Implementing Memorandums of Understanding (MOU) for Pandemic Preparedness

Between Pharmacy and Public Health – from Concept to Implementation

MEETING REPORT

Sunday, March 6, 2016
Baltimore Hilton – Johnson Room
Baltimore, MD

Program Collaborators:

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Implementing Memorandums of Understanding (MOU) for Pandemic Preparedness between Pharmacy and Public Health – from concept to implementation

Purpose: Expand engagement and utilization of pharmacists within state based vaccination preparedness plans. Through this session we will ***improve preparedness*** for the possibility of future pandemics and support the development and implementation of the model MOU for engagement of pharmacies and public health in pandemic vaccinations.

Collaborators: APhA, ASTHO, CDC, NACDS, and NASPA

Outcome: Development of action plans for state pharmacy associations to assist pharmacies to put in place formal pandemic agreements with their local/state health departments

Objectives: Upon completion of this session attendees will be able to

- Describe the key components of the model MOU between pharmacy and public health for implementing a pandemic preparedness plan
- Identify strategies for addressing challenges and opportunities related to the engagement of pharmacies in pandemic planning and response
- Discuss best practices that state pharmacy and public health organizations have utilized in implementing MOUs and other activities
- Describe an action plan for moving activities related to the MOU forward within their state, as well as strategies and milestones for progress

Agenda:

1: 30 p.m.	**Welcome and Call to Order**
1:40 p.m.	**Overview of MOU** *Kim Martin, ASTHO* *Sam Graitcer, CDC*
2:05 p.m.	**"Perspectives on the MOU and Partnership between Pharmacy and Public Health – What Worked in Our State?" Panel Discussion** *Andi Clark, PharmD, Director of Clinical Services, Rite Aid Corporation* *Dianne E. Malburg, BS Pharm, Chief Operations Officer, Michigan Pharmacists Association* *Jim Myatt, PD, Pharmacy Services Branch Chief, Arkansas Department of Health*
3:15 p.m.	**Break**
3:30 p.m.	**Round-table Discussions: Develop Action Plans for Your State Pharmacy Association**
4:30 p.m.	**Report Out and Next Step Discussions**
5:00 p.m.	**Adjourn**

Meeting Summary

Welcome and Call to Order

Becky Snead, meeting facilitator, introduced the session indicating the general purpose was to expand engagement and utilization of pharmacists and pharmacy-based programs in emergency and preparedness planning and to improve preparedness for the possibility of future pandemics by supporting the development and implementation of the model Memorandum of Understanding (MOU) for engagement of pharmacies and public health in pandemic vaccinations. The stated outcome for the session was to develop action plan frameworks for state pharmacy associations to assist pharmacies in placing formal pandemic agreements with their local/state health departments. This program is just one of many activities to assist communities in preparing for the next pandemic and the increased collaboration and communication between public health and the community of pharmacies/pharmacists. Work conducted in this area could lead to expanded engagement between stakeholders in other public health initiatives.

Overview of MOU

Sam Graitcer, CDC; Kim Martin, ASTHO

Dr. Sam Graitcer, CDC medical epidemiologist and pandemic influenza response program deputy, and Kim Martin, Association of State and Territorial Health Officers (ASTHO), provided an overview of the MOU. Dr. Graitcer reported that most public health programs see coordination with pharmacies as important in emergency planning. Based on a CDC national review, there are significant gaps in state preparedness planning efforts.

Through work conducted to date, several issues have been identified needing further discussion as public health departments and pharmacies negotiate MOU agreements. These issues include:

- Tracking of multiple vaccine doses during a pandemic; how will adjuvants be managed, stored and documented; how to handle patients who don't go to same site/provider for both doses?; documentation and utilization of registries
- Will extra security and/or security procedures be needed
- Reminder systems for patient completion of multi-dose regimens (use of cell phones, etc)

Overall, Dr. Graitcer identified a need for best practices, identification of consistent approaches and allowing flexibility.

ASTHO's Kim Martin reviewed activities facilitated by ASTHO to date and the state public health department experiences. She reviewed pilot work underway with Arkansas, Georgia, and

Tennessee related to the implementation of MOUs. Webinars have been held with partnering health departments, pharmacies and other stakeholders to educate them about the MOU components, the players, and suggested steps for implementation. Engagement of the appropriate stakeholders, partners and expertise is important for successfully advancing progress toward MOU implementation. Each state and provider group will engage their appropriate legal teams, with the understanding that the MOU is a template that can be altered to meet state needs. The challenge is getting the right people to the discussion table. ASTHO and CDC, working with APhA, NACDS and NASPA have shared the MOU with corporate pharmacies, public health, and other pharmacy representatives to stimulate engagement in the process.

"Perspectives on the MOU and Partnership between Pharmacy and Public Health – What Worked in Our State?" Panel Discussion

Andi Clark, PharmD, Director of Clinical Services, Rite Aid Corporation
Dianne E. Malburg, BS Pharm, Chief Operations Officer, Michigan Pharmacists Association
Jim Myatt, PD, Pharmacy Services Branch Chief, Arkansas Department of Health

Andi Clark, PharmD, Director of Clinical Services, Rite Aid Corporate, Dianne Malburg, BS Pharm, COO, Michigan Pharmacists Association and Jim Myatt, PD, Pharmacy Services Branch Chief, Arkansas Department of Health participated in a panel discussion of what worked in their states related to the MOU and a partnerships between pharmacy and public health.

Andi Clark noted that the challenges in forming MOUs were (1) the distribution process; (2) manual response to registries – every state is different; and (3) individual provider agreements. Ms. Clark's wish was that all MOUs be the same. She also noted that a decision needed to be made regarding what data points should be collected. Regarding preparing for conversations with legal departments, Andi Clark stated that it was important to look at the logistical standpoint first; work with state representatives and adhere to governing law; and try to anticipate legal issues.

