable to any other party under any theory of tort or contract, whether at law or equity. Under no circumstances may any Party recover from any other party, any damages, losses, lost profits, expenses, costs, fees, attorney or expert fees, under any theory, whether at law or equity. Each party shall, under all circumstances, bear his/her/its own damages, losses, lost profits, expenses, costs, fees, attorney and expert fees and further covenants not to bring any action seeking any of the same from any other party.

If this Agreement has been triggered after a federal public health emergency declaration by the Secretary of the Department of Health and Human Services under the PREP Act, immunity under state and federal law may extend to covered persons and entities involved in dispensing, distributing, and administering countermeasures/prophylaxis under 42 U.S.C.A. §247d-6d. Any available immunity under the PREP Act does not apply to willful misconduct or acts conducted outside the scope of the declaration.

Notwithstanding anything to the contrary in this Agreement, once MCMs are received by a Pharmacy, the LHD will retain the risk of loss with respect to the inventory unless the loss is the result of the Pharmacy’s negligence, gross negligence or intentional act or failure to act.

Each party is relying upon its own independent judgement in deciding to enter into and/or to act under this agreement. No party is relying upon any statement, representation and/or promise of any other party or non-party, except as expressly stated herein. Each party has consulted with independent attorneys of its own choosing and has received and relied upon such independent advice and counsel and is not relying upon any statement, promise, assurance, information and/or representation of IDPH, its employees or attorneys or of any other party or non-party.

ARTICLE X
INFORMATION SHARING

Pharmacy shall provide IDPH and Local Health Department with information IDPH and/or Local Health Department deems necessary for managing response efforts, documenting the actions taken, and services provided under this Agreement, all of which is available under the public health exemption of HIPAA, 45 CFR §164.512(b) and the Health Care Information Act.
Local Health Department will advise Pharmacy of the information needed to protect the public health and to prevent or control disease, injury or disability and will only request the information necessary to protect the public health and to prevent or control disease, injury or disability.

ARTICLE XI

TERM AND TERMINATION

This Agreement shall become effective immediately upon its execution by any one Pharmacy and one Local Health Department. After the first two such executions, this Agreement shall become effective as to any other Pharmacy or Local Health Department upon its execution by such Pharmacy or Local Health Department. The Agreement shall remain in effect as between each and every Pharmacy and Local Health Department until participation in this Agreement is terminated by a withdrawing Party by written notice to all of the other signatories to the Agreement. Termination of participation in this Agreement by a withdrawing Pharmacy or Local Health Department shall not affect the continued operation of this Agreement as between the remaining Pharmacies and Local Health Departments so long as at least one Pharmacy and one Local Health Department remain.

Either Local Health Department or Pharmacy may terminate this Agreement for convenience with written notification to all of the other signatories to the Agreement no less than thirty (30) calendar days in advance of the termination date.

ARTICLE XII

AMENDMENTS

No provision of this Agreement may be modified, altered or rescinded by any individual Pharmacy or Local Health Department without the unanimous concurrence of the other Pharmacies and Local Health Departments thereby impacted. Modifications to this Agreement must be in writing and will become effective only upon the approval of the modification by all Pharmacies and Local Health Departments impacted by any such amendment. Modifications must be in writing and signed by each Pharmacy and Local Health Department.

ARTICLE XIII

INDEPENDENT CAPACITY

The employees or agents of Pharmacy, IDPH and LHDs who are engaged in the performance of this Agreement are and shall continue to be employees or agents of that respective party and shall not be considered for any purpose to be employees or agents of any other party to this Agreement.

ARTICLE XIV

SEVERABILITY

If any provision of this Agreement or any document incorporated by reference shall be held invalid, such invalidity shall not affect the other provisions of this Agreement which can be given effect without the invalid provision, if such remainder conforms to the requirements of applicable law and the fundamental purpose of this Agreement, and to this end the provisions of this Agreement are declared to be severable.

ARTICLE XV

NO THIRD PARTY BENEFICIARIES

6

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This Agreement is entered into solely for the mutual benefit of the parties to this Agreement. This Agreement is not entered into with the intent that it shall benefit any other person and no other such person shall be entitled to be treated as a third-party beneficiary of this Agreement.

ARTICLE XVI

DISPUTE RESOLUTION

If a dispute between any parties to this Agreement arises out of or related to this Agreement, or the breach thereof, and if the dispute cannot be settled through direct discussions, the parties may agree to first endeavor to settle the dispute in an amicable manner by mediation. Thereafter, any unresolved controversy or claim arising out of or related to this Agreement, or breach thereof, may be settled in a court having jurisdiction thereof.

ARTICLE XVII

NOTICES

Whenever this Agreement provides for notice to be provided by one party to another, such notice shall be in writing and directed to the Authorized Representatives identified on Appendix 1.

ARTICLE XVIII

SURVIVORSHIP

All clauses intended to be enforceable after termination shall survive termination. The obligation to account for MCMs and the records pertaining to receipt, dispensing/administration, contact information, several liability, confidentiality, third party beneficiaries, and dispute resolution shall all survive any termination.

IX. Immunity, Indemnification, and Limitations
XIV. Severability
XV. No Third Party Beneficiaries
XVI. Dispute Resolution

ARTICLE XIX

OTHER OR PRIOR AGREEMENTS

If a Pharmacy and Local Health Department have a prior written agreement that relates to the subject matter of this Agreement, namely, using existing Pharmacy infrastructure to assist in addressing health and medical needs of an affected population during an Incident, including but not limited to mass dispensing of antibiotics, antiviral medications or vaccines to the general public during times of health and medical disasters, then, at such time that said Pharmacy and said Local Health Department both execute this Agreement, such prior written agreement between them shall become null and void and of no further force and effect.

Notwithstanding the above provision in this Article XIX, any Pharmacy and/or Local Health Department may enter into other agreements with other Pharmacies and/or Local Health Departments provided such other agreements govern subject matter not governed by this Agreement.

ARTICLE XX
AUTHORIZED REPRESENTATIVES

Appendix 1 contains the position titles of persons who are authorized to act for the listed Pharmacy or Local Health Department as the Authorized Representative under the MOU or to connect the caller to the person who is authorized to act. The Pharmacies and Local Health Departments will revise Appendix 1 as each new Pharmacy and Local Health Department joins the agreement, and from time to time, as deemed necessary. Each revised Appendix 1 shall supersede all prior versions of said Appendix and is incorporated herein by this reference as if set forth at length.

ARTICLE XXI

GOVERNING LAW

This Agreement shall be interpreted, construed and enforced in accordance with the laws of the State of Illinois.

ARTICLE XXII

EXECUTION IN COUNTERPARTS

This Agreement may be executed in two or more counterparts, each of which shall be deemed an original, but all of which together shall constitute one and the same instrument. For purposes hereof, a facsimile copy of this Agreement, including the signature pages hereto, shall be deemed to be an original.

IN WITNESS WHEREOF, this Agreement has been executed and approved and is effective and operative as to each Pharmacy and each Local Health Department as herein provided.

By: __________________________________________
It's: __________________________________________
Date: ________________________________

APPENDIX 1

AUTHORIZED REPRESENTATIVES

The following position titles are authorized to act for the listed Pharmacy or Local Health Department as the Authorized Representative under this MOU or to connect the caller to the person who is authorized to act:

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<tr>
<th>Health Department/District</th>
<th>Title</th>
<th>Contact Information</th>
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<tr>
<td>Pharmacy</td>
<td>Title</td>
<td>Contact Information</td>
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8 2017.01.12