

Oregon Statewide Pharmacy – Local Public Health Authority Memorandum of Understanding

ARTICLE I PURPOSE

The purpose of this memorandum of understanding (MOU) is to utilize existing Pharmacy infrastructure to help address health and medical needs of an affected population during a Public Health Incident, Emergency or Disaster ("Incident"), using coordinated and standardized protocols statewide. The Conference of Local Health Officials (CLHO), Oregon State Pharmacy Association (OSPA), Oregon Society of Health System Pharmacists (OSHP), Oregon Board of Pharmacy (BoP), and Oregon Public Health Division (OPHD) support the development of this MOU.

ARTICLE II DEFINITIONS

- (1) "Administer" has the meaning given that term in Oregon Revised Statute (ORS) 689.005.
- (2) "Dispense" has the meaning given that term in ORS 689.005.
- (3) "Drug" means a drug or vaccine or medical device, or any combination of these terms.
- (4) "Emergency" has the meaning given that term in ORS 401.025.
- (5) "Local Public Health Authority (LPHA)" has the meaning given that term in ORS 431.260.
- (6) "Operational Guidance" is a document containing templates and procedures for MOU implementation, as well as screening forms, tracking requirements, and treatment protocol templates developed pursuant to this MOU.
- (7) "Oregon Public Health Division" (OPHD) means that division of the Oregon Health Authority that is responsible for planning for and responding to a public health emergency.
- (8) "Pacific Northwest Emergency Management Arrangement" (PNEMA) means the compact, ratified in Chapter 25 Oregon Laws 2008, between the states of Alaska, Idaho, Oregon and Washington, the Province of British Columbia, and the Yukon Territory, to provide mutual assistance in an emergency or public health emergency.
- (9) "Pharmacy" means a signatory to this MOU who meets the definition of a pharmacy as defined in ORS 689.005.
- (10) "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 LPHA may respond pursuant to its authority under ORS 431.262, or other applicable law, and that, in the judgment of the LPHA, results or may result in circumstances sufficient to exceed the day-to-day operational capabilities of immediate local or regional public health response.
- (11) "Strategic National Stockpile" (SNS) means the US Government stockpile of antiviral drugs and other drugs and medical supplies that can be made available to a state in an emergency.

ARTICLE III PARTICIPATION

The Pharmacies have a desire to assist the LPHAs in addressing health and medical needs of an affected population during an Incident. The LPHAs and Pharmacies agree that this MOU does not create a legal duty to do so. The LPHAs and Pharmacies agree that any and all actions taken pursuant to this MOU shall be voluntary and in each LPHA's and Pharmacy's sole discretion.

ARTICLE IV
HOW TO INVOKE ASSISTANCE

An LPHA may request assistance of a Pharmacy by contacting the Pharmacy directly or by contacting the BoP. If desired, signatory pharmacies can share with LPHAs contact information for preferred recipients within their organizations of requests for assistance under this MOU. Requests may be verbal or in writing. If verbal, the request shall be confirmed in writing as soon as possible to the extent practical. The process is outlined in greater detail in the Operational Guidance.

ARTICLE V
EFFECT OF DECLARATION OF EMERGENCY

The LPHAs 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 county or state declarations of emergencies, or any conditions for the distribution and dispensing of the Strategic National Stockpile (SNS) or administration of vaccines established by the federal or state governments. In a state of declared emergency certain rules of the BoP, contained in OAR Chapter 855 Division 007, will be activated. These rules would broaden the options available to Pharmacies and LPHAs in response to an incident. In a declared emergency, pharmacists and other healthcare volunteers who are enrolled in the state's SERV-OR health volunteer registry are considered agents of the state under ORS 401.651-401.670 for activities within the scope of assigned responsibilities related to the response, and will be afforded workers' compensation and liability coverage. Notwithstanding these effects, the activities under this MOU are not limited to situations in which an emergency has been declared.

ARTICLE VI
RESPONSIBILITIES OF LOCAL PUBLIC HEALTH AUTHORITY

LPHA responsibilities:

- a. Coordinate with OPHD, BoP and/or signatory Pharmacies to ensure statewide consistency with screening forms, tracking, training and other Pharmacy requirements if applicable.
- b. Provide planning, training and technical assistance to Pharmacy, including but not limited to, supply lists, fact sheets, dispensing algorithms, and applicable requirements.
- c. Provide statewide consistent medical screening forms to Pharmacy as guidance for implementing dispensing operations.
- d. Provide a clear description of the mission LPHA is requesting Pharmacy to undertake, including specific information about the population to be immunized or given prophylaxis, specific statewide protocol (standing order) templates to be used, and specific displaced or sheltered populations whose pharmaceutical needs must be met, as well as the vaccine or medication to be used, dosage, route of administration, and follow-up procedures.
- e. Activate community-wide mass vaccination and dispensing plans as necessary.
- f. Notify OPHD of the activation of MOU. Notification may be verbal or in writing. If verbal, the notification shall be confirmed in writing as soon as possible to the extent practical.
- g. Notify Pharmacy that community dispensing plans should be implemented.
- h. Request appropriate amounts and type of medication or vaccine, and available supplies, from local, state or federal sources, including use of SNS resources, or specify that Pharmacy is requested to supply these materials.
- i. Facilitate a discussion with Pharmacy regarding the most appropriate locations for distribution.
- j. Request OPHD to deliver, or have delivered medications to distribution centers as determined by the LPHA in consultation with the BoP and Pharmacy.
- k. With OPHD, modify treatment protocol templates from the Operational Guidance as needed to guide Pharmacy response.