Andi Clark stated that an account for states of emergency should be available to address the payment challenges. She added that the language of protocols was key to the execution of MOUs and that the needs of the chains should be taken into consideration to ensure better partnerships.

Jim Myatt noted that his state of Arkansas addressed cross border issues through state data sharing. He noted that state pharmacy associations needed the legal department involved first and also the planning board.

Dianne Malburg noted state pharmacy associations could be used to monitor what areas are doing well. The development of MOUs could be looked at as an opportunity to communicate with state pharmacy associations and other organizations before a crisis.

Dianne Malburg pointed out that the state pharmacy associations need to tap into relationships with pharmacies and make them aware of what they can do.

Charlie Thomas, representing the Alabama Pharmacy Association and the retired Director of the Alabama Department of Health Pharmacy Program, noted that in Alabama, the governor declares an emergency and he has complete authority. The state health officer has full control to handle health emergencies. The head of the public health department also works with the board of pharmacy to keep all informed. According to Mr. Thomas, "Alabama pharmacists did a good job following the protocols and there were no complaints from any system." In regards to the issue of payment, he noted the department's social services area found funding so pharmacies could obtain access to dispense needed medications to patients.

Becky Snead suggested that scenario planning be used in preparedness work.

The panel was asked to respond to the following set of questions:

- **Question: What are/were some challenges in incorporating a partnership between pharmacies and public health?**
    - Distribution process
        - During H1N1 pharmacies received vaccine from both public health departments and their distributors sometimes making it challenging to manage vaccine supply.
    - Reporting to the registry
        - It was felt that this has come a long way since 2009. There is some reporting to registries still being done manually and the requirements by states vary and are a challenge to building consistency, especially for providers serving multiple jurisdictions.
    - Individual provider agreements
        - The requirements of these agreements differs between states and it was felt that the challenge is whether a single document can cover a single store or a group of stores. This necessitates and challenges the process for obtaining agreements.

- Challenges for Public Health
    - Health departments have been working extensively with their legal department on MOU. The pilot state health departments have begun meeting with the state pharmacy associations, but because of staff turnover at the state pharmacy associations and health departments maintaining momentum has been challenging. There are existing conflicts with organization priorities that could also impact engagement of the various parties. In addition, there may be individuals or organization entities with conflicting viewpoints. These should be addressed or at least obtain an understanding before having bigger group discussions.

- **Question: How did your state association form a relationship with the public health department?**
    - The Michigan Pharmacists Association has had a contract with the state health department since 2003 that has allowed them to build upon. What has assisted in this process has been the long-term engagement of staff, providing continuity and historical perspective of project participants. One approach Michigan has utilized is that their MOU is focused on "any type of pharmaceutical," which led to expansion of partner collaboration.
    - The state pharmacy association created a list of pharmacies and posted it on a website for use by the health department and others.
    - Participants were encouraged to reach out to health departments and let them know what they can bring to the table, what pharmacies are currently doing, and other pertinent information that demonstrates interest and ability of pharmacies/pharmacists.

- **Question: If you had a wish, how would you make registries easier to access and upload?**
    - Promote consistency between state registries as much as possible and identify point persons on both sides who will work together to resolve issues and work on plan implementation.
    - Think about what data points will be reported during a pandemic and whether they are different or correlated with what the providers are reporting for non-pandemic vaccines.

- **Question: What do you do in planning to address cross-border issues?**
    - Interstate data planning would be ideal. It was mentioned that there is work underway by ASTHO to pilot regional approaches to data exchange and reporting.

- **Question: How have you dealt with reimbursement for VFC programs?**
    - In regards to reimbursement, it was identified that the age of patients for which reimbursement to pharmacists is available varies by state. Some are paying pharmacists for VFC administration, but they are at different reimbursement rates than for physicians. Some of the participants identified low number of pharmacies enrolled in VFC programs and the requirement for keeping VFC stock separate from regular inventory can be challenging. It was also noted that some of the VFC programs only reimburse for administration of vaccine and not supplies. In addition, recognition of pharmacists' ability to administer vaccine beyond influenza is an issue that needs to be addressed.

- **Question: Working through an MOU, how long have you been working on it and are there any resources that you have used?**
    - The amount of time individuals have been working on an MOU varies and the models used or would need to be followed can vary. Depending on the state, the approach to achieve the intended outcome will vary, and a limiting factor will be engagement of the state's legal counsel and public health priorities.
    - Many states (pharmacy associations and health departments) need to be educated about the template.

- **Question: Why is distribution through public health still necessary?**
    - The MOU is a step in the right direction and CDC recognizes the contributions of the private-sector. In terms of the distribution of product through public health, CDC is exploring various models that could be utilized.
    - Driving decisions in this area is whether we will have enough supply. Will there be tiered or restricted supply? And if so, public health departments want to control who gets supply.
    - A description of the Alabama system was provided
        - The Governor declares an emergency and he has complete authority over everything happening in the state; they appoint individuals to take care of all health-related situations related to that emergency. There is an established computer system for ordering by pharmacies (as well as physician's offices and clinics). There had to be an agreement on who they would dispense to, how they distributed them, and a means of reporting back to the public health department. The health department allocated orders and the health department works with the board of pharmacy and state associations.

- **Question: What conversations have you/will you have with legal regarding the MOU?**
    - One of the first things that involved parties do is to look at the MOU from a logistical standpoint first, confirming that they can accomplish it all, before consulting legal counsel. It can be a time consuming issue especially because of proactive measures needed versus having to deal with reactive responses. There are also legal concerns with following state regulations (pharmacy practice law, governing law)

- **Question: If we know these discussions are important to have, how should we track these conversations and discussions?**
    - Already tracking it in Michigan, but many state associations have multiple priorities. Some regions have more challenges than others.
    - Consider providing continuing education courses around the MOU.

