



Operational Framework for Partnering with Pharmacies for Administration of 2009 H1N1 Vaccine

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Introduction

The mass vaccination campaign for the 2009 H1N1 influenza vaccine will require the coordination and collaboration of multiple partners to fully vaccinate the United States population. Pharmacies are in a unique position to reach mass numbers of people. Many pharmacies already function as immunization sites; however, due to the specific situation with the H1N1 vaccine (it is federally purchased and provided with distribution and administration supervised by state and local health agencies), detailed plans and procedures for distributing and administering this vaccine at pharmacies requires working under the auspices of state public health, which is different than the traditional model used for seasonal flu vaccine.

The Centers for Disease Control and Prevention (CDC) released a provider agreement ([Appendix A](#)) for state and territorial public health departments (S/THDs) to establish relationships with providers who volunteer to administer the H1N1 vaccine. CDC has issued these minimum requirements to ensure that a degree of uniformity and the operational objectives are met, and to streamline the administration of 2009 H1N1 vaccine. S/THDs do, however, have the authority to *add* to the document to address the needs in their jurisdictions. The CDC provider agreement allows for S/THDs to sign with one entity/facility and for all authorized vaccinators to be covered under the one agreement.

This *Operational Framework for Partnering with Pharmacies for Administration of 2009 H1N1 Vaccine* ("Framework") is intended to serve as a guide for state and territorial health officials (S/THOs) to establish effective partnerships with pharmacies to administer the H1N1 vaccine. Relationships between S/THDs and hospitals and other healthcare facilities are more common; relationships with pharmacies, in comparison, are more limited. A supplemental agreement between S/THDs and pharmacies may be needed to address the unique nature and potential contributions of pharmacists and pharmacies in vaccine administration. While all providers who wish to administer the H1N1 vaccine will need to complete the CDC provider agreement, this Framework and companion template agreement described herein, are meant to expand on the requirements within that agreement and address other aspects unique to the relationship between S/THDs and pharmacies. These requirements and nuances may be necessary in order to more fully enlist the services of community pharmacies (national and regional chain, independent, mass-merchandise, supermarket, community health centers and clinic-based) in vaccination planning.

The Framework includes background information, planning considerations, and elements needed for an agreement between the entities. S/THOs will need to work with the pharmacies in their jurisdictions, either directly with local store management or at the regional or national corporate level, to develop specific procedures and agreements that are applicable to their particular needs, policies, and communities. ***None of the information contained in any part of this document should be considered legal advice. S/THOs are encouraged to consult with legal counsel prior to formulating partnerships.*** The Framework was created in consultation with the American Pharmacists Association, CDC, National Alliance of State Pharmacy Association, National Association of Chain Drug Stores, National Association of County and City Health Officials, National Community Pharmacists Association, Office of the Assistant Secretary for Preparedness and Response at the Department of Health and Human Services, Office of Medical Affairs at the Department of Homeland Security, and Rx Response.



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BENEFITS TO PARTNERING WITH PHARMACIES: There are more than 56,000 community retail pharmacy outlets, including chain drug stores, mass merchants, supermarkets, and independent drug stores in the United States.¹ Pharmacies offer convenience, accessibility, and extended hours of operation. The American Pharmacists Association (APhA) states that there are 112,000 pharmacists in community pharmacies and 21,000 in “consulting, government, academic, industry and other settings.”² Almost 80,000 pharmacists are trained to, and experienced in, administering vaccinations, and are projected to administer more than 5 million seasonal influenza vaccinations in the 2009/2010 influenza season.³ Ancillary supplies such as hand sanitizer are available within pharmacies, and these venues are technologically proficient (with extensive customer databases and over 95 percent of providers computerized) and have marketing capabilities for education campaigns. Patient demographics within these databases provide an opportunity for targeted messaging (e.g., age, prescription tag to medical conditions). In addition to patients within the databases, public educational and awareness signage and services in the pharmacy setting allows for messaging to the broader population. (One entity has already established a communication campaign promoted hand hygiene in 3600 pharmacies.⁴) Some pharmacies also offer mobile health units that can help reach remote or underserved populations. Additionally, pharmacies with retail clinics and other patient care delivery collaborations can extend the availability of services to the public. Pharmacies also have the ability to access additional payers of services to efficiently document and bill for services.

Pharmacists serve as trusted members of the community – according to a Gallup poll from December, 2007, pharmacists rank third on the list of the most trustworthy professionals.⁵ They serve communities through the provision of immunization education, facilitation of vaccine delivery by other healthcare providers, and/or administration of vaccines. For preventive medicine, such as the H1N1 vaccination campaign, pharmacies provide an additional provider venue to address the needs of the healthy patient population, drawing these individuals to a location that can help reduce the burden on traditional practice sites and emergency rooms. During Hurricane Katrina, for example, pharmacies collaborated with other healthcare providers to play an essential role in delivery of patient care.

Pharmacies have begun planning for the fall vaccination campaign and are ready to assist S/THDs in maximizing vaccination coverage in their jurisdictions. A grocery store chain has stated that they are prepared to administer 2.4 million H1N1 vaccinations.⁶ (See [Appendix B](#) for a sample plan from Kroger.)