- l. Manage public information activities with regard to the overall health and medical response across the LPHA's jurisdiction.
- m. Provide educational materials, if appropriate, to Pharmacy for the purposes of distributing to all persons in emergencies affecting the public's health.
- n. Provide guidance and criteria to Pharmacy for tracking levels of activity, supplies and inventory, as applicable to the response and consistent across signatory LPHA jurisdictions.
- o. Participate, as appropriate, in mass vaccination or medication dispensing training and exercises, and in exercises to promote emergency response surge capacity as outlined in the Oregon Crisis Care Guidance.
- r. If an Oregon Emergency Response System (OERS) number has been issued by the Oregon Office of Emergency Management for the Incident leading to activation of the MOU, LPHA is encouraged to use the OERS number in communications with emergency management personnel and OPHD.

ARTICLE VII
RESPONSIBILITIES OF OREGON PUBLIC HEALTH DIVISION

OPHD responsibilities:

- a. Coordinate any future updates of this MOU and establish a webpage on which the most current MOU and Operational Guidance are posted,
- b. Oversee development of statewide screening forms and tracking requirements, and make these available to LPHAs as components of the Operational Guidance accompanying this MOU.
- c. Oversee development of statewide treatment protocols that could be used in incident response and make them available to LPHAs in a timely fashion as needed to support response efforts.
- d. Deliver, or arrange delivery of medications to distribution centers as needed, in consultation with the LPHA, BoP, and Pharmacy.
- e. Coordinate public health activities, including collection of information regarding medication administration and dispensing activities, during incidents involving multiple counties.
- f. Determine any limits on administrative fees that can be charged by Pharmacies for dispensing or administration of SNS or other stockpile medications, and disseminate this information.

ARTICLE VIII
RESPONSIBILITIES OF PHARMACIES

Pharmacy responsibilities:

- a. Coordinate with OPHD, BoP, and/or signatory LPHAs to ensure statewide consistency with screening forms, tracking, training, and other Pharmacy requirements.
- b. Comply with Pharmacy standards in effect during the Incident.
- c. Upon receipt of a request for action by an LPHA, determine the Pharmacy's anticipated capacity to respond to the request, including, as appropriate, the approximate number of vaccine or medication doses that could be administered by Pharmacy in a specified time period, the approximate number of displaced persons who could be screened and provided with emergency supplies of medications under provisions of OAR 855-007-0090(1)-(2), or the approximate number of patients that could be accommodated by the Pharmacy under a treatment protocol as outlined in the Operational Guidance; communicate that information to the LPHA.
- d. Identify Pharmacy sites to receive medication deliveries and communicate site locations to the LPHA.
- e. Communicate to LPHAs each site location's scope of Pharmacy practice regarding affected populations, e.g., convey age or prescriptive authority limitations.
- f. Receive and store medication deliveries, consistent with federal, state or local government requirements, at Pharmacy-identified facilities during Incidents.

- g. Ensure that Pharmacy site locations serve the general public.
- h. At Pharmacy's discretion, ensure that its own employees, including those employed by its parent company, and their families, are cared for consistent with public health recommendations.
- i. As appropriate when the BoP emergency rules in OAR chapter 855, Division 7 have been activated, and if agreed to by Pharmacy, oversee participation in response efforts by pharmacists and pharmacy technicians, licensed in other jurisdictions, but participating in response efforts under PNEMA or EMAC, provided that the individual supplies evidence that he or she holds a valid, current, unrestricted, comparable license by another signatory to PNEMA or EMAC in accordance with OAR 855-007-0050(2).
- j. As appropriate, and if agreed to by Pharmacy, oversee participation in response efforts by pharmacists and pharmacy technicians who have had previously inactive licenses re-activated by the BoP in accordance with OAR 855-007-0050(4).
- k. Conduct medical screening of individuals receiving medications, based on guidance provided by LPHA, to identify potential contraindications and complications, and assure dispensing and administration consistent with federal, state and local government requirements.
- l. Allow pharmacists to prescribe and dispense medications under a treatment protocol under authority of a licensed healthcare prescriber or lawful health order issued by a local health officer or an authorized representative of OPHD.
- m. Maintain accurate records of medications dispensed, administered, and remaining inventory.
- n. Maintain and inventory the local, state or federal stock of medications, vaccines and supplies and physically separate them from the regular inventory. The local, state and federal stock cannot be used in place of commercial pharmacy stock at any time. Pharmacy stock may be used as a substitute for the local, state or federal stock and Pharmacy may seek reimbursement for this action, if available, in accordance with the then current state or federal guidance.
- o. Track contact information of individuals receiving medications.
- p. Communicate information regarding medications dispensed, administered, and, for medical countermeasure from a state stockpile or SNS, provide contact information for recipients to LPHA as required by LPHA, through a secure method. [Release of information to public health in this setting is permitted under HIPAA. See Operational Guidance, Section VI., bullet 4.]
- q. Provide educational materials, supplied by LPHA, when possible to all individuals receiving medications.
- r. Participate, as appropriate, in LPHA-sponsored mass vaccination or medication dispensing training and exercises, and in exercises to increase healthcare response capacity as outlined in the Oregon Crisis Care Guidance.
- s. If they choose to, qualified Pharmacy personnel who would take part in response activities under this MOU can register as Emergency Volunteer Workers with the State's health volunteer registry, SERV-OR pursuant to OAR 333-003-0100 to 333-003-0140 and ORS 401.651 to 401.670. In a declared emergency, pharmacy personnel so registered would be considered agents of the state for actions performed as part of response to the emergency, would have liability limited under ORS 30.260 to 30.300, and would be eligible for workers' compensation protection to the extent allowed by Oregon law.