- **Question: Tell me about the volunteer registry**
    - Several states have a healthcare provider registry so they can put their name on lists accessible to the state's emergency preparedness coordinators. These providers are pre-certified by the state.
    - How does the medical reserve corp play a role?
        - They have different roles, but are coordinated with what. In some states, volunteers for the states have certain levels of liability.

- **Question: To Kentucky - can you share information about managing the stockpile?**
    - The state pharmacy association has formally contracted with public health to maintain and manage the stockpile of antivirals. These items are tracked in terms of pedigrees. Some of the products came directed through the CDC and the state allocated funds to buy additional stock. The pharmacy association has a 30 hour pharmacist staff position with public health, and they also work closely with their board of pharmacy. This work allows the state to have an operational plan and maintain records of supplies.

- **Question: How do statewide protocols fit into the discussion?**
    - It was suggested that states work ahead of time to get these addressed before a declared emergency. You can always alter a protocol, if needed, but having most issues addressed ahead of time will be beneficial. The pharmacy association, board of pharmacy, public health department and other pertinent entities should be engaged.
    - In many states, the governor's declaration must reference statute in emergency order and discussions with the governor's office beforehand to ensure everything needed will be in place is important.
    - Address how refills will be handled and how pharmacies can best serve patients in need.

        - Some state agreements add “follow CDC protocol/recommendations” etc to ensure providers stay up to date.
        - Some states allow for the health department medical director to sign the statewide protocol.
        - There was some discussion regarding payer restrictions and the need for statute language to eliminate barriers to providers being compensated for providing service.
        - States should also address how individuals who can’t pay for the service and vaccine will receive services and providers to be paid. Does Medicaid pay or these individuals for the service when the vaccine is provided by the government? Are there vouchers that county social workers can provide for non-controlled prescriptions?
            - Is there an electronic mechanism for billing or is it a manual bill back to the health department?

- **Take away messages from panelists**
    - Look at legal first
    - Strong relationship with state pharmacy association
    - Board of Pharmacy involvement
    - Build relationships with board of health and state associations

Round-table Discussions: Develop Action Plans for Your State Pharmacy Association

Reporting out from the roundtable discussions, the primary needs were identified as:

- Legislative flexibility
- Standardize protocols access at state level
- Emergency contact for each state association
- Looking at state association websites
- Educational resources for federal resources
- Communication from CDC and national partners to states regarding resources
- Easier access to license immunization
- If state emergency association is shutdown, who has contact access?
- Government administration challenges
- Wholesale distribution of vaccines
- Interconnectedness of statewide registry
- Information from CDC re what other processes/practice groups are available
- Process to access registries
- Resources at state level/contact
- Churning of personnel

The critical challenges were:

- Lack of intrastate consistencies
- Working with computer vendors for reporting numbers
- Communication between states and emergency providers (email or text)
- Connectivity with state health departments

Additional partners/contacts suggested: pharmacy care associations, software vendors, immunization network, legislators, military and first responders.

- **Midwest Region Table Discussion Report Out**
    - How to build relationship with health department
        - Find leverage, look at what they need and offer it
        - Look at projects they want to get done and help with that
    - Concerning: in state of emergency, suspending pharmacy practice, may be grabbing anyone to administer vaccines
    - In state of emergency, suspending rules vs creating new emergency rules
    - Health department seems to have too many tasks (not a priority)
    - Rural areas: looking at other healthcare professionals (veterinarians, etc)
    - Same platforms for registries for across state borders
    - How to use existing distribution methods instead of through public health
        - Storage concerns
    - Billing for administration (cash vs 3rd party vs health department)
    - Connecting with the right people in department of health and emergency preparedness
    - VFC lots of additional requirements, but limited incentives
    - Adding question about emergency preparedness at time of license renewal
    - Allocation—law enforcement, first responders, etc
    - Funding in providing contact information

    - Needs
        - Legislative flexibility
        - Standardized protocols across state lines (with state associations)
        - Emergency contact at health department
        - Links on state association sites for resources and protocols
        - Educational resources
        - Communication between national partners and states
            - Potential seminars (local) to allow for networking with regional public health representatives
        - Department of health contacts
        - Expanding age range of immunizations (pediatrics)
        - Pharmacy/pharmacists checklists for pursuing an MOU

        - Identifying other entities that may already have similar protocols within the state (chains, physician groups, etc)
    - Challenges
        - Individual practice restrictions
        - Lack of consistency between state response systems
        - Data input challenges (match records with IIS systems)
        - Training to check the IIS
        - Easier access to licensed immunizers of the state
        - Wholesalers
    - Other Contacts
        - Software vendors
        - Primary care associations
        - Physician/prescriber groups
        - Retail associations
        - Hospital associations
        - Medicaid
        - Mental health
        - Governor's associations
        - Insurers
        - Immunization networks
        - Association of Infectious Control and Epidemiology
        - Disaster Management Academy
        - Legislators
        - Military/law enforcement/first responders

- **<u>Northeast Region Table Discussion Report Out</u>**
    - Needs
        - Department of health contacts
        - Easier access to licensed immunizers from board
        - Off site access to information when things shut down
        - Expanding age range of immunizations (pediatrics)
        - Pharmacy/pharmacists checklists for pursuing an MOU
        - Identifying other entities that may already have similar protocols within the state (chains, physician groups, etc)
    - Challenges
        - Government and administration challenges (who is in charge?)
        - Wholesaler participation
        - Participation Checklist
        - Pharmacist Checklist
    - Partners

- Immunization Networks
- Disaster Management Academy
- Legislators

- **Southwest Region Table Discussion Report Out :**
  - Needs and Challenges
    - Interconnectability with state live registries
      - Share across state lines
    - How to increase priority level of this issue
  - Partners
    - Military
    - Local Law enforcement on first responders

- **Southeast Region Table Discussion Report Out:**
  - Needs
    - Information from CDC
      - Above what is being done in their states
    - Access to registry
    - Automation
    - Updated Systems
    - Resources at state level outdated
  - Challenges
    - Changing of Personnel

Report Out and Next Step Discussions

Becky Snead closed the session by acknowledging great discussion and noting that signing the MOU is milestone but just a step in process.