SAMPLE BEST PRACTICES: Some states have already begun planning and developing procedures for working with pharmacies for administration of H1N1 vaccine. For example, the North Carolina Division of Public Health (NC DPH) received a list from the NC Board of Pharmacy of pharmacists in the state who are

¹ National Association of Chain Drug Stores. Industry Statistics. Accessible at: <http://www.nacds.org/wmspage.cfm?parm1=72>

² American Pharmacists Association. Facts about Pharmacists and Pharmacies. Accessible at: http://www.pharmacist.com/AM/Template.cfm?Section=Public_Relations_Resources&Template=/CM/HTMLDisplay.cfm&ContentID=2680.

³ Rothholz, M. American Pharmacists Association. Personal communication. August 28, 2009.

⁴ Ziegler, C. AmeriSource Bergen Corporation. Personal communication. September 14, 2009.

⁵ Gallup. (2007). Lobbyists Debut at Bottom of Honesty and Ethics List. Accessible at: <http://www.gallup.com/poll/103123/Lobbyists-Debut-Bottom-Honesty-Ethics-List.aspx>

⁶ Feltman, M. The Kroger Company. Personal communication. August 28, 2009.



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recognized as vaccinators. NC DPH then disseminated county-specific lists to clinicians and local health departments in the state to encourage collaboration.⁷

The Texas Department of State Health Services (TX DSHS) has drafted contracts for both community chain pharmacies and independent pharmacy providers for distributing state-controlled antiviral medications (can be adapted for vaccine) and includes pharmacies in the list of providers on its H1N1 vaccine pre-registration form.⁸ (See [Appendix C](#) for draft documents.)

The Alabama Department of Public Health has initiated agreements with pharmacies to dispense limited quantities of government-supplied antiviral medications to qualified patients who cannot pay for the drugs.⁹ This system can be adapted for vaccine administration.

Planning Considerations

The following considerations are meant to provide S/THOs with broad, primary points of planning that they will most likely need to consider in order to efficiently establish effective relationships with pharmacies to administer the H1N1 vaccine.

EXPECTED AVAILABILITY OF VACCINE: Due to the continuing fluctuations in estimates of vaccine quantity and timing, expected availability cannot be confirmed at the time of this writing; however, CDC states that planners should assume that shipping will begin in mid-October (CDC's Vaccination Planning Q&A is updated regularly at: <http://www.cdc.gov/h1n1flu/vaccination/statelocal/qa.htm>). Flexibility in planning for vaccine distribution is required. S/THDs and pharmacies will need to rely on projected quantities and dates to "size" the vaccination event, assign required staff, and to advertise. For example, pharmacies may be able to provide previous years' data on seasonal flu vaccine administration to estimate the minimum number of people they can expect to vaccinate.

VACCINE RECEIPT AND DISTRIBUTION: Vaccine distribution will be conducted by McKesson Specialty, CDC's contractor for centralized distribution under the management of S/THDs in a similar mechanism to the Vaccines for Children (VFC) Program. Any provider who has the ability to receive, store, and administer the vaccine can be considered eligible to function as a vaccination site; however, a maximum number of sites will be designated in each state by the S/THD based on each jurisdiction's plans. S/THDs will be responsible for entering the vaccine receiving site information into a dedicated database established by CDC; pharmacies will need to register with their S/THD to be officially designated as a provider/receiving site. The minimum dose order is 100; all orders will need to be increments of 100 doses. Pharmacies may be able to use central pharmacy distribution centers to allocate vaccine among chain pharmacy locations; S/THDs will need to make the appropriate adjustments in ship-to site allocation in order to take advantage of this capacity. In addition, some pharmacies currently serve as a storage depot in rural areas to provide vaccines to small medical practices and may be able to assist in helping providers who are unable to meet minimum order requirements.

⁷ North Carolina Department of Health and Human Services Division of Public Health Epidemiology Section Public Health Preparedness and Response Branch. North Carolina H1N1 Vaccine Frequently Asked Questions for Clinicians and Health Departments, Question 30. Accessible at: <http://flu.nc.gov/epi/gcdc/pdf/vaxfaq.pdf>.

⁸ Texas Department of State Health Services. Healthcare Provider Pre-Registration Texas Novel H1N1 Vaccine. Accessible at: <https://vaccineregistration.questionpro.com/>.

⁹ C. Thomas, Alabama Department of Public Health. Personal communication. August 28, 2009.



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CDC maintains a Vaccine Distribution Q&A at

http://www.cdc.gov/H1N1flu/vaccination/statelocal/centralized_distribution_qa.htm.

PHARMACY CAPACITY: Vaccination throughput is dependent upon the capabilities of the individual pharmacy, availability of vaccine, frequency of influenza vaccination events, and use of ancillary personnel (student pharmacists, visiting nurses, other vendors, or retail health clinic personnel). Models of providing immunization services at pharmacies include:

- Providing immunizations within current operations (within workflow of prescription-related services);
- Providing immunizations via appointments or during set times of day;
- Conducting immunization clinics within the pharmacy with pharmacists administering and/or with retail clinics or other community immunizers; and
- Conducting immunization services out in the community to businesses, senior centers, etc.

Pharmacies are able to adapt to a community's needs, but will need to provide S/THDs with their baseline capacity and projections as to the numbers of vaccinations that can be effectively and safely administered during a specific time period (e.g., per shift, per business day, per week). S/THOs will need to provide pharmacies with any available lead time on vaccine delivery, while pharmacies will need to recognize the constraints that the program is under and that limited notice is likely.

