



Pharmacy Legal Toolkit

Guidance And Templates For State And Territorial Health Agencies When Establishing Effective Partnerships With Pharmacies During Routine And Pandemic Influenza Seasons



Introduction

Public health experts believe that broadening the number of eligible health professionals who can administer vaccine will further reduce the burden of flu in both seasonal and pandemic situations. In recent years, there has been a widespread effort on behalf of pharmacists to offer vaccination services at pharmacies throughout the United States, and pharmacists are being recognized as valued members within the immunization neighborhood. With more than 59,000 community pharmacy outlets in the United States, including chain drug stores, mass merchants, supermarkets, and independent drug stores, pharmacies offer convenience, accessibility, and extended hours for a wide population seeking vaccine.¹ The increased accessibility has had a dramatic effect on the number of adults seeking vaccination services at pharmacies, which has risen from 4 percent from 1998-99 to more than 18 percent from 2010-11.²

According to the American Pharmacists Association (APhA), the number of pharmacists trained to administer vaccines has increased from 40,000 in 2007 to more than 200,000 in 2013.³ However, state and territorial health departments, pharmacists, and physicians face legal barriers that continue to hinder the expansion and inclusion of pharmacist vaccinators.

The Pharmacy Legal Toolkit is intended to provide guidance and templates for state and territorial health agencies on establishing effective partnerships with pharmacies during routine and pandemic influenza seasons. None of the information contained in this document should be considered legal advice. Health agencies are encouraged to consult with their legal counsel prior to forming partnerships.

Identifying the Legal Issues

The Association of State and Territorial Health Officials (ASTHO) reached out to public health partners to further define the perceived legal barriers for pharmacy vaccinators and help determine potential tools that could address them. Through this process, a total of 34 immunization representatives from pharmacies, state health agencies, and associations were surveyed to determine perceived legal barriers during routine seasonal influenza vaccination efforts. The results of this survey indicate that barriers continue to hinder the process by which pharmacists can successfully administer vaccines to the public.

Variances in State Law

Although vaccine administration is regulated by federal and state governments, most legal issues related to pharmacists as vaccinators are state matters. All states allow pharmacists to administer influenza vaccine to adults as defined by state statutes (i.e., not all states define an adult as someone 18 years or over), but for other kinds of vaccinations, laws vary by state. For example, some states do not allow pharmacists to administer other vaccines or they limit the age to which pharmacists are allowed to administer vaccine. Some states require a prescription from the provider. Others require a protocol supported by a private physician, public health official, or state-provided guidance that describes the scope and procedures for pharmacists administering vaccines, similar to the process followed by nurse practitioners and physician assistants. The state-by-state patchwork of regulation alone is a barrier. APhA and the National Alliance of State Pharmacy Associations (NASPA) track the current state laws regarding the types of vaccine that pharmacists are authorized to administer, and that information is available on the APhA (<http://www.medscape.com/viewarticle/819981>) website.

Compensation

Barriers to compensation for adult flu vaccine are complex because each state has multiple ways to compensate pharmacists: Medicare, Medicaid, private insurance, and self-pay. Most barriers are the result of payers failing to recognize pharmacists as vaccinators. Survey respondents indicated that pharmacists are usually paid under pharmaceutical—not medical—benefits, and because many payers reimburse vaccinations as a medical benefit, this may leave some pharmacists with lower reimbursement rates. In addition, other impacts of these barriers identified by survey respondents include requiring patients to self-pay and then submit

Survey Results: Perceived Legal Barriers for Pharmacy Vaccinators During Routine Vaccinations for Seasonal Influenza

- Variations in State Laws
- Compensation
- Standing Orders
- Immunization Information Systems
- Liability
- Scope of Practice

(*In order of respondent frequency.)

paper claims, situations in which parallel contractual arrangements with insurers must be specifically developed for vaccine reimbursement, discrepancies in payer reimbursement levels, or pharmacists not being recognized as providers under federal and state immunization programs.

Medicare, Medicaid, and the Children’s Health Insurance Program (CHIP) billing can be complex and the process requirements may vary from state to state. States have the flexibility to choose whether to cover vaccinations for adults through their Medicaid programs, and they also decide on the providers who are recognized within their networks.

Medicare has paid for influenza virus vaccines and their administration since 1993.⁵ Under federal law, any individual or entity, such as a pharmacist or pharmacy meeting state licensure and training requirements, may qualify to have payment made for furnishing and administering the influenza virus and pneumococcal vaccine.⁶ A physician order (written or verbal), plan of care, or any other form of physician approval is not required for Medicare coverage. Again, however, individual state law may require a physician order or other physician involvement.

Medicare generally poses fewer barriers to compensation because duly licensed pharmacies and pharmacists may register as “mass immunizers” and be reimbursed for most vaccines and administration costs. Some vaccines, however, are not eligible to be reimbursed for mass immunizers.

The Medicare Part B deductible and coinsurance do not apply to vaccines.⁷ Note that the administration of the influenza virus and pneumococcal vaccine is a Part-B-covered service only. Additionally, Medicare is considered the primary payer for influenza virus vaccination; no other beneficiary insurance need be billed. Some vaccines are covered under Medicare Part D programs such as the shingles vaccine, combined tetanus, diphtheria, and pertussis vaccines (Tdap), and others.⁸



Legal Authority

States may separate pharmacists’ authority to prescribe and their authority to administer flu vaccines. In a few states, pharmacists have the authority to directly administer flu vaccines without a prescription, so they do not need to rely on another provider for a prescription or a protocol. However, a majority of states require pharmacists to obtain some form of formal permission to administer flu vaccines to adults. The formal permission required can be:

- ✓ A patient-specific prescription.
- ✓ A population-applicable vaccine protocol or standing order issued by either a private provider (such as a doctor or advanced practice nurse in private practice) or a public provider (such as a health department medical director).
- ✓ A combination of both.

The use of any of these mechanisms may occur under a formal agreement between a pharmacist and an authorized provider, generally a physician. For immunizations, these agreements may be called a protocol, standing order, or collaborative practice agreement (CPA). The concepts for these authorities are similar to those used for nurses and physician assistants.

According to APhA, approximately 89 percent of pharmacies have a vaccine protocol with a physician (corporate, family medicine, internal medicine, pediatric, or emergency room physician) and 8 percent have an agreement with a public health department.⁹ State and territorial health officials should seek advice from their legal counsel before entering into a vaccine protocol agreement with a pharmacist or pharmacy. In some instances, it is prohibitive for a state or territorial health official to enter into a vaccine protocol agreement.

In our survey of stakeholders, respondents suggested that incorporating assurance measures, such as vaccination training and reporting, into the protocol could enhance accountability. Survey respondents also suggested that giving pharmacists the authority to administer vaccine under their own license, versus having to attain it through an authorizing physician, could reduce barriers to participation and enhance access.