Her closing thoughts were:

- Coordinate with State Health Departments (they have a wealth of knowledge)
- Get a work group together to look at sample laws and checklists
- Facilitate MOU discussions
- Seek grant funding to support this work

SESSION WORKSHEET
Memorandum of Understanding between State and Pharmacy for the Coordination of A Pandemic Influenza Vaccination Campaign in Planning for and Responding to An Influenza Pandemic

http://www.astho.org/Infectious-Disease/Pandemic-Influenza/MOU-State-Pharmacy-Pandemic-Influenza-Vaccination-Campaign/

I. Questions You Should Be Prepared to Address

Responsibility of Pharmacy

By signing this MOU, the Pharmacy and the STATE acknowledge their understanding that Pharmacy is responsible for dispensing, delivering, and administering the influenza vaccine, when notified to do so by the STATE, per established medical protocols or algorithms, in accordance with the directives provided by the State and is expected to sign a Pandemic Vaccine Provider Agreement Form, if and when available and required by CDC.

Pharmacists and other vaccinating personnel employed or contracted by Pharmacy are not required to register and enroll as individual pandemic influenza vaccine providers with STATE. By signing this MOU, Pharmacy pre-registers and enrolls with STATE all pharmacists and other vaccinating personnel of Pharmacy as pandemic vaccine providers. In exchange, Pharmacy will ensure all pharmacists and other vaccinating personnel employed or contracted by Pharmacy:

❑ Are appropriately licensed in the state or otherwise properly authorized to administer or dispense pandemic vaccines and pandemic vaccine constituent products;

❑ Follow guidance on vaccine prioritization and recommendations of CDC's Advisory Committee on Immunization Practices, as adopted by the Centers for Disease Control and Prevention;

💻 Where are pharmacies getting updated information and how can your state pharmacy association assist in getting information to pharmacies?

❑ Properly handle and store the influenza vaccine as directed by the state, Food and Drug Administration (FDA)-approved regulatory requirements and any CDC guidance on storage, handling, and temperature control;

💻 What information can you provide pharmacies to assist them in proper vaccine storage, handling and temperature control?

❑ Use STATE'S immunization information system (IIS), where applicable or available, to document doses administered and assess timing and type of prior pandemic vaccination, if multiple doses are required;

💻 Are pharmacists able to enroll in the state's IIS?

💻 How many pharmacies are currently enrolled and able to access the state's IIS?

💻 What will it take to get pharmacies on boarded?

❑ Mix vaccine antigen and adjuvant at the point of vaccine administration (if needed), and match the vaccine antigen and adjuvant type between vaccine dose one and vaccine dose two (if required); and

❑ Exercise all other necessary skills required by STATE for patients to safely receive the proper and effective pandemic influenza vaccinations.

Responsibility of State

STATE will provide technical assistance, material, information, and resources, as available, to assist Pharmacy in providing the appropriate training and certifications, as required by STATE, for all pharmacists and other vaccinating personnel employed or contracted by Pharmacy in the skills listed above prior to (when feasible) and/or in the event of an influenza pandemic.

❑ What resources do you envision needing from the STATE to support the engagement of pharmacists/pharmacies as part of this MOU?

Pandemic Vaccine Product Allocation

In general, STATE will manage all individual provider orders and make allocations to individual providers on a weekly basis at a minimum (if vaccine is consistently available). For the purposes of ordering and allocating pandemic vaccine in this MOU, Pharmacy company will be considered a single "end-user" in STATE's overall vaccine orders to CDC.

Weekly Allocation to Pharmacy by the State

The Federal government will purchase and procure all pandemic vaccine and STATE will receive a weekly pro-rata allocation of pandemic vaccine from the Federal supply (if vaccine is consistently available). The general understanding is that allocation of pandemic vaccine to the Pharmacy and its individual sites will be based on a number of factors. To ensure equity across providers, the amount of pandemic vaccine allocated to Pharmacy during the first few weeks of vaccination may be based on:

- ✓ Epidemiology of the influenza pandemic
- ✓ Pharmacy capacity, as reported by Pharmacy
- ✓ Pharmacy shall provide STATE with an estimate of the number of pandemic vaccines:
  - 1) that it stores, and
  - 2) that staff can administer per week or day, including the minimum, maximum, and typical numbers of vaccines which can be administered
- ✓ Availability of pandemic vaccine, as allocated to STATE;
- ✓ Location of Pharmacy sites and need for geographic distribution of public access pandemic vaccination points, as determined by the STATE;
- ✓ Capacity of other pandemic vaccine providers and entities to administer pandemic vaccines;
- ✓ Potential need to vary pandemic vaccine provider allocations based on vaccine prioritization guidelines for special populations; and
- ✓ Any other method of allocation as the STATE in its discretion deems most appropriate to best serve public health, in accordance with any Federal guidelines.

Allocations to Pharmacy Stores/ Sites
Pharmacy, their contracted vaccine distributor, or designee will be responsible for allocating pandemic vaccine to individual stores/ sites within STATE's jurisdiction from Pharmacy's weekly allocation of STATE's supply of pandemic vaccine. Pharmacy's authorized representative will work in collaboration with STATE in planning for vaccine allocation to stores.