**ARTICLE IX
RESPONSIBILITIES OF THE BOARD OF PHARMACY**

BoP responsibilities:

- a. Develop and maintain an accurate roster of Pharmacies in Oregon that includes contact information for all co-signatory Pharmacies.
- b. Upon request from an LPHA or from OPHD, convey request for assistance under this MOU from the requesting public health entity to the requested Pharmacy or Pharmacies.
- c. With OPHD and other parties to this MOU, develop and review treatment protocol templates to ensure that they are in keeping with relevant Oregon statutes and rules.

**ARTICLE X
COST AND PAYMENT**

When LPHA provides the medications that are to be dispensed or administered by Pharmacy from a local, state, or federal stockpile, it will do so at no cost to Pharmacy. Pharmacy shall dispense or administer these medications to patients or customers at no charge to the patient or customer except for an administrative fee not to exceed an amount set by OPHD, or under emergency federal or state current guidance 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. When Pharmacy provides the medications that are dispensed or administered by Pharmacy during implementation of this Agreement, this restriction shall not apply, and Pharmacy, at its discretion, can bill for services and medications in its usual and customary manner. All other costs incurred by either LPHA or Pharmacy through implementation of this Agreement shall be borne by each respective agency.

**ARTICLE XI
LIABILITY, INDEMNIFICATION, AND LIMITATIONS**

The Parties acknowledge that 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 will extend to covered persons involved in dispensing, distributing, and administering countermeasures/prophylaxis under 42 U.S.C.A. §247d-6d. Immunity under the PREP Act does not apply to willful misconduct or acts conducted outside the scope of the declaration.

The Parties further acknowledge that if this Agreement has been triggered after a locally or state declared emergency under ORS 401.165 or ORS 433.441-433.452, a pharmacist who meets the definition of a "qualified emergency service volunteer" under ORS 401.358 or is an emergency healthcare provider under ORS 401.651, who otherwise complies with ORS 401.358 to 401.368 and ORS 401.651 to 401.670, will be considered an agent of the state and will have liability coverage for activities within the scope of assigned responsibilities related to the response. Liability coverage does not apply to gross negligence, willful or wanton misconduct, or acts outside the scope of the assigned responsibilities or not under the direction of the local emergency management organization.

If the provisions of ORS 401.358 to 401.368 and ORS 401.651 to 401.670 do not apply, each party agrees to be responsible and assume tort liability for its own wrongful acts or omissions, or those of its officers, agents or employees to the fullest extent required by law.

Notwithstanding anything to the contrary in this Agreement, once the LPHA has delivered the inventory to the Pharmacy, the LPHA 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.

**ARTICLE XII
INFORMATION SHARING**

Pharmacy will provide LPHA with information LPHA deems necessary for documentation of 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 through authorities outlined in ORS 433.004. This information is protected from subsequent disclosure under ORS 433.008. LPHA 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 XIII
TERM AND TERMINATION**

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

Either LPHA 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 XIV
AMENDMENTS**

No provision of this Agreement may be modified, altered or rescinded by any individual Pharmacy or LPHA without the unanimous concurrence of the other Pharmacies and LPHAs. Substantive modifications to this Agreement must be in writing and will become effective upon the approval of the modification by all signatory Pharmacies and LPHAs. Modifications must be signed by each Pharmacy and LPHA. This article does not apply to updating of contact information that may, from time to time, become necessary to ensure current information is available.

**ARTICLE XV
INDEPENDENT CAPACITY**

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

**ARTICLE XVI
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 XVII
NO THIRD PARTY BENEFICIARIES**

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 XVIII
DISPUTE RESOLUTION**

If a dispute between any parties to this Agreement arises out of or related to this Agreement, or the breach thereof, the parties agree to endeavor to settle the dispute in an amicable manner by direct communication between or among each other before terminating the Agreement.