VACCINATOR TRAINING AND CERTIFICATION: While all states authorize pharmacists to administer flu vaccines, state regulations vary on patient age limitations and administration authority ([Appendix D](#)) and some require a physician's prescription for some groups. Pharmacists' immunization training is based upon current CDC guidelines as well as those guidelines adopted by the American Pharmacists Association (APhA) and others. The vaccine administration portion of the training covers intramuscular, subcutaneous, and intranasal administration of a variety of vaccines across the lifespan. The APhA Pharmacy-Based Immunization Certificate Training Program trains pharmacists to immunize all ages and prepares pharmacists to assume broad immunization roles. S/THD might consider partnering with pharmacists to administer vaccines to patients aged 3 and up. Current restrictions on patient age are due to state laws or provider/protocol decisions based on provider comfort level or corporate policy. For example, one pharmacy chain stated that its pharmacists are certified to provide immunizations to patients aged 9 and up (younger in certain locations) in those states that allow pharmacists to administer immunizations in the adolescent or pediatric population. They also receive training to provide a comprehensive emergency response when vaccinating high-risk groups of individuals.¹⁰ In addition, pharmacists obtain CPR and OSHA blood-borne pathogen training; however, some CPR training programs may only be for ages 12 and up and company policy may limit authority around those parameters.

Each state will need to review their laws on pharmacist authority to vaccinate and plan accordingly. States may also want to consider enacting emergency orders or other measures to amend pharmacists' authorities in order to allow for increased opportunities to vaccinate. For example, in order to best target those at highest risk for H1N1 infection, states may need to expand the age groups that pharmacists are authorized to immunize. The ACIP vaccine prioritization recommendations (<http://www.cdc.gov/mmwr/preview/mmwrhtml/rr58e0821a1.htm>) include individuals as young as six months of age. States may want to consider including language that authorizes pharmacists to

¹⁰ Cohen, E, Walgreens. Personal communication. September 1, 2009.



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administer H1N1 vaccine to patient populations included within the ACIP recommendations consistent with training. (For example, in the interest of reducing barriers to vaccination, it would be convenient for an entire family to be vaccinated at the same location; turning some away due to a younger age will reduce the likelihood that those individuals will be vaccinated at all.) Establishing state-wide protocols may reduce barriers related to access and administrative issues, such as requiring prescriptions when a state-wide protocol may serve as the appropriate immunization order, or the lengthy amount of time that it takes to complete license amendments.

A template executive order is listed in [Appendix E](#). The implementation of the authority will ultimately be based upon the systems and comfort level of the provider. As an example, the Commonwealth of Massachusetts issued an executive order on August 12, 2009 proposing emergency amendments: to ensure all hospital and clinic employees are vaccinated against both seasonal and pandemic influenzas; and to expand the number of health care workers who would be authorized to administer vaccines. The proposed amendments were revised to include medical and nursing students as authorized vaccinators. The documents can be found at:

http://www.mass.gov/?pageID=eohhs2terminal&L=5&L0=Home&L1=Government&L2=Laws%2c+Regulations+and+Policies&L3=Department+of+Public+Health+Regulations+%26+Policies&L4=Proposed+Amendments+to+Regulations&sid=Eeohhs2&b=terminalcontent&f=dph_legal_vaccine&csid=Eeohhs2.

As another example, the Louisiana Department of Health and Hospitals issued an “Emergency Order and Protocol for the Administration of Influenza Vaccination by Eligible Pharmacists” on September 14, 2009. This order changes Louisiana pharmacist authorization for administering vaccinations by protocol, rather than by physician prescription. The order also includes requirements for pharmacists to record vaccination data in the statewide database – “LINKS.” The order is available at:

<http://www.dhh.louisiana.gov/offices/publications.asp?ID=88&Detail=2785>.

VACCINATOR LIABILITY COVERAGE: Liability immunity for “activities related to administration and use of the vaccine” is provided as part of the Secretary’s declaration under the Public Readiness and Emergency Preparedness (PREP) Act.

On June 15, 2009, Secretary Sebelius signed a declaration under the PREP Act to extend liability immunity against tort claims (except for willful misconduct) to individuals and entities involved in all stages of 2009 H1N1 influenza vaccine development, testing, manufacture, distribution, prescribing, administration, and use. Liability immunity means that there is no legal tort claim that can be pursued in state or federal court. Individuals and entities that receive liability immunity under the declaration include manufacturers, distributors, states, locals, tribes, and other entities that supervise or administer a vaccination program; and healthcare professionals or others authorized under state law to prescribe, administer, and dispense vaccines when they are carrying out activities in accordance with the conditions stated in the declaration. The declaration covers all vaccination activities related to present or future federal contracts, grants, cooperative agreements, interagency agreements, or memoranda of understanding, including all activities using vaccine procured by HHS. The PREP Act also authorizes HHS to establish a compensation program when a declaration is issued under the Act. The PREP Act liability protections under the declaration pertain to anything



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causally related to administration and use of the vaccine, but do not extend to general medical care rendered in emergencies.^{11,12}

The Pandemic Influenza Vaccines Amendment to the January 26, 2007 Declaration under the PREP Act is available at: <http://edocket.access.gpo.gov/2009/E9-14948.htm>. Questions and answers on the PREP Act are available at: <http://www.hhs.gov/disasters/emergency/manmadedisasters/bioterrorism/medication-vaccine-qa.html>.