STATE acknowledges that it intends to share information with Pharmacy authorized representative as needed and authorized under state and federal law, which may include relevant epidemiologic information and information on underserved populations and geographic areas, in order to work in collaboration with the Pharmacy in making decisions about allocations to individual stores/ sites or regions of the STATE.

Pandemic Vaccine Product Secondary Distribution to Pharmacy Sites or Stores
Once the VFC distributor distributes the pandemic vaccine to the Pharmacy's or its distributor's depot, the Pharmacy and its designees, which may include the Pharmacy's existing distributor and/or vaccine wholesalers, are responsible for final distribution of pandemic vaccine to Pharmacy's individual sites and/or stores. Pandemic vaccines allocated to Pharmacy by STATE may not be distributed outside of STATE's jurisdiction, unless authorized by STATE and allowable by federal government. Pharmacy shall disclose to STATE the location of its designated distribution depot(s) for STATE's jurisdiction. The Pharmacy warrants that its distribution network information is proprietary to the Pharmacy and not made publicly available.

❑ What concerns, if any, do you envision with the criteria to determine product allocation to pharmacies in your state and are there additional resources/ tools needed to assist pharmacies in meeting the requirements?

❑ Is the issue of state boundaries / jurisdiction a concern for your state? If yes, how can you address the issue or what are the issues you will need to address?

Tracking of Pandemic Vaccine Distribution and Administration

Vaccine Distribution Data
Under the assumptions that during an influenza pandemic the Federal government directly contracts with vaccine manufacturers to develop, fill, and finish all pandemic vaccine and that the STATE is responsible for receiving and managing vaccine orders and allocation within the STATE, the Pharmacy, through its authorized representative, will share data with STATE on pandemic vaccine distributed, including type of antigen and adjuvant distributed and on hand in inventory by each Pharmacy store address (street, city, state, zip code). The Pharmacy's data on pandemic vaccine distributed will be shared with STATE through electronic spreadsheet via email to STATE's authorized representative at least weekly or as determined by STATE law/policies for the duration of time requested by STATE.

❑ What issues, if any, do you perceive encountering from pharmacies in regards to the sharing of this information required under the MOU?

❑ How can your state pharmacy association assist in the compilation and gathering of this information?

- 💻 Do you have a recommendation for how this might occur? Is there something existing or might be created to facilitate the collection of this data?

- 💻 Other concerns?

Vaccine Administration:
During an influenza pandemic, it is possible that persons of all ages will need multiple doses of pandemic vaccine separated by recommended time intervals in order to mount an appropriate level of immune response to be protected from pandemic virus infection. It may also be possible that adjuvant would be required in each pandemic vaccine dose, with the need to be mixed at the point of administration to patient. Furthermore, it may be possible that only certain types or brands of adjuvant will be approved for use with certain types or brands of pandemic vaccine antigen. Also, many patients will likely receive their first and second pandemic vaccine dose from different providers at different locations. These complexities will make the need for complete and accurate vaccine administration documentation extremely important for patient safety, so that all pandemic vaccine providers are able to access this documentation to correctly assess and therefore correctly match pandemic vaccines and adjuvants between doses in each patient.

❑ What issues, if any, do you perceive encountering from pharmacies in regards to the documentation of the antigen and adjuvant administered to patients?

💻 Where would pharmacists document the vaccine administration? (Pharmacy Record, IIS, both, other?) Do you have a recommendation for how this might occur?

💻 Other concerns?

Assessing Pandemic Vaccination Dose Status at the Point of Vaccine Administration
Pharmacy will ensure that all pharmacists, other vaccinating personnel, and designated personnel employed or contracted by Pharmacy have the resources, training, and equipment to assess the timing and type of prior pandemic vaccine and adjuvant, administered (if multiple vaccine doses are required) for each person presenting to a Pharmacy site or stores for pandemic vaccination. Assessment of prior pandemic vaccination by Pharmacy personnel should preferentially be made through the STATE or jurisdiction's IIS at the point of administration and then by other means, such as through a patient's individual shot card.

❑ What issues, if any, do you perceive encountering from pharmacies in regards to the assessment of patient prior immunization status?

💻 How many pharmacies are enrolled and able to report and access immunization data within the state's IIS?

💻 What steps can you take now to engage and enroll pharmacies as reporters and utilizers of the data contained with the state's IIS?

💻 Is there a need to access IIS data from other states and what needs to be addressed in order to facilitate this data exchange ability?

Submitting Doses Administered Data to STATE IIS
Pharmacy will submit data on pandemic vaccine administered by pharmacists and other vaccinating personnel employed or contracted by Pharmacy to jurisdiction's IIS, where available. This will allow a provider to assess a patient's prior vaccination status with the current pandemic vaccine. This will also allow the STATE to account for use of publicly funded pandemic vaccine.

For both the vaccine antigen and the adjuvant (if required), Pharmacy must ensure administration data is recorded in the patient's STATE's IIS or in a permanent office log, if IIS submission is not feasible. The record needs to include the **patient's name, the date of administration, the site of administration, the vaccine and adjuvant manufacturer, the type and lot number of the vaccine and adjuvant dose, and the name and address of the immunization provider for each individual vaccinated.** The record must be kept for a minimum of three years following vaccination (or longer if specified by state law). Medical records must be made available as requested by the state or local health department to the extent authorized by law. Further, data submitted to IIS must additionally include **all core elements as required for IIS submission for seasonal influenza vaccine administration** as designated by STATE and/or the Association of Immunization Registries of America's (AIRA) core elements (http://www.cdc.gov/vaccines/programs/iis/core-data-elements.html). All data submission will comply with the Health Insurance Portability and Accountability Act (HIPAA), as applicable, and any applicable STATE law.