COMPONENTS OF A VACCINE PROTOCOL

- Identify an individual(s) who has delegated activity.
- Identify pharmacist(s) authorized to administer vaccine.
- Determine types of vaccines pharmacist is authorized to administer.
- Define procedures, decision criteria, or the plan that a pharmacist should follow, including when to refer patient.
- Identify procedure for emergency situations.
- State record keeping and documentation procedures.

Immunization Information System (IIS)

State immunization information systems (IIS) track the vaccination status of patients who may be mobile and unknown to new providers. They also provide health officials with population-based vaccination data for epidemiologic planning and response purposes. All but one state have an immunization registry. However, pharmacists' access to the registries may be limited by law or circumstance. For example, sometimes pharmacists' employers restrict Internet access or impose technical limitations, or some states may preclude pharmacy technicians from entering immunization information, which slows pharmacists' work. A survey by the American Immunization Registry Association (AIRA), revealed that of the 45 project areas responding, pharmacies reported doses administered to the IIS in 36 (80%) jurisdictions and are required to report in 22 (49%).¹⁰

In addition, there is variation between state IIS data reporting elements, which has been raised as a challenge for national pharmacy chains that would prefer one system or a standardized minimum dataset for all state reporting. Although CDC generates functional standards (<http://www.cdc.gov/vaccines/programs/iis/func-stds.html#appB>) with recommended core data elements (<http://www.cdc.gov/vaccines/programs/iis/core-data-elements.html>) to which state IIS's must adhere, individual states often will require more information than the basic standards, which can make it challenging for a national pharmacy chain to conform to each state data set requirement. There is also variation of data transmission standards, which can create additional difficulties.



Liability

In our survey of stakeholders, respondents stated that most pharmacists are protected by their company's liability or routine malpractice coverage if their activities fall within the scope of practice. Individual pharmacists may also have their own malpractice insurance to supplement the coverage provided by their employer.

In the late 1980s, there was an upswing in lawsuits against manufacturers and health professionals that blamed vaccines for a variety of recipient injuries. Consequently, manufacturers decided to cease vaccine production. In response, Congress established the national Vaccine Injury Compensation Program (VICP) (<http://www.hrsa.gov/vaccinecompensation/index.html>), a no-fault alternative to court, to resolve claims and provide compensation to people found to be injured by certain vaccines. People allegedly injured by influenza vaccine are eligible for VICP. A person contending they were injured by a VICP-covered vaccine must first seek redress through the program. Providers cannot be sued while the plaintiff is seeking redress under VICP and, if the plaintiff accepts an award under VICP, they cannot later bring a suit in tort for malpractice.

Health professionals are not always familiar with VICP, and it is helpful for public health officials to periodically remind professional communities of the blanket protection that VICP offers. To be protected, providers must give the patient a current copy of the Vaccine Information Statements (VIS) (<http://www.cdc.gov/vaccines/hcp/vis/index.html>), before vaccinating them, record specific information about the patient and the vaccine, and report any adverse events to the Vaccine Adverse Event Reporting System (VAERS). However, even with VICP protection, there is always a risk of lawsuits being brought against health professionals for



injuries thought to be vaccine-related, particularly if professionals allegedly have acted negligently—meaning failed to use reasonable care—or if they failed to properly warn vaccine recipients of potential side effects or vaccine complications. Other grounds for lawsuits may be asserted by plaintiffs. However, providers that follow generally accepted professional standards of care, including providing potential vaccine recipients with adequate information about the benefits and risks through VIS (<http://www.cdc.gov/vaccines/hcp/vis/index.html>), may avoid liability for such claims if the state pharmacy practice act includes flu vaccination and the pharmacist is acting within those guidelines. In addition, professional malpractice and business liability insurance policies almost always provide coverage for vaccine administration as part of routine care.

Physician Liability. The medical field is set up to avoid risks to patients, and it embraces change cautiously, including devolution of services such as vaccination formerly provided exclusively by physicians. Consequently, physicians and other prescribers may be reluctant to issue vaccine protocols to pharmacists due to liability concerns, concerns about siphoning away patients, inadequate compensation, or inertia. When pharmacists administer flu vaccine under a physician’s order—whether it is through a vaccine protocol or prescription—physicians may be concerned that they could be held liable for adverse vaccine outcomes. Physicians may worry about criminal or civil liability or discipline for unprofessional conduct.

Some states explicitly exempt physicians who are in collaborating arrangements with pharmacists from vaccine-related liability. When this is not the case, physician risk is still minimal. If a physician has reviewed a vaccine protocol for accuracy and to ensure it meets standards of care, and if the physician reasonably believes a pharmacist is competent to administer injections (for example, if the pharmacist holds a recognized pharmacist-immunizer training certificate and participates in relevant continuing education programs), the physician will not be held liable should any negligence by the pharmacist occur. Pharmacists, just like other members of the immunization neighborhood, are guided by recommendations and guidelines issued by CDC and recognized medical and pharmacy organizations.



Health officials should confer with their legal counsel prior to establishing vaccine protocols with pharmacies to ensure they are appropriately protected under the state or territorial health agency medical malpractice coverage. Health officials should also note that coverage may be different during emergency situations, such as pandemic influenza vaccination efforts. In addition, as the healthcare system moves toward integrated care models (patient-centered medical homes, ACOs, etc.), a greater number of vaccines will be administered by non-physicians operating under protocols.

Training

Survey respondents noted that the gold-standard American Pharmacists Association training program, which consists of a 20-hour course, has been very successful in training pharmacists about different aspects of vaccine administration. The training program covers vaccinations across the lifespan, even though state authority regarding the types of vaccines and age of patients that pharmacists can vaccinate may vary. Pharmacists completing this training can serve their communities as knowledgeable and accessible resources and providers of immunizations. More than 200,000 pharmacists have completed training.¹¹ Depending on the community needs, pharmacists may need additional training in some areas, such as vaccine administration to certain populations. The national accreditation standards for colleges and pharmacy schools have increased focus on public health in curriculums, particularly regarding pharmacists' role as immunization providers. The profession is reaching the point where all graduating student pharmacists are receiving this training. Thirty-nine states and territories allow trained student interns, under the supervision of a trained immunizing pharmacist, to administer vaccines as well.¹²



Flu Vaccination in Emergencies

As with all preparedness planning, advanced communication is critical. Most applicable state law is specific about seasonal flu, but there is less clarity regarding pandemic influenza. In some states, the same laws can apply in both situations; in others, there are separate provisions for each, often with the pandemic provisions being a subset of general emergency or public health emergency laws. Some states do not have clear law on pandemic flu; when the law is silent or ambiguous, pandemic flu outbreaks are handled on an ad hoc basis.