PATIENT PRIORITIZATION: Pharmacies will need to agree to prioritize patients according to the ACIP recommendations in order to administer federally-funded vaccine. S/THDs have flexibility in adjusting the recommendations based on their distinct populations and vaccine allotment; pharmacies will also need to comply with any modifications that the S/THD makes to the prioritization plan. Pharmacy representatives included in discussions as part of the development of this document have stated that pharmacists are willing and able to follow the prioritization plan. S/THDs will need to support pharmacies by providing guidance, educational material for patients, and being a resource for information on prioritization. As more vaccine becomes available, S/THDs will need to ensure to provide pharmacies with up-to-date information and changes in prioritization schemes.

Patients should not be asked to provide proof of their eligibility for prioritized vaccine – the “honor system” will be followed.

STORAGE/HANDLING: Recipients of vaccine must abide by the package insert instructions and CDC guidelines on storage and handling of vaccine (<http://www2a.cdc.gov/vaccines/ed/shtoolkit/>). Storage requirements may limit shipment amounts to some pharmacies due to sizing of shipment boxes and/or availability of cold storage.

OTHER RESOURCE NEEDS/PROCUREMENT: Vaccine ordering will take place through the S/THD, which in many cases will be a new ordering system for pharmacies and a new vendor for S/THDs. These procedures will need to be integrated into company processes (purchase orders, vendor setup, etc.), which will vary across companies.

Pharmacies that receive H1N1 vaccine will also receive the following ancillary supplies: needles, syringes, sharps containers, and alcohol swabs at no cost.¹³ These items will be distributed to the same ship-to site as the vaccine, although not necessarily at the same time or in the same shipment. Patient immunization cards will be provided with vaccine shipments.

VACCINATOR PROTECTION: Pharmacists who administer the vaccine fall into the Advisory Committee on Immunization Practices (ACIP) prioritization recommendations to be offered vaccination prior to wide-scale availability to the general public. Other pharmacy personnel are not considered healthcare workers; unless they fall into one of the other personal risk categories, they should not receive prioritized vaccine. The presumption is that pharmacists will vaccinate healthy people; however, pharmacies are likely to have high traffic of ill people in their facilities seeking over-the-counter treatments for self-care at home. Employees in this environment may be considered “medium-risk” for

¹¹ Sherman, S, Office of the General Counsel, HHS. Personal communication. August 27, 2009.

¹² Parker, G. Office of the Assistant Secretary for Preparedness and Response, HHS. Personal communication. September 16, 2009.

¹³ CDC. (2009). CDC Novel H1N1 Vaccination Planning Q&A. Accessible at: <http://www.cdc.gov/h1n1flu/vaccination/statelocal/qa.htm>



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exposure.¹⁴ Pharmacies may wish to consider providing other protections for their personnel per CDC employer guidance (<http://www.cdc.gov/h1n1flu/business/guidance/>).

ADMINISTRATION FEE COVERAGE: The vaccine itself will be provided by the federal government at no charge; non-public health vaccinators may charge an administration fee. The government requires that any provider agreeing to administer the H1N1 vaccine may not charge an administration fee exceeding the regional Medicare rate (or Medicaid rate if the fee is charged to Medicaid). Current Procedural Terminology (CPT) codes have been established and fee-for-service questions and answers developed (available at: <http://www.cms.hhs.gov/H1N1/>). The Centers for Medicare and Medicaid Services (CMS) states that they will cover administration of H1N1 vaccine as they do for seasonal influenza. States may need to clarify Medicare and Medicaid coverage for pharmacist-delivered services in their jurisdiction.

Not all private insurers recognize pharmacists as providers of medical services. Many insurers in varying states have officially stated that they will cover the H1N1 vaccine; however, these plans often do not cover vaccinations administered in pharmacies, but will when administered in a doctor's office. America's Health Insurance Plans (AHIP) told CDC that, "...public health planners can make the assumption that health plans will provide reimbursement for the administration of a novel (A) H1N1 vaccine to their members by private sector providers in both traditional settings e.g., doctor's office, ambulatory clinics, health care facilities, and in non-traditional settings, where contracts with insurers have been established."¹³ States may want to consider working with insurance groups in their state to determine availability of coverage in pharmacies. ASTHO is also working closely with AHIP and the major insurers to clarify this matter.

UNINSURED PATIENTS: The truly uninsured have no insurance coverage whatsoever; the *underinsured*, in this situation, may apply to individuals who have health insurance, but whose benefits do not include vaccination coverage at a pharmacy. Some of the latter may be able to pay out-of-pocket, while it would be a hardship for others. For the purposes of the Framework, "uninsured" refers to individuals who have no reasonable method of payment for the administration fee.