It is expected that Pharmacy will submit all data on pandemic vaccine administered during the prior week by Pharmacy to STATE's IIS by 8:00 AM each Monday. Consistency in requirements across jurisdictions within the STATE shall be facilitated by the STATE.

❑ What issues, if any, do you perceive encountering from pharmacies in regards to the data submission requests articulated in the MOU?

💻 How much of the requested data do pharmacies currently document and/or report to the IIS or other entity?

💻 What, if any, challenges do you anticipate regarding the stated time frame for submission of vaccine administration data?

💻 Are there other concerns related to the documentation of vaccine administered?

Vaccine Cost and Payment

Under the assumptions that during an influenza pandemic the Federal government directly contracts with vaccine manufacturers to develop, fill, and finish all pandemic vaccine and with other entities for ancillary products, **Pharmacy is prohibited from charging patients, health insurance plans, or other third-party payers for the cost of the vaccine or ancillary supplies provided at no cost to the Pharmacy by the Federal government**. Pharmacy is also prohibited from selling the vaccine and ancillary supplies to other third parties.

Pharmacy will be expected to follow STATE/Federal guidelines for all providers in retrieving, administering and/or disposing of pandemic vaccine. **Pharmacy may charge a fee for the administration of the vaccine to the patient, their health insurance plan, or other third-party payer. The administration fee cannot exceed the regional Medicare vaccination administration fee. If the administration fee is billed to Medicaid, the amount billed cannot exceed the STATE Medicaid administration fee, if one exists.**

Pharmacy is strongly encouraged to administer pandemic vaccines to all customers seeking vaccine in their stores. If the Emergency Prescription Assistance Program (EPAP) is enacted by the Federal government for use during an influenza pandemic, and pandemic influenza vaccine administration is included in that enactment, Pharmacy may utilize the EPAP mechanism, if allowable under Federal law, to obtain vaccine administration fees for vaccine administered to these persons (see reference for EPAP). **Pharmacy acknowledges that it has enrolled with EPAP prior to signing this MOU.**

Neither the STATE nor Pharmacy will charge the other any fee, or be reimbursed for any costs, associated with or related to the performance under this MOU, except as specifically set forth in this MOU.

❑ What issues, if any, do you perceive encountering from pharmacies in regards to vaccine cost and payment articulated in the MOU?

💻 How will you approach health insurance plans or other third-party payers in regards to coverage to pharmacies/pharmacists for the administration of these vaccines?

💻 How can state legislators/regulators assist in ensuring coverage for pharmacist-administered vaccine?

💻 Are there other concerns related to the payment for vaccine administered?

Communications and Additional Activities

The STATE will provide planning and technical assistance to Pharmacy, including but not limited to, use of IIS, fact sheets, electronic newsletters and alerts, CDC guidance, and other requirements, especially if multiple pandemic vaccines doses and adjuvants are required. In addition, the STATE will:

✓ Provide statewide consistent medical screening forms to Pharmacy as guidance in implementing pandemic vaccine administration.

✓ Provide Pharmacy with releasable information regarding the pandemic influenza emergency and response.

✓ Provide timely updates to Pharmacy regarding vaccine allocations and changes in guidance on pandemic vaccine prioritization.

✓ Manage public information activities with regard to the overall health and medical response across STATE and publicly acknowledge Pharmacy as a source for pandemic vaccination.

✓ Provide educational materials, if appropriate, to Pharmacy for the purposes of distributing to all persons during the influenza pandemic, including but not limited to Vaccine Information Statement (VIS), if available, or Emergency Use Authorization (EUA) patient documents, if applicable.

✓ Coordinate with STATE Pharmacy Association and/or Board of Pharmacy in advance of a pandemic to include a representative in the STATE's Incident Command Structure and Emergency Operation Team or other such designated team for the influenza pandemic response.

✓ Coordinate with Pharmacy to retrieve and/or dispose of any unused pandemic vaccine from Pharmacy facilities according to STATE/Federal guidelines.

✓ If available and possible, coordinate with Pharmacy on security personnel to protect pandemic vaccine supply and assist in vaccination process in Pharmacy sites.

The Pharmacy will:

✓ In the absence of an Emergency Use Authorization issued by FDA, Emergency Use Instructions issued by CDC, other Federal action, or STATE *policy/ statute/declaration* waiving or altering vaccination use, age restriction, or other requirements for pharmacists, Pharmacy will ensure that all of its pharmacists administer pandemic vaccines under existing influenza vaccination regulations and authority (protocol, prescription) with/from a licensed health care prescriber or lawful order issued by local or STATE health officer, as applicable in STATE. In addition, Pharmacy will ensure that all pharmacists adhere to any state and CDC-specific guidance or agreements on pandemic vaccine use and administration, which may be issued at the time of an influenza pandemic declaration.

✓ Ensure that all of its personnel licensed to vaccinate during the influenza pandemic adhere to any applicable Emergency Use Authorization or Emergency Use Instructions as well as STATE and CDC recommendations on which populations can receive pandemic vaccinations, including pregnant women.

✓ Coordinate with STATE to ensure statewide consistency with implementation of screening forms, educational material, billing, training, and other Pharmacy activities and requirements.

✓ Document vaccinations administered in State IIS or as required by the STATE (as above).

✓ Conduct medical screening of persons receiving pandemic vaccination, based on guidance provided by STATE, to assure consistency with Federal government guidance.

✓ Coordinate with STATE Pharmacy Association, so that a Pharmacy representative participates on in STATE Pharmacy Association meetings, if applicable.

✓ Provide education materials (e.g. VIS, EUA, or EUI, if applicable) to all persons receiving pandemic vaccination.