Our survey revealed that many of the same barriers raised in seasonal flu situations also exist in pandemic conditions. However, there are some issues that are specific to pandemic situations, which are described below.

Liability

In our survey, many respondents reported that they believe that health professionals are concerned about legal liability during emergency situations. However, the federal Public Readiness and Emergency Preparedness Act (PREP Act) (<http://www.phe.gov/Preparedness/legal/prepact/Pages/default.aspx>) provides immunity from tort liability claims to almost all persons and entities formally involved in the administration and use of covered countermeasures, such as influenza vaccine. PREP Act immunity becomes available when the HHS secretary issues a declaration of a public emergency. Acts of willful misconduct by the covered persons are ineligible for immunity. The PREP Act also authorizes HHS to establish a compensation program when a declaration is issued under the act.

Survey Results: Perceived Legal Barriers for Pharmacy Vaccinators During One-time Emergency Situations

- Liability
- Training
- Logistics
- Standing Orders
- Compensation
- Coordination
- Scope of Practice

(*In order of respondent frequency.)

For example, in June 2009, HHS Secretary Sebelius signed a declaration under the PREP Act to extend liability immunity to individuals and entities involved in all stages of 2009 H1N1 influenza vaccine development, testing, manufacture, distribution, prescribing, administration, and use. The covered parties included manufacturers, distributors, states, localities, tribes, and other entities that supervised or administered a vaccination program, and health-care professionals or others authorized under state laws to prescribe, administer, or dispense vaccines when they were carrying out activities in accordance with broad conditions stated in the declaration.

In addition to the PREP Act's extensive protections, many states also provide situation-specific immunity from liability or indemnification. Thus, health professionals serving during a public health emergency have additional state and federal protections against liability for their actions that are unavailable during non-emergency situations. However, many practitioners are not aware of these protections.

Training

An emergency order may overrule limitations under current practice guidelines for pharmacy vaccinators. Survey respondents suggested that this should be better communicated to both pharmacists and healthcare providers because just-in-time training may be needed. However, some state laws restrict the scope of practice waivers that an emergency declaration can authorize.



Logistics

During the 2009 H1N1 influenza outbreak, one logistical issue was that some pharmacies received either an overwhelming supply or negligible allocation of vaccine, and therefore were not able to adequately vaccinate the public. Additionally, shipments of vaccine and ancillary supplies from the government were not synchronized. One lesson from these challenges is that pharmacies may need to adjust staffing patterns to meet increased demand for vaccinations or availability of supplies. Pharmacies may also consider modifying workflow or store layout to meet increased patient demand.

Legal Authority

The failure of vaccine protocols to recognize situations outside the normal scope of seasonal flu activities—such as vaccine administration by pharmacists outside of a licensed pharmacy—can be a barrier if laws are not waived or if there are not laws applicable to emergencies. In this case, vaccinating pharmacists must arrange for an emergency protocol, which can result in delays or unanticipated problems. In some states, protocols may not be readily available during an emergency. In states that require a prescriptive order, legislation may be needed to change this process.

During the 2009 H1N1 influenza response, state health departments worked directly with pharmacists. In general, this process was different than during routine vaccinations when there are vaccine protocols between pharmacists and prescribing authorities. In anticipation of future outbreaks, some health departments are starting to draft model agreements for local health departments to contract directly with pharmacists during emergencies in order to expedite the process once an emergency occurs.

Compensation

Survey respondents indicated that reimbursement for the cost of non-vaccine related supplies can be a barrier to administering vaccine. Additionally, compensation may be further complicated in a public health emergency situation if vaccine is provided without cost or there are situation-specific rules for reimbursement of administration costs.

The Emergency Prescription Assistance Program (EPAP) (<http://www.phe.gov/Preparedness/planning/epap/Pages/pharmacies.aspx>), an HHS-managed program, may minimize this barrier. EPAP provides an efficient way for pharmacies to process claims for prescription medications and limited durable medical equipment provided to individuals in federally-designated disaster areas who do not have any health insurance coverage. Claims for individuals with private insurance, such as an individual health insurance policy or employer-sponsored coverage, public insurance, such as Medicare, Medicaid, or other third party coverage, are ineligible for payment under EPAP.

Scope of Practice

When an emergency rule is made, the state may expand the type of vaccinations that pharmacists can administer or the patient populations to which they may provide them. Thus, the change can create new responsibilities for a pharmacist, and may require training and administrative process revisions.

Another barrier is that states may regulate the ratios of pharmacy technicians to pharmacists. Ratios restricting the number of technicians that pharmacists can supervise may substantially impede their ability to meet an increased demand for immunization services while also performing their usual duties. These ratio impediments should be addressed in rulemaking on emergencies to facilitate increased accessibility of pharmacy-based vaccinations.

Determining the Law that Applies in Your State During Emergency Situations: **Getting Ready**

The 2009 H1N1 influenza outbreak demonstrated that pharmacies can be of great assistance during public health emergencies. During the outbreak, many pharmacies were willing to partner with public health agencies to ensure increased access to vaccination for the public. The best time to build partnerships, update materials, and plan for a public health emergency are during times of regular activity, such as seasonal influenza cycles. Public health agencies should consider reviewing applicable laws and taking the following steps regularly to ensure they are up-to-date in case of a future pandemic:

- ✓ **Communication:** According to APhA's 2013 Annual Immunization Survey, 23 percent of pharmacy practice sites collaborate with their state or local public health department and another 35 percent would like to collaborate.¹³ Thus, it may be beneficial for public health officials to reach out to pharmacists in their states to determine collaborative work practices. In addition, public health officials can have discussions with their legal counsel, state boards of pharmacy or medicine, or other outside governmental counsels that specialize in legal matters for pharmacy vaccinators.
- ✓ **Gather Resources:** Determine resources such as websites, documents, or professional contacts that may be able to assist with legal aspects of vaccination. These may include:
 - State board of pharmacy website.
 - State and local health department or emergency operations department websites.
 - State board of medicine website.
 - State and national professional association websites.
 - Official online databases of state law, if accompanied by explanatory language.
 - Federal government agency websites such as those for HHS, CDC, CMS, FDA, and HRSA.
- ✓ **Update Materials:** Determine if documents such as vaccine protocols or state IIS access procedures are already in place or need to be updated.
- ✓ **Account for Other Scenarios:** During the 2009 H1N1 flu pandemic, the federal government provided vaccine at no charge to states, localities, and healthcare professionals, who could charge for vaccine administration but were prohibited from charging for the vaccine itself. However, future outbreaks may have different arrangements. Pharmacists and providers should consider how they will request, pay for, and be reimbursed for vaccine and other supplies during a flu emergency. They should also consider whether they need to scale up vaccine administration volume, including staffing and space requirements. For all these logistical details, legal considerations related to scope of practice, licensing, payer contracts, health facility regulation, and others may apply.