The CDC provider agreement states that non-public health vaccinators, "May either administer the 2009 Influenza A (H1N1) monovalent vaccine for free to individuals who cannot afford the administration fee, or refer these individuals to a public health department clinic or affiliated public health provider for vaccination." According to a project of the Robert Wood Johnson Foundation, approximately 45 million people in the United States were uninsured as of 2008.¹⁵ The fall 2009 H1N1 vaccination campaign aims to eventually vaccinate all who wish to be vaccinated. People who are turned away at pharmacies (or other provider sites) because they are unable to pay may be less likely to then go to a public health department-sponsored clinic or mass vaccination event for the vaccine. Pharmacies are encouraged to provide vaccine free of charge to individuals who cannot pay the administration fee; S/THDs should take into consideration this factor as they continue to identify and secure viable vaccination providers in their jurisdiction.

REPORTING/DOCUMENTATION: Pharmacies will need to abide by the documentation requirements laid out in the CDC provider agreement, including information sheets for patients, recording data on

¹⁴ OSHA (2009). Guidance on Preparing Workplaces for an Influenza Pandemic . Accessible at: http://www.osha.gov/Publications/influenza_pandemic.html#classifying_exposure.

¹⁵ Cover the Uninsured. (2009). Current Population Survey Annual Social and Economic Supplements, 1995-2008. Accessible at: <http://covertheuninsured.org/content/overview>.



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administration, and maintaining records for three years. Pharmacies will need to provide individual patient vaccination information to the health department with which they are collaborating. These vaccination records may be entered electronically as a patient vaccination record. S/THDs will need to provide guidance on the record-keeping requirements for their particular needs. Pharmacies' existing technology may be beneficial to this process.

Patient immunization cards will be provided with the vaccine. Pharmacists should complete this form for the patient and provide instruction on receiving the second dose, if determined necessary.

UNUSED SUPPLIES: Any unused doses of vaccine must be reported to the S/THD and destroyed according to applicable state regulation. If unused vaccine has not expired and demand is seen elsewhere, pharmacies should work with the S/THD to determine whether transfer of vaccine is permissible under applicable regulations. If allowable, S/THDs and pharmacies should develop plans and procedures for moving vaccine in accordance with regulations. Ancillary supplies do not need to be returned if the vaccine is to be destroyed.

PHARMACY GUIDANCE: S/THDs should provide pharmacies with all guidance needed to effectively function as an H1N1 vaccination site. Primary and secondary points of contact for both routine matters and emergencies should be identified at both the S/THDs and at the pharmacies for the purposes of this activity.¹⁶ A routine schedule of communications is advised. Pharmacies should keep public health updated on vaccination uptake, issues, concerns, successes, etc., in an ongoing manner.

ADVERTISING: Advertising should be consistent with ACIP recommendations and S/THD campaigns. S/THDs will need to ensure that pharmacies have the information they need to advertise appropriately.

SEASONAL/H1N1 FLU MESSAGING: Educational campaigns will need to be clear about the difference between the seasonal and H1N1 flu vaccines, including target groups and importance of receiving all appropriate vaccinations.

Formalizing Partnerships

S/THDs should consider formulating agreements with pharmacies at an aggregate level where possible (i.e., an agreement with the corporate office of chain stores and franchises to cover all retail stores in one state versus formulating agreements with each individual store). This is recognized as one way to more efficiently and expeditiously consummate arrangements between larger pharmacy corporations and S/THDs. A "national" agreement would not encompass individual state regulations involving pharmacist authority to provide vaccines or individual jurisdictional needs. Each state has diverse levels of authority, statutory restrictions and variance in state and local emergency response plans and will need to use a format and specific language appropriate for their state. A template agreement is available in [Appendix F](#) to provide S/THDs and pharmacies with a starting point for establishing relationships within their communities. Community (chain and independent) pharmacy representatives have indicated that this is a feasible approach and stand ready to assist and partner with public health. S/THDs may find that their State Pharmacy Association is a useful resource. Contact information is available at: <http://www.naspa.us/statepharmacy.html>. The National Association of Chain Drug Stores can also help to provide connections: www.nacds.org.

¹⁶ CDC maintains a list of S/T contacts for the H1N1 vaccine at: <http://www.cdc.gov/h1n1flu/vaccination/statecontacts.htm>.



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Parties involved will need to consider applicable state law and authority and what type of agreement best suits their needs. The template outlined in this document encompasses the input from state and local public health leadership, pharmacy representatives, and federal partners. It is meant to guide entities in their planning and offers a comprehensive template for planners to build upon for their own purposes. S/THDs and pharmacy officials will need to revise this agreement based on their needs and the advice from the appropriate counsel.

Appendix A: CDC Vaccine Provider Agreement

2009 Influenza A(H1N1) monovalent vaccine

Vaccine Provider Agreement

(refer to http://www.cdc.gov/H1N1flu/vaccination/statelocal/provider_agreement_qa.htm
for Qs and As on this agreement)

PIN: _____

H1N1 Immunization Provider Names and applicable medical/nursing/other licensure numbers of

Facility Name (and facility licensure number, if any)

Addresses of primary facility

Address for receipt of vaccine

Your participation in the 2009 Influenza A(H1N1) monovalent vaccine vaccination effort is greatly appreciated as a vital service that will protect individuals and the public against 2009 H1N1 influenza. The 2009 Influenza A(H1N1) monovalent vaccine has been purchased by the federal government as a means of protecting the public against 2009 H1N1 influenza. It is being made available to immunization providers working in partnership with state and local public health departments to vaccinate individuals for whom the vaccine is recommended. This Provider Agreement specifies the conditions of participation in the 2009 Influenza A(H1N1) monovalent vaccine vaccination effort in the U.S. and must be signed and submitted to the immunization program prior to receipt of the vaccine.