✓ Report any pandemic vaccine adverse events following vaccination to the Vaccine Adverse Event Reporting System (1-800-822-7967, http://vaers.hhs.gov/contact.htm

✓ Secure any unused pandemic vaccine until a time when STATE can provide arrangements or directives for retrieval or disposal.

✓ Participate in all planning discussions and exercises with STATE, as requested.

❑ What issues, if any, do you perceive encountering from pharmacies in regards to the above requirements?

💻 Are there additional items or changes that will be needed to this section? If yes, what are they?

💻 What does your state currently have in place for the issuing of declarations and waivers of state laws and regulations that would enable pharmacists to serve all patients in need of vaccination?

💻 If the answer is nothing then what are the steps needed to address the issue?

II. Who Are Your Target Participants In This Process?

STATE AND LOCAL GOVERMENT

State Public Health Department
Lead Contact:
Other State Health Department Participants:
Role:

Local Public Health Department
Lead Contact:
Other Local Health Department Participants:
Role:

State Board of Pharmacy
Lead Contact:
Other Board of Pharmacy Participants:
Role:

STATE PHARMACY ASSOCIATION

Lead Contact:
Other Participants:
Role:

OTHER STATE PHARMACY GROUPS or OTHER ORGANIZATIONS

Organization:
Lead Contact:
Other Participants:
Role:

Organization:
Lead Contact:
Other Participants:
Role:

Organization:
Lead Contact:
Other Participants:
Role:

Organization:
Lead Contact:
Other Participants:
Role:

Action To-Do List

State: Lead:

Activity	State Pharmacy Association / Other Pharmacy Groups in State	State Government (Public Health, Legislature, Board of Pharmacy, other)	RED FLAG
Identify Partners			
Conduct outreach to determine interest in participating in process to achieve outcome of having pharmacies enter into MOU with state ✓ identify entities willing to be first signers			
Host meeting (live or webinar) with interested parties – if needed, conduct one-on-one discussions vs group discussion			
Create a working / steering committee			
Address issue / concerns raised from steering committee members, attorneys and other stakeholders			
Adapt model MOU to your state's needs and agree on allowable modifications to MOU			
Have MOU reviewed by appropriate pharmacy and state decision makers			
Schedule a signing ceremony for the first			

Activity	State Pharmacy Association / Other Pharmacy Groups in State	State Government (Public Health, Legislature, Board of Pharmacy, other)	RED FLAG
set of MOUs signed (obtain press coverage if agreed to by parties)			
Continue to recruit pharmacies to sign MOU through outreach, publications and presentations			

ISSUES TO BE ADDRESSED (select ones that apply to your situation)	State Pharmacy Association / Pharmacy Orgs in State	State Government (Public Health, Legislature, Board of Pharmacy, other)	RED FLAG
Allocation of Vaccine Product			
Distribution of Vaccine Product and Supplies			
Reporting Inventory Data			
Documentation of Vaccine Administration			
Assessment of Vaccination Dose Status			

ISSUES TO BE ADDRESSED (select ones that apply to your situation)	State Pharmacy Association / Pharmacy Orgs in State	State Government (Public Health, Legislature, Board of Pharmacy, other)	RED FLAG
Submitting Doses Administered Data to State IIS			
Vaccine Cost and Payment			
Other:			

Attendee List

Name (First)	Name (Last)	Title	Organization	Email	Have you done any work already in establishing a memorandum of understanding (MOU) between pharmacy and public health related to vaccinations/pandemics?	If yes, what has been done?
Speakers/Facilitators						
Andi	Clark	Director of Clinical Services	Rite Aid	aclark@riteaid.com	Yes	in the beginning stages of reviewing and MOU with the state of TN
Samuel	Graitcer	Pandemic Influenza Vaccine Response Program Deputy	CDC	igc6@cdc.gov	Yes	CDC coordination
Dianne	Malburg	Chief Operations Officer	Michigan Pharmacists Association	dianne@michiganpharmacists.org	Yes	
Kim	Martin	Director, Immunizations	ASTHO	kmartin@astho.org	Yes	
Jim	Myatt	Branch Chief, Pharmacy Services	Arkansas Department of Health	james.myatt@arkansas.gov	No	
Participants						
Anna	Armstrong	Pharmacist	Kroger	mary.armstrong@stores.kroger.com	No	
Elise	Barry	CEO	New Jersey Pharmacists Association	ebarry@njpharma.org	No	
Debra	Billingsley	Executive Director	Oklahoma Pharmacists Association	dbillingsley@opha.com	No	
Micah	Cost	Executive Director	Tennessee Pharmacists Association	micah@tnpharm.org	Yes	H1N1 pandemic and increasing pharmacy use of state's immunization information system.
Joni	Cover	CEO	Nebraska Pharmacists Association	jonicover@gmail.com	Yes	Initial discussions

Natalie	DiPietro Mager	Associate Professor of Pharmacy Practice	Ohio Northern University (But attending on behalf of the Ohio Pharmacists Association)	n-dipietro@onu.edu	No	
Pat	Epple	CEO	PPA	pepple@papharmacists.com	No	
Kathy	Febraio	Executive Director	PSSNY	kathy.febraio@pssny.org	No	
Kelly	Fine	CEO	AzPA	kelly@azpharmacy.org	No	
Ron	Fitzwater	CEO	Missouri Pharmacy Association	ron@morx.com	No	
Ouita	Gatton	Patient Care Coordinator	Kroger	ouita.gatton@kroger.com	No	
Betty	Harris	President-elect	Maine Pharmacy Association	beejpharm@gmail.com	No	
Mike	Larkin	Executive Director	Kansas Pharmacists Association	mike@ksrx.org	No	
Bob	McFalls	Executive Director	Kentucky Pharmacists Association	rmcfalls@kphanet.org	Yes	Contracted Partnership between KDPH and KPhA.
Marsha	Millonig	Interim Executive Director	Minnesota Pharmacists Association	mmillonig@catalystenterprises.net	No	
Tim	Musselman	Executive Director	Virginia Pharmacists Association	Tim@virginiapharmacists.org	No	
Anthony	Pudlo	Vice President, Professional Affairs	Iowa Pharmacy Association	apudlo@iarx.org	No	
Garth	Reynolds	Executive Director	Illinois Pharmacists Association	greynolds@ipha.org	No	
Jon	Roth	Chief Executive Officer	California Pharmacists Association	jroth@cpha.com	No	
Sarah	Sorum	Vice President, Professional & Educational Affairs	Pharmacy Society of Wisconsin	sarahs@pswi.org	No	