**ARTICLE XIX
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 designated representative of the party.

**ARTICLE XX
SURVIVORSHIP**

The following clauses survive the termination of this Agreement:

- IX. Liability, Indemnification, and Limitations
- XVI. Severability
- XVII. No Third Party Beneficiaries

**ARTICLE XXI
OTHER OR PRIOR AGREEMENTS**

If a Pharmacy and LPHA 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 LPHA 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 XXI, any Pharmacy and/or LPHA may continue or enter into other agreements with other Pharmacies and/or LPHAs provided such other agreements govern subject matter not governed by this Agreement

**ARTICLE XXII
GOVERNING LAW**

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

ARTICLE XXIII
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 Public Health Authority as herein provided.

Yamhill County Board of Commissioners
Company/Agency

Allen Springer
Signature

Allen Springer, Chair
Print Name and Title

11-30-15
Date

Approved As To Form
by Christian Boenisch
Christian Boenisch
County Counsel
Yamhill County

Accepted by Yamhill County
Board of Commissioners on
11.23.15 by Board Order
15-481

Purpose

During many events affecting the public's health, pharmacies can play a critical role in effective response. This memorandum of understanding (MOU) provides a framework for timely, effective pharmacy response to public health events. Pharmacies can:

- Distribute and dispense vaccine during communicable disease outbreaks
- Dispense antibiotics for treatment or prevention of illness during outbreaks
- Under Board of Pharmacy emergency rules (OAR 855-007-0090), assess and meet needs for medication among those displaced by storms or other events
- Expand healthcare capacity in a public health emergency by managing therapy for specific conditions under a state-issued treatment protocol (ORS 431.264)

The MOU helps pharmacies and public health plan effective interventions and work together to meet the needs of the community.

Background

- Patterned after a similar agreement in Washington where signatories include multiple public health agencies and representatives of 256 pharmacies.
- Oregon document drafted by representatives of Oregon State Pharmacy Association, Oregon Society of Health System Pharmacists, Conference of Local Health Officials, Oregon Board of Pharmacy, and Oregon Public Health Division, with broader input from public health and pharmacy communities.

What the MOU does and does NOT do

Does:

- Help standardize response across communities
- Provide structure to simplify pharmacy-public health collaboration

Does NOT:

- Require participation by signatories; this is not a contract

Next Steps

Local Health Departments

- Submit MOU to your authorized county officials for signature
- Return signed MOU to OHA to be added as a signatory
- Oregon Health Authority is working with major pharmacy chains to obtain signatures, if you know of local pharmacies that should sign on, feel free to approach them and share

**OREGON GUIDANCE FOR COLLABORATIVE
PHARMACY-LOCAL PUBLIC HEALTH AUTHORITY RESPONSE
TO PUBLIC HEALTH INCIDENTS**

**For Use with Oregon Statewide Pharmacy – Local Public Health Authority
Memorandum of Understanding**

This work was supported by the Oregon Health Authority. Its contents are solely the responsibility of the authors and do not necessarily represent the official views of the State of Oregon.

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RECORD OF REVIEW

| Change Number | Date of Review/Change | Review Led By (Reviewers noted) |
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ACRONYMS

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| BoP | Oregon Board of Pharmacy |
| CLHO | Council of Local Health Organizations |
| HAN | Health Alert Network |
| HIPAA | Health Insurance Portability and Accountability Act |
| LPHA | Local Public Health Authority |
| MCM | Medical Countermeasures |
| MOU | Memorandum of Understanding |
| OAR | Oregon Administrative Rules |
| OERS | Oregon Emergency Response System |
| OPHD | Oregon Public Health Division at Oregon Health Authority |
| ORS | Oregon Revised Statutes |
| OSHP | Oregon Society of Health-System Pharmacists |
| OSPA | Oregon State Pharmacy Association |
| SNS | Strategic National Stockpile |
| SOP | Standard Operating Procedures |

PHARMACY-LOCAL PUBLIC HEALTH AUTHORITY GUIDANCE

I. AUTHORITY

This guidance was developed in accordance with the Oregon Statewide Pharmacy-Local Public Health Authority Memorandum of Understanding (MOU). Its contents have been reviewed by the Task Force that developed the MOU, as well as signatory Pharmacies and Local Public Health Authorities (LPHAs).

II. PURPOSE

The purpose of the guidance is to outline simple, straightforward processes through which LPHAs and Pharmacies can establish partnerships to meet the medical needs of Oregonians during public health incidents. It also provides templates of forms that can be used to request pharmacy participation in response, outline the specific activities requested, and describe treatment protocols that can be used by pharmacists during event response, as described in the Oregon Statewide Pharmacy-Local Public Health Authority MOU.

III. POINTS OF CONTACT

If desired, signatory pharmacies can share with LPHAs contact information for preferred recipients within their organizations of requests for assistance under the MOU. Otherwise, pharmacies will be contacted using contact information maintained by Oregon Board of Pharmacy (BoP). Point of contact for activities under the MOU for BoP will be the Compliance Officer (971-673-0001) MOU point of contact for LPHAs will be the LPHA Preparedness Coordinator. MOU point of contact for the Oregon Public Health Division (OPHD) will be the Public Health Duty Officer (971-246-1789).