The immunization provider agrees to:

1. Administer the 2009 Influenza A(H1N1) monovalent vaccine according to the recommendations of CDC's Advisory Committee on Immunization Practices as adopted by the Centers for Disease Control and Prevention.
2. Store and handle the vaccine in accordance with the package insert provided with the vaccine including in compliance with cold chain requirements.
3. Provide a current Vaccine Information Statement to each individual before vaccination, and answer questions about the benefits and risks of vaccination, including different indications for live versus inactivated vaccines.
4. Record in the patient's medical record or in an office log the date of administration, the site of administration, the vaccine type and lot number, and the name of the immunization provider for each individual vaccinated. The record must be kept for a minimum of three years following vaccination.
5. Report moderate and severe adverse events following vaccination to the Vaccine Adverse Event Reporting System (1-800-822-7967, <http://vaers.hhs.gov/contact.htm>).

In addition, the provider:

6. Cannot charge patients, health insurance plans, or other third party payers for the vaccine, the syringes or the needles as these are provided at no cost to the provider. The provider/facility is also prohibited from selling H1N1 vaccine, syringes or needles.
7. 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 vaccine

administration fee. If the administration fee is billed to Medicaid, the amount billed cannot exceed the state Medicaid administration fee.

8. May either administer the 2009 Influenza A (H1N1) monovalent vaccine for free to individuals who cannot afford the administration fee, or refer these individuals to a public health department clinic or affiliated public health provider for vaccination.
9. Must report the number of doses of 2009 Influenza A (H1N1) monovalent vaccine administered to individuals as requested by the state or local public health department.
10. Must report to the state health department the number of doses of vaccine that were not able to be used because the vaccine expiration date was exceeded or the vaccine was wasted for other reasons. These doses must be disposed of in accordance with state regulations for biological waste.
11. Are strongly encouraged to provide an immunization record card to the vaccine recipient or parent/guardian to provide a record of vaccination, to serve as an information source if a Vaccine Adverse Event Reporting System report is needed, and to serve as a reminder of the need for a second dose of vaccine (if necessary). Immunization cards will be included in each shipment of vaccine.
12. [Optional – States can insert additional requirements as long as they are not contrary to the federal requirements noted above.]

Receipt of H1N1 vaccine shall constitute acceptance of the terms of this agreement.

Agreed to on behalf of the above-named providers and facility(ies):

(signed or electronic submission) _____

(printed) _____
Medical Director/Date

Appendix B: Sample Pharmacy Plan: Kroger Vaccination Plan for Novel H1N1 Influenza

Introduction

This document provides general guidance and outlines the proposed plan that The Kroger Family of Pharmacies would undertake in assisting with the administration of novel H1N1 vaccine. Incorporated into the document is information specific to the process for 2009-2010 H1N1 influenza vaccination clinics. Due to the fact that many unknowns still remain about the impact that novel H1N1 influenza may have, this plan has been designed to be flexible and accommodate various scenarios that would allow The Kroger Family of Pharmacies to best serve our communities.

General Preparedness

1. Access to Certified Immunizing Pharmacists: Kroger is very proud of our pharmacists and their abilities. The Kroger Family of Pharmacies currently has employed nearly 3,000 certified immunizing pharmacists across our 1963 pharmacies. On average across all our banners, over 90% of our locations have at least 1 immunizing pharmacist on staff. Although, the precise number of pharmacy staff needed for any one clinic will vary, depending on the size and layout of our store, the geographic area being served by the pharmacy, the method of vaccine delivery (mass clinic or routine course of business – explained below) and the estimated number of vaccine recipients, The Kroger Family of Pharmacies has the capability to deliver almost 2.4 million H1N1 vaccinations.
2. Use of The Kroger Family of Pharmacies Stores as Vaccination sites: Individual store sites have been selected based upon:
 - Their ability to Reach as many patients as possible,
 - The number of available vaccinating pharmacists,
 - The estimated number of people expected to be served in that community
 - Handicap access for all patients and,
 - The size and layout of the store

In addition, The Kroger Family of Pharmacies is interested in working with the various State and County governments, as allowed by regulations and our vaccination protocol, to immunize children either at our store or at off-site clinic locations, such as community schools.

3. Authorization to Vaccinate / Standing Orders: The Kroger Family of Pharmacies currently has standing orders on file from protocol physicians throughout our 38 States of operation, with varying authorization to administer influenza vaccine.
4. Community Awareness of Vaccination Campaign: The Kroger Family of Pharmacies is committed to assisting in informing the public regarding the availability of H1N1 vaccine at our stores through our normal channels of customer engagement. These may include:
 - Weekly circulars,
 - Radio and TV,
 - www.kroger.com and all our other banner web pages
 - In store communication

With respect to the content of all H1N1 immunization communications materials, information from the CDC will act as the primary content provider. These may include:

- Priority groups for vaccination,

- Clinic locations and directions,
- Dates and times of operations,
- Tips on type of clothing to wear.

Any available printed materials will be at reading levels suitable for their intended audiences.

In order to ensure a streamline approach to communications between our organizations, two points of contact at The Kroger Family of Pharmacies should be used.