Tools

Appendix A

Immunization Action Coalition (IAC) Standing Orders

Standing orders are one form of population-based vaccine protocols that authorize nurses, pharmacists, and other healthcare personnel, where allowed by state law, to independently assess a client's immunization status and administer vaccinations according to a protocol approved by a physician or other authorized practitioner. A state may use the following standing order document verbatim or adapt it as needed consistent with state law.

Appendix A

Standing Orders for Administering Seasonal Influenza Vaccine to Adults

Purpose: To reduce morbidity and mortality from seasonal influenza by vaccinating all adults who meet the criteria established by the Centers for Disease Control and Prevention’s Advisory Committee on Immunization Practices.

Policy: Under these standing orders, eligible nurses and other healthcare professionals (e.g., pharmacists), where allowed by state law, may vaccinate patients who meet any of the criteria below.

Procedure:

1. Identify adults with no history of influenza vaccination for the current influenza disease season.
2. Screen all patients for contraindications and precautions to influenza vaccine:
 - a. **Contraindications:** serious reaction (e.g., anaphylaxis) after ingesting eggs or after receiving a previous dose of influenza vaccine or an influenza vaccine component. For a list of vaccine components, go to www.cdc.gov/vaccines/pubs/pinkbook/downloads/appendices/B/excipient-table-2.pdf. Do not give live attenuated influenza vaccine (LAIV; nasal spray) to an adult who is pregnant, is age 50 years or older, or who has chronic pulmonary (including asthma), cardiovascular (excluding hypertension), renal, hepatic, neurologic/neuromuscular, hemotologic, or metabolic (including diabetes) disorders; immunosuppression, including that caused by medications or HIV.
 - b. **Precautions:** moderate or severe acute illness with or without fever; history of Guillain Barré syndrome within 6 weeks of a previous influenza vaccination; for LAIV only, close contact with an immunosuppressed person when the person requires protective isolation, receipt of influenza antivirals (e.g., amantadine, rimantadine, zanamivir, or oseltamivir) within the previous 48 hours or possibility of use within 14 days after vaccination
3. Provide all patients with a copy of the most current federal Vaccine Information Statement (VIS). You must document in the patient’s medical record or office log, the publication date of the VIS and the date it was given to the patient. Provide non-English speaking patients with a copy of the VIS in their native language, if available and preferred; these can be found at www.immunize.org/vis.
4. Administer 0.5 mL of injectable trivalent inactivated influenza vaccine (TIV) IM (22–25g, 1–1½" needle) in the deltoid muscle. (Note: A 5/8" needle may be used for adults weighing less than 130 lbs (<60 kg) for injection in the deltoid muscle *only* if the skin is stretched tight, subcutaneous tissue is not bunched, and the injection is made at a 90 degree angle.) Alternatively, healthy adults younger than age 50 years without contraindications may be given 0.2 mL of intranasal LAIV; 0.1 mL is sprayed into each nostril while the patient is in an upright position.
5. Document each patient’s vaccine administration information and follow up in the following places:
 - a. **Medical chart:** Record the date the vaccine was administered, the manufacturer and lot number, the vaccination site and route, and the name and title of the person administering the vaccine. If vaccine was not given, record the reasons(s) for non-receipt of the vaccine (e.g., medical contraindication, patient refusal).
 - b. **Personal immunization record card:** Record the date of vaccination and the name/location of the administering clinic.
6. Be prepared for management of a medical emergency related to the administration of vaccine by having a written emergency medical protocol available, as well as equipment and medications.
7. Report all adverse reactions to influenza vaccine to the federal Vaccine Adverse Event Reporting System (VAERS) at www.vaers.hhs.gov or (800) 822-7967. VAERS report forms are available at www.vaers.hhs.gov.

This policy and procedure shall remain in effect for all patients of the _____ until rescinded or until _____ (date).
(name of practice or clinic)

Medical Director’s signature: _____ Effective date: _____

Appendix B

Vaccine Protocol

Vaccine protocols may be required by state law or pharmacy board regulation. In some states, vaccine protocols may be called CPAs or collaborative drug therapy agreements, but they also refer to the same type of protocol that helps prevent later misunderstandings about what authority has been delegated from practitioners to pharmacists. A challenge for pharmacists and other practitioners is attaining an authorizing physician.

The following is a generic vaccine protocol form that may be used to document a formal relationship in which a pharmacy or pharmacist work under the licensed prescribing authority of a physician or other health professional to administer flu vaccine. It also includes a non-patient-specific immunization protocol, which could be, if preferred, substituted for the IAC standing orders.

Appendix B

Collaborative Agreement for Immunizations

Collaborative Agreement for Immunizations between _____ pharmacist(s) and
PHARMACY NAME
_____ prescriber (MD/NP/DO)
PRESCRIBER NAME

I, _____ MD/NP/DO licensed in the State of _____, do hereby authorize the pharmacists listed below of _____ Pharmacy to administer influenza vaccine to adults aged _____ and older in accordance with the laws (insert citation) and regulations (insert citation) of the State of _____.

- In exercising this authority the pharmacists shall comply with the recommendations of the Advisory Committee on Immunization Practices (ACIP).
- The pharmacist will document all vaccines administered as required by statute, and on each patient's personal immunization record.
- As the authorizing prescriber I will, on a quarterly basis, be available to review the activities of the pharmacists administering the vaccines.

This authorization will be in effect for two years, unless rescinded earlier in writing to the _____ State Board of Pharmacy by either party. Any significant changes in the protocol must be agreed upon by the participants and submitted to the Board.

Prescriber License Number Date

Pharmacists License Number Date

Pharmacists included in the protocol (may be included on a separate sheet)

Name	License #
_____	_____
_____	_____
_____	_____
_____	_____
_____	_____
_____	_____
_____	_____

Appendix B

Prescriptive Protocol for Immunizations

Knowledge and Skill Base:

Pharmacists will obtain an immunization certificate in accordance with state law, to give them the knowledge and understanding to prescribe vaccinations. Pharmacists will maintain knowledge of current ACIP vaccine policy and recommendations. Current adult CPR certification must be maintained to participate in this Collaborative Agreement.

Patient Screening and Evaluation:

Each patient shall be screened for contraindications. The Immunization Patient Informed Consent Form will be utilized in conjunction with professional judgment and current ACIP Vaccination guidelines to make decisions concerning administration of vaccine. If the pharmacist encounters a patient for whom one of the contraindications or precautions is present, the prescriber must be contacted prior to administration of the vaccine, or the patient must be referred back to the prescriber without the vaccine having been administered.