IV. ACTIVATION PROCESS FOR THE MOU

A. Who Can Activate the MOU

The MOU can be activated by a signatory LPHA and signatory Pharmacy or Pharmacies who have come to agreement on specific activities that the Pharmacy will undertake in response to a Public Health Incident. The MOU can also be activated by OPHD, in consultation with LPHAs and Pharmacies.

B. Templates to Specify Requested Pharmacy Activities

Appendix C contains templates that can be used to clarify the specific pharmacy response activities requested. These templates are intended to support the development of appropriate, specific, feasible roles for Pharmacies in incident response, and to standardize response requests across jurisdictions. Appendix D contains templates, stockpile inventory tracking forms, and examples of treatment protocols that can be adapted to the specific incident, and may be used by pharmacists in the case of incident response.

C. Activation Process

1. Notifications of intent to activate the MOU

Upon requesting Pharmacy assistance under the MOU, LPHA(s) will immediately notify OPHD of the request by contacting the Public Health Duty Officer at 971-246-1789. When BoP receives a request for Pharmacy assistance, BoP will also contact the Public Health Duty Officer.

2. Type of incident

Single Jurisdiction: For incidents that affect a single county, the LPHA can request pharmacy assistance through the BoP or contact the Pharmacy directly. The LPHA will outline a plan describing how the Pharmacy can be incorporated into the public health response, and in consultation with OPHD as needed, will describe the specific activities that can be carried out by the Pharmacy. The scope and nature of pharmacy activities can be clarified as needed through a coordination call led by the LPHA, with participation by the pharmacies involved and, if necessary, OPHD. The LPHA will follow the draft agenda that is included in Appendix A. Following the coordination call, requests for assistance from the LPHA and actions agreed to by participating Pharmacies will be documented using an *Assistance Request Form* (Appendix B).

Multi-Jurisdiction: When incidents affecting multiple jurisdictions necessitate response activities by Pharmacies in more than one county, OPHD will serve as the contact point for any LPHAs that may need Pharmacy assistance. When notified by more than one LPHA of the need for Pharmacy assistance under the MOU, BoP will notify OPHD. OPHD will then alert all LPHAs throughout Oregon, notify them of the incident, and request that any LPHA arranging Pharmacy assistance for the incident contact OPHD and participate in coordination conference calls. BoP and OPHD will notify appropriate Pharmacies and all LPHAs requesting assistance of the time and contact number for coordination calls. OPHD will then facilitate coordination calls following the agenda included in Appendix A. Requests for assistance from each LPHA and actions agreed to by participating Pharmacies will be documented using the *Assistance Request Form* included in Appendix B.

3. MOU activation

LPHAs or OPHD may activate the MOU by:

- a. contacting a signatory Pharmacy, either directly or through the BoP;
- b. coming to agreement with responding pharmacies on the scope and exact nature of Pharmacy activities in the context of incident response;
- c. documenting the Pharmacy's activities in incident response using the *Assistance Request Form* template in Appendix B; and
- d. Sharing the *Request Form* with responding Pharmacies. Use of the *Assistance Request Form* template by signatories is encouraged to promote clarity and specificity in the activities being requested, and standardization when similar Pharmacy activities span more than one LPHA jurisdiction.
- e. In a single-jurisdiction incident:
 - i. LPHA may confirm Pharmacy approval of response activities described in the *Assistance Request Form*, or, as needed, can request that BoP forward the form to assisting Pharmacies for review and approval.
 - ii. In a single-jurisdiction incident, Pharmacy will communicate directly with LPHA acknowledging approval of activities described in the *Assistance Request Form* and readiness to implement them.
- f. In multi-jurisdiction incidents:
 - i. OPHD will coordinate with BoP to circulate *Assistance Request Forms* to appropriate Pharmacies for review and approval.

- g. Pharmacy will communicate with OPHD through the Public Health Duty Officer, acknowledging approval of activities described in the *Assistance Request Form* and readiness to implement them.
- h. OPHD Public Health Duty Officer is then responsible for communicating approval to all affected LPHAs through their Administrator and Preparedness Coordinator.
- i. Any amendment to a previously approved *Assistance Request Form* shall be in writing, and agreed between the parties.

V. INVENTORY TRACKING AND REPORTING

- 1. Pharmacy will maintain an ongoing inventory record of all medical countermeasures supplied by public health throughout the duration of the period of activation of the MOU. These records shall be kept in accordance with applicable rules and regulations, including OAR or ORS and Centers for Medicare and Medicaid guidance.
- 2. If multiple LPHAs have activated the MOU for the same event, standardized inventory tracking and reporting forms, based on templates included in Appendix C, can be used.
- 3. LPHA or, as appropriate, OPHD, shall specify the minimum detail of information needed from Pharmacy for inventory tracking and reporting for dispensing of stockpile medical countermeasures.
- 4. Pharmacy shall work with LPHA to determine the format, mechanism, and timing of reporting the minimum dataset. The format should accommodate the potential need for multiple methods of data submission, given internal restrictions on internet access in some pharmacies.