For information directly relating to immunization operations, please contact:

Matthew Feltman RPh
Health Strategy Coordinator
matthew.feltman@kroger.com
513.762.1492
513.762.1014

For media inquiries and, please contact:

Meghan Glynn
Corporate Communications
meghan.glynn@kroger.com
513-762-1304

H1N1 Immunization Operations Process

1. The Vaccination Clinic Process

Step One: Request for H1N1 Vaccine: Based upon the ability of The Kroger Family of Pharmacies pharmacy to administer over 980,000 doses of seasonal flu vaccine during 2008-2009 and another anticipated 1.2 million doses during the 2009-2010 season, and our current storage capacity for vaccine and immunization supplies, The Kroger Family of Pharmacies pharmacy requests that 2.395 million doses of H1N1 vaccine be allocated to our stores in the effort to immunize patients against novel H1N1.

Step Two: Distribution of Requested for H1N1 Vaccine: The Kroger Family of Pharmacies clearly understands the logistical opportunity that this immunization effort presents. Taking those into consideration and hoping to maximize patient outreach, The Kroger Family of Pharmacies suggests that H1N1 vaccine can be accommodated by our divisions as seen below.

Division	Requested H1N1 Vaccine Doses for Consideration	Division	Requested H1N1 Vaccine Doses for Consideration
Atlanta	200,000	SouthWest	250,000
Cincinnati	240,000	Dillons	125,000
JayC	400	KingSoopers	100,000
Columbus	300,000	Frys	150,000
Michigan	200,000	FredMeyer	120,000
Central	150,000	Ralphs / F4L	45,000
MidSouth	200,000	QFC	10,000
Delta	40,000	Smiths	100,000
MidAtlantic	165,000	Total	2,395,400

Individual divisions will include a detailed list here or attach excel spreadsheet.

List will contain the following minimum information:

- *Pharmacy Name*
- *Pharmacy Address (Street, City, State, Zip)*
- *County that pharmacy resides in*
- *Pharmacy Phone #*
- *Pharmacy Fax #*
- *Primary Contact (may be division office contact)*
- *Primary Contact e-mail*
- *Secondary Contact (may be division office contact)*
- *Secondary Contact e-mail*
- *Pharmacy Hours of Operation (S-S) (Available to receive shipment)*

Step Three: Storage and Security of Requested for H1N1 Vaccine: All involved pharmacy staffs will be provided both verbal and written directions for the proper receipt and storage of H1N1 vaccine and related supplies. Based upon The Kroger Family of Pharmacies' previous experiences with providing seasonal influenza vaccine, the staff providing vaccine already has in place proper procedures and best practices for receiving and securing vaccine.

Since the demand for influenza vaccine for novel H1N1 may be high, the following will be done to protect the vaccine supply from theft, fraud and waste:

- All H1N1 vaccine and supplies will be stored, until ready for use, under "lock and key"
- Doses/vials will be inventoried after each clinic session, if applicable.
- Reporting, as required, will be completed
- Vaccine will be stored under refrigeration at a temperature of 36-46° F (2-8° C).
- In the event that vaccine will be transferred to another The Kroger Family of Pharmacies pharmacy, based on need and the ability to vaccine additional individuals, cold chain, 36-46° F (2-8° C), will be ensured by the use of insulated coolers* that guarantee an internal temperature for 72 hours. *Assuming vaccine is delivered by McKesson to pharmacy in these insulated coolers.

In the event that H1N1 vaccine remains at the end of the vaccination period, and neither the Federal Government nor Operational Health Department requests the product be directly returned to them, H1N1 vaccine will be inventoried and then disposed of by the pharmacy. The Kroger Family of Pharmacies will return product, following existing Kroger Company pharmacy Return Procedures. This would entail return and disposal by our contracted reverse distributor, MedTurn.

Step Four: Immunization Methods and Pre-Screening Best Practices: The Kroger Family of Pharmacies intend on employing various methods of immunizing patients. These methods will be used to:

- Maximize the number of participants to the number of vaccinations received
- Triage patients effectively during the High Priority Vaccination period
- Allow for an orderly flow of patients that does not disrupt our existing business
- Minimize crowd control and security incidents
- Provide a safe environment for all participants

The Kroger Family of Pharmacies may use any combination of the following methods for immunizing:

- In-Store Mass Immunization Clinics
- By appointment through the pharmacy
- Ad Hoc Vaccinations – administering vaccine without an appointment, as a normal course of pharmacy business

The Kroger Family of Pharmacies is also interested in participating in off-site vaccination efforts, such as at schools, provided that our Immunization Protocol and staffing will allow participation. To request to inquire about participation in off-site immunization clinics please contact:

Matthew Feltman RPh
Health Strategy Coordinator
matthew.feltman@kroger.com
513.762.1492
513.762.1014

Regardless of venue or method chosen by the pharmacy for providing H1N1 immunizations, The Kroger Family of Pharmacies will employ pre-screening best practices to ensure the health and proper prioritization of all participants. The Kroger Family of Pharmacies will follow CDC guidelines and recommendations for:

1. The pre-screening and potential rerouting of patients to an alternative vaccination area for all patients who present with Influenza Like Illness.
2. Prioritization of High Priority H1N1 immunization groups
3. Identifying individuals to whom the vaccine may be contraindicated

The Kroger Family of Pharmacies will use a patient self-declaration form for determining eligibility for high priority determination. The Kroger Family of Pharmacies may use a combination of either verbal and/or written materials to determine if the patient is presenting with ILI symptoms. The Kroger Family of Pharmacies will utilize both verbal and written Vaccine Information Sheets. In the event of a reported adverse effect following immunization with the H1N1 vaccine, The Kroger Family of Pharmacies will employ the use of the VAERS web site, <http://vaers.hhs.gov> to report the event.