Emergency Procedures for Adverse Reactions:

An emergency kit containing a blood pressure cuff and stethoscope (or automated cuff), 2 epi-pens or injectable epinephrine (prescribed as part of this protocol), and diphenhydramine orally or injectable will be available to the pharmacist for all immunizations/immunization clinics. Adverse events will be reported as indicated below.

Documentation:

The Informed Consent form will be utilized to record necessary information regarding the vaccine administered and the patient, and kept on file at the pharmacy. Each patient will be given a current influenza VIS form. Moderate and severe events following vaccination will be reported to the Vaccine Adverse Event Reporting System (VAERS) at <http://vaers.hhs.gov/esub/index>, or via fax using a [VAERS form](#) to 1-877-721-0366.

Health Information Sharing:

If the patient has a regular health care provider in the community, the pharmacist may provide the immunization record information to that provider. Otherwise, the pharmacy personnel will provide documentation on the administration of vaccines to primary health providers in the community upon request and consent of the patient. The pharmacist will utilize the State Immunization Registry to document vaccines administered and verify patient eligibility for vaccine administration.

Appendix C

Vaccine Protocol Review Form

State health departments can collaborate with their state boards of pharmacy to generate checklists to guide practitioners in developing collaborative practice agreements and make sure all relevant laws are met. The Washington State Board of Pharmacy (WSBP) provided the example below, which it uses to review vaccine protocols (known in Washington as collaborative drug therapy agreements) between pharmacists and prescribers to ensure all terms required by Washington state law are included. In Washington, WSBP must review and approve vaccine protocols before they are effective.

Appendix C



Washington State Board of Pharmacy

Collaborative Drug Therapy Agreement Review Form

Chapter 246-863-100 WAC

Date: _____

Pharmacist Applicant:
(Attach list if applicable): _____ License #: _____

Pharmacy Name: _____ License #: _____

Practice Site Address: _____

Telephone #: _____ Fax: _____ Email: _____

Name/Type of Agreement: _____

Authorizing Prescriber: _____ License #: _____

	Applicant	Board Staff	Comments
1. Agreement contains signed statement delegating prescriptive authority to pharmacist?			
2. The agreement identifies by name and license number all pharmacists who are party to the agreement?			
3. A time period for the agreement (not to exceed 2 years) is specified?			
4. Did the responsible pharmacist sign the program proposal?			
5. Agreement specifies patients who are eligible to receive services under the agreement?			
6. Delegated prescribing activities are specified (i.e., disease, drugs, categories)?			
7. Does agreement include controlled substances?			
8. The agreement specifies the type of prescriptive authority delegated to the pharmacist (e.g. initiation, continuation, or modification of drug therapy)?			
9. Agreement contains a plan or guideline for making prescribing decisions?			
10. Procedures for documenting prescribing decisions are specified?			
11. Describes a plan for periodic feedback from the authorizing prescriber and other quality assurance activities?			
12. Forms used are provided?			
13. Describes pharmacist training? Specialized training required for Immunizations and Emergency Contraception.			

Comments _____

For Staff Use Only		Agreement Type:
Review completed on _____ by _____		<input type="checkbox"/> New
Staff decision: <input type="checkbox"/> Approved <input type="checkbox"/> Revisions Needed <input type="checkbox"/> Board Agenda		<input type="checkbox"/> Renewal
Board decision: <input type="checkbox"/> Approved <input type="checkbox"/> Denied <input type="checkbox"/> Notice sent to investigator		

Appendix D

Memorandum of Understanding (MOU)

MOUs implement coordinated and standardized protocols statewide, which increase access to pharmacy infrastructure and help address health and medical needs of affected populations during public health emergencies, such as flu outbreaks or pandemics. The advantage of using an MOU is that it provides uniformity and predictability for participating health departments and pharmacies. A disadvantage is that it is less effective if it is not adopted by all local health departments in a state.

The Washington State Department of Health has introduced the following example for use by local health departments and pharmacies around the state. It was created cooperatively by the local and state health departments, pharmacy stakeholders, and legal counsel.

Appendix D

WASHINGTON STATEWIDE PHARMACY-LOCAL HEALTH JURISDICTION MEMORANDUM OF UNDERSTANDING

This Washington Statewide Pharmacy-Local Health Jurisdiction Memorandum of Understanding (“MOU”) is made and entered into by the signatory Health Department or signatory Health District, or signatory County within the State of Washington that operates a public health department or division within its county government, (“Local Health Jurisdiction” or “LHJ”) and each signatory pharmacy entity licensed in the State of Washington (“Pharmacy”), individually, and with all other signatory LHJs and signatory Pharmacies.

ARTICLE I

PURPOSE

The purpose of this MOU is to utilize existing Pharmacy infrastructure to assist in addressing health and medical needs of an affected population during a Public Health Incident, Emergency or Disaster (“Incident”), using coordinated and standardized protocols statewide. The Washington State Department of Health (“DOH”) supports the development of this MOU.

ARTICLE II

DEFINITIONS

Local Health Jurisdiction: A signatory health department, health district, or county within the State of Washington that operates a public health department or division within its county government, pursuant to authority granted under Chapters 70.05, 70.08, 70.46 RCW or other applicable law. Each signatory party shall designate a representative for purposes of accepting requests for assistance and notice.

Pharmacy: A signatory to this MOU who meets the definition of a pharmacy as that term is defined in RCW 18.64.011.

Plan: a written Operation Plan or procedure developed pursuant to this MOU.

Public Health Incident, Emergency, or Disaster (“Incident”): Any occurrence, or threat thereof, whether natural or caused by man, in war or in peace, to which an LHJ may respond pursuant to its authority under chapter 70.05, 70.08 or 70.46 RCW, or other applicable law, and that, in the judgment of the LHJ, results or may result in circumstances sufficient to exceed the day to day operational capabilities of immediate local or regional public health response.

ARTICLE III

PARTICIPATION

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

ARTICLE IV

HOW TO INVOKE ASSISTANCE

An LHJ may request assistance of a Pharmacy by contacting the designated representative of that Pharmacy. The provisions of this MOU shall only apply to requests for assistance made by and to such designees. Requests may be verbal or in writing. If verbal, the request shall be confirmed in writing as soon as possible to the extent practical. LHJs intend to activate community-wide mass vaccination and dispensing plans, to include delivery of medications by Pharmacy with Pharmacy's agreement, only (a) after a declaration of "Public Health Emergency" made by the Secretary of the Department of Health and Human Services under the Public Readiness and Emergency Preparedness Act (PREP Act), 42 U.S.C.A. §247d-6d, or (b) a locally or state declared emergency, under chapter 38.52 RCW, requiring a public health and medical response, or (c) the issuance of an event mission number by the Emergency Management Division of the State Military Department for a public health and medical response.

ARTICLE V

EFFECT OF DECLARATION OF EMERGENCY

The LHJs 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.