VI. Communications and Updates in the Course of Incident Response

- 1. LPHAs are encouraged to provide regular updates on incident status of the incident to OPHD and Pharmacies. Communication between LPHAs and Pharmacies during the response may occur through email, fax, and phone calls. Frequency of updates can be negotiated by the involved parties.
- 2. Pharmacies are encouraged to provide regular updates on Pharmacy activities (e.g., number of clients vaccinated or provided prophylaxis, number of displaced persons assessed and served) and any barriers to response (MCM availability, other resource limitations) to LPHAs with which they are collaborating. Frequency of updates can be negotiated.
- 3. When vaccines are provided, Pharmacies shall enter dispensing information into the *Oregon ALERT* Immunization Information System, as with other immunizations.
- 4. When response activities involve a Pharmacy dispensing MCMs from the Strategic National Stockpile or State stockpile, Pharmacy shall supply the Oregon Immunization Program with name and contact information for all stockpile medication recipients, as permitted under the Health Insurance Portability and Accountability Act (HIPAA), 45 CFR 164.512(b).

VII. DEMOBILIZATION

1. The decision to return to normal operations and discontinue Pharmacy activities under the MOU will be made by the LPHA after consultation with the appropriate parties. Triggers for demobilization will be based on the following factors:
 - a. Targeted population has received needed medications,
 - b. Sufficient distribution can be achieved through other mechanisms, and/or
 - c. Mechanisms exist to supply medication to those without the ability to pay for them.
2. As appropriate, guidance for Pharmacy will be provided by LPHA for handling of and final reporting on unused state or federal stockpile drugs and/or vaccines, or other medical products.,.
3. In the event that multiple LPHAs have activated the MOU concurrently, the coordination of demobilization activities will be facilitated by OPHD and will be communicated via conference call and website updates as necessary.

VIII. OPERATIONAL GUIDANCE REVIEW

1. The Operational Guidance and MOU will be reviewed for possible updates every 5 years. This review will be convened by the OPHD Medical Countermeasures Coordinator and will include representatives from OSHP, OSPA, CLHO, BoP, and OPHD. It will address recommendations from after-action reports of MOU activations and other issues that may arise related to the MOU.
2. Signatory personnel who would potentially be involved in activating this MOU are encouraged to review re-familiarize themselves with the document annually.

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APPENDIX A: TEMPLATE FOR COORDINATION CALL AGENDA

The intent of the coordination call is for public health personnel to share information with Pharmacies about the public health event, and to determine realistic, effective roles for Pharmacies in event response.

| Topic | Summary of Topic Discussion | Time Allotted |
|---|-----------------------------|---------------|
| 1. Introductions | | 5 min. |
| 2. General description of public health hazard (i.e. type of disease outbreak, environmental health threat, infrastructure impacts, etc.) | | |
| 3. Type of assistance needed. (Types of medications to be dispensed; specific populations or priority groups to be served; including estimated number of recipients; types of information to be communicated to the public) | | |
| 4. When and where assistance is needed | | |
| 5. Initial assessment of pharmacy resources available from Public Health for response (if any) | | |
| 6. Information or other support required by pharmacy from Public Health to clarify and accomplish mission | | |
| 7. Other issues to be addressed | | |
| 8. Next Steps, with responsible parties and timelines | | |

APPENDIX C:

SAMPLE TREATMENT PROTOCOL AND INVENTORY TEMPLATES

**These Are Examples Only. Actual Protocols Will Be Issued, as Needed,
by Oregon Health Authority in Response to Public Health Incidents**

The Oregon Immunization Program (OIP) produces vaccination standing orders for public providers and vaccination protocols for pharmacists. During an incident that requires activation of this memorandum of understanding, routine orders and protocols may be used, or OIP may release emergency documents if the event involves a new vaccine or specific populations are targeted. Routine and emergency orders and protocols are posted at the following websites:

Model vaccine standing orders: <http://1.usa.gov/OregonStandingOrders>

Pharmacy vaccine protocols:

https://public.health.oregon.gov/PreventionWellness/VaccinesImmunization/ImmunizationProviderResources/Pages/p_harmpro.aspx

OREGON HEALTH AUTHORITY
IMMUNIZATION PROTOCOL FOR PHARMACISTS
RECOMBINANT MENINGOCOCCAL B VACCINE

Date: 03-13-2015

On February 27, 2015, ACIP made recommendations for the use of the following recombinant meningococcal B vaccines:

- Bexsero[®] (Novartis); 2-dose series at days 0 and ≥ 1 month¹ (See page 3, section III A for further information about this vaccine)
- Trumenba[™] (Pfizer); 3-dose series at days 0, 2 months, and 6 months² (See page 3, section III B for further information about this vaccine)

The Oregon Health Authority, Immunization Program Medical Director authorizes use of Bexsero[®] and Trumenba[™] under the following parameters:

- For high-risk individuals ≥ 11 years of age (ACIP recommendation, Feb. 27, 2015).
- To control the outbreak of meningitis B associated with the University of Oregon. This use of the vaccine will expire on June 30, 2015, at which point ACIP should have released its general recommendations for these vaccines.