Steve	Stewart	Clinical Field Coordinator (Pharmacist)	Fred's	sstewart@fredsinc.com	No	
Kristyn	Williamson	Pharmacy Resident	Virginia Commonwealth University	williamsonkm@mymail.vcu.edu	No	
Additional Participants						
Irene	Croswell	Adjunct Faculty/APhA/OSPA Liaison	Pacific University Oregon / School of Pharmacy	lcroswell@pacificu.edu		
Aliyah	Horton	Executive Director	Maryland Pharmacists Association	aliyah.horton@mdpha.com		
William	Wynn	Experiential Education Coordinator & Assistant Professor	South University	wwynn@southuniversity.edu		
Don Becky Mitch Susan Sara	Smith Snead Rothholz Katz Roszak	Government Relations Manager Facilitator Director, Research	Pennsylvania Pharmacists Association NASPA APhA APhA National Association of Chain Drug Stores	dsmith@papharmacists.com sroszak@nacds.org	No Yes	 working with our members

Attendee Post Session Survey Results:

Implementing MOU for Pandemic Preparedness between Pharmacy and Public Health

Answer Options	Agree	Disagree	Rating Average	Response Count
1. The stated learning objectives were covered in the MOU Session.	11	1	3.75	12
2. The content of the session was appropriate and informative.	11	0	4.00	11
3. The information presented provided new ideas or information that I expect to use.	11	0	4.00	11
4. Overall, speakers were knowledgeable and information was presented clearly.	11	0	4.00	11
			answered question	12
			skipped question	0

Educational Experience				
Answer Options	**Agree**	**Disagree**	**Rating Average**	**Response Count**
1. The session format (i.e., full group activities/small group activities, didactic/discussion-based) provided for optimal learning.	12	0	4.00	12
2. I felt comfortable asking questions to the panelists.	11	0	4.00	11
3. The session met my expectations.	10	1	3.73	11
			answered question	12
			skipped question	0

Question: What session(s) were most valuable to you? Why?

Answered Question:

Skipped Question:

Responses:

- **Learning about the need for preparedness**
- **Needed both panel discussions and breakout discussions to engage us as participants.**
- **The panel discussion.**
- **Hearing what other associations were doing to get ideas of how we might improve in our state.**
- **The overview from CDC - gave great context and information**
- **I enjoyed the questions we were able to ask the panelists.**
- **This was quite a bit of new information for me so all was greatly appreciated**
- **Feedback session at the end**
- **Q/A**

Question: What session(s) was least valuable to you? Why?

Answered Question: 9
Skipped Question: 3
Responses:

- **They were all good**
- **For those who have not worked with emergency preparedness planning, I think more background information would have been helpful.**
- **All were valuable.**
- **The public health official information because we have a great relationship already in our state.**
- **None - all were valuable**
- **None.**
- **None**
- **All sessions were good**
- **None**

Question: What information did you learn from the round table discussion?

Answered Question: 9
Skipped Question: 3
Responses:

- **Could not attend**
- **Activities that various state pharmacy associations are doing/thinking about doing.**
- **Ideas that other states incorporate in their discussions with health departments for MOU implementation.**
- **Additional areas for collaboration.**
- **Insights into logistical challenges at each state level**
- **Had to leave early**
- **Unable to participate**
- **Need for more engagement from state Medicaid directors and AHIPs**
- **Importance of involving Pharmacy Boards**

Question: Do you have an action plan for moving activities related to the MOU within your state? If not, did the session help you to develop an action plan?

Answered Question: 7
Skipped Question: 5
Responses:

- **We are working on one**
- **We are already doing this in Kentucky.**
- **Yes**
- **Yes**
- **Not sure if we already had an action plan (I was representing an organization that I volunteer for**

but am not in charge of) Yes, information shared in the session will be helpful

- **Yes**
- **CDC level- n/a**

Question: Did you leave the session with a take away message that will improve collaboration between the pharmacy and public health?

Answered Question: 6
Skipped Question: 6
Responses:

- **Yes**
- **I think the session was well planned to allow for a take away message, but we already have MOUs in place.**
- **Yes**
- **No, it was overwhelming to think of so many things that need to be addressed**
- **Yes**
- **Yes, need improved ability to track progress and refine contents of toolkit**

Question: Did the session help you to understand the resources available to help accelerate the time it takes to execute a MOU?

Answered Question: 6
Skipped Question: 6
Responses:

- **Yes**
- **Yes**
- **Yes**
- **Some, but not all**
- **Yes**
- **Yes**

Question: What unanswered question(s) do you have from the MOU Session?

Answered Question: 6
Skipped Question: 6
Responses:

- **None**
- **None**
- **How to improve pharmacist engagement in MOU particularly corporate chains.**
- **More on the practical implementation**
- **None**
- **How to better coordinate with state Medicaid groups**

Question: Please provide any additional feedback here.

Answered: 2
Skipped: 10
Responses:

- **Great session, well facilitated - just a complicated issue!**
- **Great job facilitating**