ARTICLE VI

RESPONSIBILITIES OF LOCAL HEALTH JURISDICTIONS

Local Health Jurisdictions responsibilities includes:

- Coordinate with DOH and/or signatory pharmacies to ensure statewide consistency with screening forms, tracking, training and other Pharmacy requirements if applicable.
- Provide planning and technical assistance to Pharmacy, including but not limited to, supply lists, fact sheets, dispensing algorithms, and applicable requirements
- Provide statewide consistent medical screening forms to Pharmacy as a guidance for implementing dispensing operations
- Provide technical assistance and training, as mutually agreed upon by LHJ and Pharmacy
- Activate community-wide mass vaccination and dispensing plans as necessary
- Notify Pharmacy that community dispensing plans should be implemented
- Request appropriate amounts and type of medication or vaccine, and available supplies, from local, state or federal sources, including use of SNS resources
- Facilitate a discussion with Pharmacy regarding the most appropriate locations for distribution
- Request DOH to deliver, or have delivered medications to distribution centers as determined by the local health jurisdiction in consultation with the DOH and Pharmacy
- Provide Pharmacy with statewide consistent medical protocols regarding the Pharmacy's response including, but not limited to, dosing and follow-up procedures
- Provide Pharmacy with releasable information regarding the public health emergency situation
- Manage public information activities with regard to the overall health and medical response across the LHJ's jurisdiction
- Provide educational materials, if appropriate, to Pharmacy for the purposes of distributing to all persons in emergencies impacting the public's health
- Make arrangements to retrieve or dispose of any unused medications from Pharmacy facilities and collect documentation forms in coordination with DOH
- Provide guidance and criteria to Pharmacy for tracking levels of activity, supplies and inventory, as applicable to the response and consistent across signatory LHJ jurisdictions

If no statewide mission number has been issued by the State Emergency Management Division, Pharmacy and Local Health Jurisdiction agree that prior to invoking this Agreement during emergencies, Local Health Jurisdiction, through the local department of emergency management, will request the issuance of a mission number from the Washington Military Department, Emergency Management Division.

ARTICLE VII

RESPONSIBILITIES OF PHARMACIES

Pharmacies' responsibilities include:

- Coordinate with DOH and/or signatory LHJs to insure statewide consistency with screening forms, tracking, training, and other Pharmacy requirements
- Comply with Pharmacy standards in effect during the Incident
- Identify the approximate number of medication doses that could be administered by Pharmacy in a specified time period and communicate that information to the LHJ
- Identify Pharmacy sites to receive medication deliveries and communicate site locations to the LHJ
- Communicate to LHJs each site location's scope of Pharmacy practice regarding affected populations, e.g., convey age or prescriptive authority limitations
- Receive and store medication deliveries, consistent with federal, state or local government requirements, at Pharmacy-identified facilities during Incidents
- Ensure that Pharmacy site locations serve the general public
- At Pharmacy's discretion, ensure that its own employees, including those employed by its parent company, and their families, are cared for consistent with public health recommendations
- Conduct medical screening of individuals receiving medications, based on guidance provided by LHJ, to identify potential contraindications and complications, and assure dispensing and administration consistent with federal, state and local government requirements
- In the absence of the issuance of an emergency use authorization, or a declared emergency triggering RCW 38.52.180 (6) waiving license requirements for registered emergency workers, prescribe and dispense medications under a collaborative agreement with a licensed health care prescriber or lawful health order issued by a local health officer
- Maintain accurate records of medications dispensed, administered, and remaining inventory
- 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
- Track contact information of individuals receiving medications
- Communicate information regarding medications dispensed, administered, and contact information to local health jurisdiction as required by local health jurisdiction
- Provide education materials, supplied by local health jurisdiction to all individuals receiving medications
- Secure any unused medications until a time when LHJ can make arrangements for retrieval or disposal

Appendix D

- Participate, as appropriate, in LHJ-sponsored mass vaccination or medication dispensing or administration training and exercises
- Register and maintain qualifications of all Pharmacy personnel working under this Agreement as Emergency Workers within the Local Health Jurisdiction pursuant to Chapters 38.52 RCW et seq., Chapters 118-04 WAC et seq., and any other applicable statute, regulation or law in order to obtain immunity from liability and the benefits of workers compensation protection to the extent allowed by law.

ARTICLE VIII

COST AND PAYMENT

Local Health Jurisdiction shall provide the medications that are to be dispensed or administered by Pharmacy as specified in this Agreement 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 the lesser of that reimbursed by the Medicare Part D schedule, or 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.

All other costs incurred by either Local Health Jurisdiction or Pharmacy through implementation of this Agreement shall be borne by each respective agency.

ARTICLE IX

IMMUNITY, INDEMNIFICATIONS 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 chapter 38.52 RCW or after the issuance of an event mission number by the Emergency Management Division of the Military Department, immunity and indemnification are provided under RCW 38.52.180 for activities within the scope of assigned responsibilities and under the direction of the local emergency management organization. Immunity and indemnification 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.

Appendix D

The Parties agree to assert immunity as applicable to any action against one or more of them. The Parties acknowledge that the indemnification and defense provisions herein do not abrogate any statutory immunity.

If this Agreement has been triggered in circumstances when there is not a federal public health emergency declaration or issuance of a state event mission number, or to the extent immunity and indemnification under 42 U.S.C.A. §247d-6d or RCW 38.52.180 are determined by a court of general jurisdiction in the State of Washington to be inapplicable, 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, and agrees to save, indemnify, defend and hold other parties harmless from any such tort liability. In the case of a determination of negligence or wrongful acts by the Local Health Jurisdiction and one or more Pharmacy, any damages allowed shall be levied in proportion to the percentage of fault attributable to each party, and each party shall have the right to seek contribution from the other parties.

Notwithstanding anything to the contrary in this Agreement, once the Local Health Jurisdiction has delivered the inventory to the Pharmacy, the LHJ 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 X

INFORMATION SHARING

Pharmacy will provide Local Health Jurisdiction with information Local Health Jurisdiction 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 the Health Care Information Act, RCW 70.02.050 (2)(a).

Local Health Jurisdiction will advise Pharmacy of the information needed to protect the public health and to prevent or control disease, injury or disability and will only request the information necessary to protect the public health and to prevent or control disease, injury or disability.

ARTICLE XI

TERM AND TERMINATION

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

Appendix D

this Agreement as between the remaining Pharmacies and Local Health Jurisdictions so long as at least one Pharmacy and one Local Health Jurisdiction remain.

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

ARTICLE XII

AMENDMENTS

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

ARTICLE XIII

INDEPENDENT CAPACITY

The employees or agents of Pharmacy or Local Health Jurisdiction 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 XIV

SEVERABILITY

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

ARTICLE XV

NO THIRD PARTY BENEFICIARIES

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

ARTICLE XVI

DISPUTE RESOLUTION

If a dispute between any parties to this Agreement arises out of or related to this Agreement, or the breach thereof, 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 XVII

NOTICES

Whenever this Agreement provides for notice to be provided by one party to another, such notice shall be in writing and directed to the designated representative of the party.