I. Order:

1. Check the ALERT Immunization Information System (IIS) to determine whether the patient needs this vaccine and any other vaccines.
2. Screen clients ≥ 11 years of age for contraindications.
3. Provide an Adolescent Well Visit Flyer to those 11–18 years of age.
4. Provide the vaccine-specific package insert, answering any questions.
5. Obtain a signed Vaccination Administration Record (VAR)
6. Give a single 0.5-mL intramuscular (IM) dose of meningococcal B vaccine according to recommendations and appropriate schedules.
 - Bexsero[®]:
www.fda.gov/downloads/BiologicsBloodVaccines/Vaccines/ApprovedProducts/UCM431447.pdf¹
 - Trumenba[™]:
www.fda.gov/downloads/BiologicsBloodVaccines/Vaccines/ApprovedProducts/UCM421139.pdf²

Immunizing Pharmacist Signature

Date

For multiple signatures see: 1.usa.gov/PharmacyImmunizationProtocols

II. LICENSED RECOMBINANT MENINGOCOCCAL B VACCINES^{1,2}

| Product Name | Vaccine Components | Acceptable Age Range | Thimerosal | Latex |
|---|--|----------------------|------------|---|
| Bexsero[®] (4CMenB) | 50 µg each of Neisserial adhesion A (NadA), Neisserial Heparin Binding Antigen (NHBA), and factor H binding protein (fHbp) = 150 µg protein plus 25 µg of Outer Membrane Vesicles (OMV) 1.5 mg aluminum hydroxide (0.519 mg of Al ³⁺) 3.125 mg NaCl 0.776 mg histidine 10 mg sucrose at pH 6.4–6.7 0.01 µg kanamycin (by calculation) | ≥11 years | No | Tip caps of pre-filled syringes (plungers are <u>not</u> made with natural rubber latex) |
| Trumenba[™] (rLP2086) | 60 µg of each of 2 fHBP variants = 120 µg protein 0.018 mg of Polysorbate 80 0.25 mg of Al ³⁺ = AlPO ₄ in 10 mM histidine buffered saline at pH 6.0 | ≥11 years | No | No |

III. RECOMMENDATIONS FOR USE^{1, 2}

- A. Approved for the following high-risk individuals ≥ 11 years of age. Those with:
- functional or anatomic asplenia
 - sickle cell disease
 - terminal complement component deficiency (e.g., C5–C9, properdin, factor H, factor D, and patients taking Eculizumab [Soliris[®]]) AND
 - microbiologists who work routinely with isolates of *Neisseria meningitidis*
- B. University of Oregon outbreak control (expires 6/30/2015): Approved for the following individuals ≥ 11 years of age:
- 1.) University of Oregon undergraduate students.
 - 2.) University of Oregon graduate students, faculty and staff who:
 - a. live in campus residence halls, fraternities, or sororities
 - b. who are at high risk (see above)
 - 3.) Undergraduate students of any college living in the 13th & Olive apartments (Capstone Buildings), including but not limited to undergraduates from the University of Oregon, Lane Community College, and Northwest Christian University
 - 4.) Refer younger children to their private providers
- C. Others may be vaccinated only with a specific physician prescription.

IV. VACCINE SCHEDULE

| Vaccine | Dose and Route: 0.5mL IM | | |
|-----------------------|--------------------------|----------------------|-----------------|
| | DOSE | MINIMUM SPACING | Recommended Age |
| Bexsero ^{®1} | 1 | | ≥11years |
| | 2 | 1 month after dose 1 | |

| Vaccine | Dose and Route: 0.5mL IM | | |
|------------------------|--------------------------|-----------------------|-----------------|
| | DOSE | MINIMUM SPACING | Recommended Age |
| Trumenba ^{™2} | 1 | | ≥11 years |
| | 2 | 2 months after dose 1 | |
| | 3 | 4 months after dose 2 | |

V. CONTRAINDICATIONS

Hypersensitivity, including severe allergic reaction, to any component of the vaccine, or after a previous dose of either Bexsero[®] or Trumenba^{™1, 2}

VI. A. PRECAUTIONS

Bexsero^{®1}:

- Individuals with altered immunocompetence may have reduced immune responses.
- Syncope can occur in association with administration. Ensure that procedures are in place to avoid injury from falling.
- Tip caps of the pre-filled syringes contain natural rubber latex.
- Use in pregnancy only if clearly indicated. Pregnancy registry: 1-877-683-4732
- Use with caution in nursing mothers.

VI. B. PRECAUTIONS

Trumenba^{™2}:

- Individuals with altered immunocompetence may have reduced immune responses.
- Use in pregnancy only if clearly indicated.
- Use with caution in nursing mothers.