ARTICLE XVIII

SURVIVORSHIP

The following clauses survive the termination of this Agreement:

- IX. Immunity, Indemnification, and Limitations
- XIV. Severability
- XV. No Third Party Beneficiaries

ARTICLE XIX

OTHER OR PRIOR AGREEMENTS

If a Pharmacy and Local Health Jurisdiction 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

Appendix D

not limited to mass dispensing of antibiotics, antiviral medications or vaccines to the general public during times of health and medical disasters, then, at such time that said Pharmacy and said Local Health Jurisdiction both execute this Agreement, such prior written agreement between them shall become null and void and of no further force and effect.

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

ARTICLE XX

GOVERNING LAW

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

ARTICLE XXI

EXECUTION IN COUNTERPARTS

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

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

Signature

Print Name and Title

Date:

Glossary

This is a list of commonly used terms related to the law and pharmacists as vaccinators and their definitions.

Advisory Committee on Immunization Practices (ACIP) (<http://www.cdc.gov/vaccines/acip/>) is a HHS-appointed advisory body of medical and public health experts that develops recommendations on how to use vaccines to control diseases in the United States.

Immunization information system (IIS) is a confidential, population-based, computerized information system that collects immunization records from multiple sources to consolidate vaccination data about all persons within a state. It also may be known as an immunization registry.

Liability means legal responsibility for a person's acts or omissions.

Medical benefit refers to a category of services provided by doctors, nurses, and hospitals that are subject to the medical deductible, copayment, or coinsurance. Pharmacists may bill for some immunizations through this benefit if they are recognized providers by the payor.

Pharmacy benefit refers to a category of services provided by pharmacists that are subject to the medical deductible, copayment, or coinsurance. Immunizations covered under Medicare Part D are billed to prescription drug plans.

Public Readiness and Emergency Preparedness Act (PREP Act) (<http://www.phe.gov/Preparedness/legal/prepact/Pages/default.aspx>) is a federal law that provides immunity from liability claims related to the administration and use of covered countermeasures (such as influenza vaccine), except for acts of willful misconduct. Immunity becomes available upon a declaration of public emergency by the HHS secretary.

Vaccine prescription is an instructing order written by an authorized medical practitioner that allows a patient to receive a medicine, vaccine, or other treatment. Although pharmacists are not authorized to prescribe in most states, authority to order, administer, and manage vaccinations emanates from statutes, protocols, or standing orders authorized by physicians or health officials.

Scope of practice includes the procedures, processes, and actions that are allowed for healthcare professionals within their disciplines.

Standing order refers to an authorization that contains rules or policies for providing patient care in certain clinical situations. A standing order can also be called a vaccine protocol.

Vaccine administration refers to the act of injecting vaccine or giving it by mouth or nose. In some cases, a pharmacist may require formal permission to administer a vaccine from an authorized provider if the pharmacist lacks independent authority. The formal permission required can be a patient-specific prescription or population-applicable vaccine

protocol. These may be issued by either private providers (such as doctors or advanced practice nurses in private practice) or public providers (such as health department medical directors) under formal agreements between pharmacists and authorized providers.

Vaccine Adverse Event Reporting System (VAERS) (<http://vaers.hhs.gov/index>) is a national vaccine safety surveillance program co-sponsored by CDC and FDA. It is a post-marketing safety surveillance program that collects information about adverse events that occur after the administration of vaccines, and provides a nationwide mechanism by which such events may be reported, analyzed, and made available to the public.

Vaccine Information Statement (VIS) (<http://www.cdc.gov/vaccines/hcp/vis/index.html>) is a CDC-produced information sheet that explains a vaccine's benefits and risks. Federal law requires that a VIS be handed out before each dose whenever certain vaccinations are given.

Vaccine protocols (also known as standing orders, collaborative practice agreements, or collaborative drug therapy agreements in some states) are agreements between pharmacists and authorized prescribers, generally physicians, which allow for the initiation, modification, or discontinuation of medication therapy by pharmacists for patients.

Vaccine Injury Compensation Program (VICP) (<http://www.hrsa.gov/vaccinecompensation/index.html>) is a no-fault program of HHS, the U.S. Department of Justice, and the U.S. Court of Federal Claims that provides compensation to people found to be injured by certain vaccines.

Additional Resources

Partner Organization Websites

- **American Pharmacists Association**

The American Pharmacists Association (APhA) is the largest association of pharmacists in the United States with more than 62,000 members. Accessed at: <http://www.pharmacist.com/>.

- **American Immunization Registry Association**

The American Immunization Registry Association works to promote the development and implementation of immunization information systems as an important tool in preventing and controlling vaccine-preventable diseases. Accessed at: <http://www.immregistries.org/>.

- **National Association of Boards of Pharmacy**

The National Association of Boards of Pharmacy supports the state boards of pharmacy in creating uniform regulations to protect public health. Accessed at: <http://www.nabp.net/boards-of-pharmacy>.

- **National Alliance of State Pharmacy Associations**

The National Alliance of State Pharmacy Associations promotes leadership, sharing, learning, and policy exchange among state pharmacy associations and pharmacy leaders nationwide, and provides education and advocacy to support pharmacists, patients, and communities working together to improve public health. Accessed at: <http://www.naspa.us/>.

- **National Association of Chain Drug Stores**

The mission of the National Association of Chain Drug Stores is to advance the interests and objectives of the chain community pharmacy industry by fostering its growth and promoting its role as a provider of healthcare services and consumer products. Accessed at: <http://www.nacds.org/>.

Tools

- “Operational Framework for Partnering with Pharmacies for Administration of 2009 H1N1 Vaccine”

A 2009 ASTHO document intended to serve as a guide for state and territorial health officials to establish effective partnerships with pharmacies to administer the H1N1 vaccine. Accessed at: http://www.astho.org/Programs/Infectious-Disease/H1N1/Op-Framework_Pharmacies_STHOs_FINAL/.

- American Pharmacists Association Immunization Center

The site provides news, tools, and other resources aimed at immunizers. Accessed at: <http://www.pharmacist.com/immunization-center>.

- “Collaborative Drug Therapy Agreement Toolkit”

A web toolkit created for local health departments to show how vaccine protocols can be developed for emergency events. Accessed at: <http://www.apctoolkits.com/collaborative-drug-therapy-agreement/>.

Policy

- “Antiviral Distribution and Dispensing: A Review of Legal and Policy Issues”
A 2012 ASTHO report that identifies legal and policy barriers related to a national strategy to distribute, dispense, and track antivirals during the 2009 H1N1 pandemic, and proposes solutions to the barriers when possible. Accessed at: <http://www.astho.org/Programs/Infectious-Disease/Antiviral-Distribution/Antiviral-Distribution--A-Review-of-Legal-and-Policy-Issues/>.
- “Assessing Policy Barriers to Effective Public Health Response in the H1N1 Influenza Pandemic”
An ASTHO report from 2010 identifying and assessing key policy barriers encountered during the 2009 H1N1 pandemic. Accessed at: <http://www.astho.org/Programs/Infectious-Disease/H1N1/H1N1-Barriers-Project-Report-Final-hi-res/>.

Evaluations and Surveys

- “Evaluation of Pharmacy Participation in the H1N1 Vaccination Campaign: Pharmacies and Public Health Summaries”
An ASTHO report evaluating pharmacy participation in the 2009 H1N1 vaccination campaign from both pharmacy and public health agency perspectives. Accessed at: <http://www.astho.org/Programs/Infectious-Disease/H1N1/Evaluation-of-Pharmacy-Participation-in-the-H1N1-Vaccination-Campaign--Pharmacies-and-Public-Health-Summaries/>.
- “Ready or Not? Protecting the Public from Diseases, Disasters, and Bioterrorism”
The report by the Trust for America’s Health and Robert Wood Johnson Foundation provides a snapshot of U.S. public health emergency preparedness. Column 4 of the chart on page 10 of this 2012 report is a state-by-state list of no co-pay Medicaid coverage of flu shots for beneficiaries under age 65. Accessed at: <http://www.rwjf.org/content/dam/farm/reports/reports/2012/rwjf403352>.

Reimbursement

- “Immunizers’ Question & Answer Guide to Medicare Part B, Medicaid, and CHIP Coverage of Seasonal Influenza and Pneumococcal Vaccinations”
A CMS document for 2012-2013 that addresses immunizers’ commonly asked coverage questions about the administration of influenza and pneumococcal vaccines to Medicare, Medicaid, and CHIP patients. Accessed at: http://www.cms.gov/Medicare/Prevention/Immunizations/Downloads/2012-2013_Flu_Guide.pdf.
- “Quick Reference Information: Medicare Immunization Billing (Seasonal Influenza Virus, Pneumococcal, and Hepatitis B)”
An August 2012 reference document from CMS on billing Medicare for seasonal flu, pneumococcal, and hepatitis B immunizations. Accessed at: http://www.cms.gov/Outreach-and-Education/Medicare-Learning-Network-MLN/MLNProducts/downloads/qr_immun_bill.pdf.

References

1. Klepser ME, Dering-Anderson AM, Klepser SA, *et al.* "The Pharmacist Will Screen You Now." *Medscape*. 2014. Available at: <http://www.medscape.com/viewarticle/819981>. Accessed 2-20-2014.
2. Rothholz M. "The Role of Community Pharmacies/Pharmacists in Vaccine Delivery in the United States." Presented at the Advisory Committee for Immunization Practice meeting, June 2013. Available at: www.cdc.gov/vaccines/acip/meetings/downloads/slides-jun-2013/01-Pharmacies-Rothholz.pdf. Accessed 2-12-14.
3. Rothholz M. "The Role of Community Pharmacies/Pharmacists in Vaccine Delivery in the United States." Presented at the Advisory Committee for Immunization Practice meeting, June 2013. Available at: www.cdc.gov/vaccines/acip/meetings/downloads/slides-jun-2013/01-Pharmacies-Rothholz.pdf. Accessed 2-12-14.
4. American Pharmacist Association. "Annual Pharmacy-Based Influenza and Adult Immunization Survey 2013 – U.S. Department of Health and Human Services National Vaccine Program Office Final Report." Available at: <http://www.pharmacist.com/sites/default/files/files/Annual%20Immunization%20Survey%20Report.pdf>. Accessed 2-12-2014.
5. CMS. "Immunizations." Available at: <http://www.cms.gov/Medicare/Prevention/Immunizations/index.html?redirect=/immunizations/>. Accessed 2-12-14.
6. CMS. "2012- 2013 Immunizers' Question & Answer Guide to Medicare Part B, Medicaid and CHIP Coverage of Seasonal Influenza and Pneumococcal Vaccinations Steps to Promoting Wellness Immunizations." Available at: http://www.cms.gov/Medicare/Prevention/Immunizations/Downloads/2012-2013_Flu_Guide.pdf. Accessed 2-12-14.
7. CDC. "Finding and Paying for Vaccines." Available at: <http://www.cdc.gov/vaccines/adults/find-pay-vaccines.html>. Accessed 2-12-14.
8. Rothholz M. "The Role of Community Pharmacies/Pharmacists in Vaccine Delivery in the United States." Presented at the Advisory Committee for Immunization Practice meeting, June 2013. Available at: <http://www.cdc.gov/vaccines/acip/meetings/downloads/slides-jun-2013/01-Pharmacies-Rothholz.pdf>. Accessed 2-12-14.
9. AIRA. "Survey of Immunization Reporting to Immunization Information Systems by Major U.S. Pharmacies. A Summary of the Methods, Successes, and Challenges of Pharmacy-IIS Interfaces." Available at: http://www.immregistries.org/resources/AIRA_Pharmacy_IIS_White_Paper.pdf. Accessed 2-14-2014.

10. Rothholz M. "The Role of Community Pharmacies/Pharmacists in Vaccine Delivery in the United States." Presented at the Advisory Committee for Immunization Practice meeting, June 2013. Available at: <http://www.cdc.gov/vaccines/acip/meetings/downloads/slides-jun-2013/01-Pharmacies-Rothholz.pdf>. Accessed 2-12-14.
11. APhA. "Pharmacists Authority to Immunize" Available at: <http://www.pharmacist.com/sites/default/files/PharmacistIAuthority.pdf>. Accessed 2-12-2014.
12. American Pharmacist Association. "Annual Pharmacy-Based Influenza and Adult Immunization Survey 2013 – U.S. Department of Health and Human Services National Vaccine Program Office Final Report." Available at: <http://www.pharmacist.com/sites/default/files/files/Annual%20Immunization%20Survey%20Report.pdf>. Accessed 2-12-2014.

This publication was supported by cooperative agreement number 5U38HM000454-05 from the Centers for Disease Control and Prevention. Its contents are solely the responsibilities of the authors and do not necessarily represent the official views of the Centers for Disease Control and Prevention.

ASTHO would like to thank Joshua Lipsman, MD, JD, MPH, principal consultant for JBL Health Systems, LLC, for conducting key informant interviews and contributing to this document.



© 2014 Association of State and Territorial Health Officials
2231 Crystal Drive, Ste 450, Arlington, VA
202-371-9090 • www.astho.org