VII. A. SIDE EFFECTS AND ADVERSE REACTIONS: BEXSERO[®] ¹

| Study Number: NCT01272180 | | | | |
|--|--------------------|--------------------|--------------------|---------------------|
| Number followed for Safety | N =110–114 | N=94–96 | N=107–109 | N=90–92 |
| Any adverse reactions after dose 1 or dose 2 of Bexsero [®] | Adverse Reaction % | Adverse Reaction % | Adverse Reaction % | Adverse Reaction % |
| Age in Years | 10–25 years | 10–25 years | 10–25 years | 10–25 years |
| | Dose 1 | Placebo | Dose 2 | Menveo [®] |
| Local Reaction, Injection site | | | | |
| Pain | 90 | 27 | 83 | 43 |
| Redness | 50 | 13 | 45 | 26 |
| Swelling | 32 | 10 | 28 | 23 |
| Rash | | | | |
| Systemic Complaints | | | | |
| Irritability | | | | |
| Fever 38.0–38.9°C | 1 | 1 | 4 | 0 |
| Alteration in appetite | | | | |
| Alteration in sleep | | | | |
| Tiredness | 37 | 22 | 35 | 20 |
| Headache | 33 | 20 | 34 | 23 |
| Muscle pain | 49 | 26 | 48 | 25 |
| Joint pain | 13 | 4 | 16 | 4 |
| Nausea | 19 | 4 | 18 | 4 |

- Bexsero[®] was used for the outbreak at Princeton University and the University of California at Santa Barbara in 2014 for individuals 16–65 years of age (N=15,351). Overall, 50 individuals (0.3%) reported serious adverse events, including one case of anaphylaxis within 30 minutes of vaccination.¹
- Blisters at or around the injection site, rash, and eye swelling were reported from post-marketing experience outside of the United States.¹

VII. B. SIDE EFFECTS AND ADVERSE REACTIONS: TRUMENBA™ 2

| Any adverse reactions after dose 1, 2 or dose 3 of Trumenba™ | | | | | | |
|--|--------------------------|-----------------------|-----------------------|-----------------------|-----------------------|-----------------------|
| Study Number: NCT01461993 | | | | | | |
| Number followed for Safety | N =1970 | N=1826 | N=1688 | N=496 | N=468 | N=438 |
| | Adverse Reaction % | Adverse Reaction % | Adverse Reaction % | Adverse Reaction % | Adverse Reaction % | Adverse Reaction % |
| Age in Years | 11- <18 years | 11- <18 years | 11- <18 years | 11- <18 years | 11- <18 years | 11- <18 years |
| | Dose 1 | Dose 2 | Dose 3 | Saline 1 | Saline 2 | Saline 3 |
| Local Reaction, Injection site | | | | | | |
| Pain | 92.8 | 86.1 | 84.5 | 36.9 | 29.1 | 23.3 |
| Redness | 20.4 | 14.9 | 15.8 | 1.2 | 1.7 | 1.1 |
| Swelling | 21.6 | 18.2 | 20.1 | 2.8 | 2.8 | 1.8 |
| Systemic Complaints | Trumenba + Saline | | | | | |
| Use of antipyretic | 27 | 17.5 | 17 | | | |
| Fever ≥38.0°C | 6.4 | 1.3 | 1.1 | | | |
| Tiredness | 62.4 | 44.8 | 42.9 | | | |
| Headache | 54.8 | 40.8 | 34.8 | | | |
| Muscle pain | 42.4 | 30.5 | 30.9 | | | |
| Joint pain | 21.6 | 15.4 | 17 | | | |
| Vomiting | 7.4 | 2.4 | 2.5 | | | |
| Diarrhea | 15.2 | 9.3 | 8.9 | | | |

VIII. STORAGE AND HANDLING^{1, 2}

| | | | |
|-----------------------------|--|--|---------------------------|
| Bexsero[®] | Store at 2°–8°C | Discard if vaccine has been frozen Do not use after expiration date | Protect from light |
| Trumenba[™] | Store at 2°–8°C (May arrive at 2°–25°C) | Discard if vaccine has been frozen Do not use after expiration date | Store flat (horizontally) |

IX. ADVERSE EVENTS REPORTING

Adverse events

following immunization must be reported to the Vaccine Adverse Events Reporting System (VAERS). The VAERS online report form is available at vaers.hhs.gov/esub/step1. In addition, a copy of the reporting form should be reported to the patient's primary provider, per Oregon Revised Statute (ORS) 855-019-0280(4).³

REFERENCES

1. Bexsero[®] (2015) package insert, available at www.fda.gov/downloads/BiologicsBloodVaccines/Vaccines/ApprovedProducts/UCM431447.pdf, accessed 10 February 2015.
2. Trumenba[™] (2014) package insert, available at www.fda.gov/downloads/BiologicsBloodVaccines/Vaccines/ApprovedProducts/UCM421139.pdf, accessed 10 February 2015.
3. Oregon Administrative Rule, August 15, 2014. Board of Pharmacy. Division 19. Licensing of pharmacists: 855-019-0270 3(b). Available at: http://arcweb.sos.state.or.us/pages/rules/oars_800/oar_855/855_019.html. Accessed 12 February 2015.

To request this material in an alternative format (e.g., Braille) or to clarify any part of the above order, contact the Oregon Health Authority Immunization Program at 971.673.0300 and 711 for TTY. For other questions, consult with the vaccine recipient's primary health care provider or a consulting physician.

Electronic copy of this protocol is available at: 1.usa.gov/PharmacyImmunizationProtocols