2. H1N1 Immunization Event Materials

Each participating Kroger Company pharmacy will be equipped with, no less than the following immunization materials.

1. General Supplies and Equipment

Paper	Stapler/staples	Telephone	Emergency Numbers
Pen, pencils	Tape, Scissors	Envelopes	Paper towel
ID badges for staff	Clipboards	Trash containers/bags	
Table pads/ covering	Tables / Chairs	Rubber bands	
Internet Access	Tissues	Computer	

2. Vaccine Administration Supplies

Cooler/refrigerator	Needles/ Syringes*	Sharps containers*
Latex gloves / Latex-free gloves	Antibacterial hand-washing solution	Alcohol wipes*
Band-aids	Antibacterial soap or Solution	Gauze

3. Emergency Supplies

Epinephrine 1:1000 SQ	Diphenhydramine 50 mg IM	Syringes with needles*
Tuberculin syringes with needles	Alcohol wipes/Sterile dry pads*	Blood Pressure Monitor
Tongue depressors	Pocket CPR masks	Instant Cold Packs
Adult and pediatric airways tubes		

4. Crowd Management Supplies

- Signs to direct patients to vaccinations
- Roping (as needed)
- Queue partitions (as needed)
- Vaccination Tickets/vouchers (as needed or as required by venue/event)

***Note: HHS will provide needles, syringes, sharps containers and alcohol swabs.**

The Kroger Family pharmacy's vaccination operations will observe universal and OSHA precautions for preventing blood exposures and blood borne pathogen. Medical waste sharps containers will be available in the area where the sharp is used. Arrangements for the transport and destruction of filled sharps containers are in place. Other medical waste, including gauze or cotton used during administration of vaccine, other potentially contaminated material, and empty vaccine vials and nasal spray containers will be bagged in appropriately marked biohazard bags.

3. Establishment / Collection of Vaccine Administration Fees

The Kroger Family of Pharmacies will:

- Be following CDC guidance with respect to the establishment and collection of H1N1 immunization fees for the administration of the vaccine by our associates.
- Seek "First Dollar Coverage" for the administration of the vaccine from public and private insurance plans that provide coverage for H1N1 influenza vaccine.
- Seek 100% reimbursement, at the established Medicare payment rate, or our usual and customary charge, whichever is less, for the administration of vaccine to eligible Medicaid and SCHIP beneficiaries.
- Reserve the right to charge the general public, up to the Medicare payment rate for administering the vaccine.
- Follow the guidelines and procedures established by the Federal Government and/or the (*Organization Health Department*), to waive the vaccine administration fee if/when an uninsured/underinsured patient presents for H1N1 vaccination.

4. H1N1 Post-Event Immunization Reporting

Individual patient vaccination specific information will be collected via a standardized vaccination record. These vaccination records will then be data entered using our pharmacy operating system, as a patient prescription. Patient Vaccination Cards, with suggested date for receiving second H1N1 immunization, will be provided to all "First Dose" patients.

The Kroger Family of Pharmacies will conduct post-event reporting, as required by the Federal Government, State or (*Organization Health Department*). The Kroger Family of Pharmacies will also conduct internal reviews, to enhance efficiency for future immunization efforts.

Appendix C: Draft Texas Antiviral Distribution Network Tool Kit

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Distribution Network

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OVERVIEW OF THE TEXAS ANTIVIRAL DISTRIBUTION NETWORK

TASK: Distribution and Re-supply of State Owned Antiviral Medication

The Texas Department of State Health Services (DSHS) considers the use of antiviral medications as one component of a comprehensive containment and treatment plan to assist in the control of an outbreak of a novel influenza virus, such as the novel H1N1 influenza virus (“swine flu”). DSHS has a limited supply of antiviral medication in a state stockpile (referred to as “state stock”) comprised of purchases made using general revenue, purchases made using federal preparedness funds, and antiviral medication received as the Texas portion of the federal Strategic National Stockpile (SNS). Since the allocated amount of antiviral medications is small compared to the Texas population, individuals and entities in need of antiviral medications are encouraged to obtain materials through normal channels in the marketplace as they would have prior to this response. The antiviral medication in the state stock is intended to meet three primary goals: serving the uninsured and underinsured, public health measures and outbreak control, and stop-gap measures in the event of routine supply channels breaking down. The primary goals of the state stock and the mechanism for distribution and re-supply of antiviral medications in order to meet the three primary goals of the state stock is documented in this plan.

Three Primary Purposes of State Stock Antiviral Medication

1. **Uninsured and Underinsured**- State stock antiviral medications can be used for uninsured or underinsured individuals who otherwise would not be able to purchase the antiviral medication they are prescribed.
2. **Public Health Measures**- State stock antiviral medications can be used for outbreak control when deemed a necessary public health measure by either the DSHS Health Service Region (HSR) or local health department (LHD).
3. **Supply Disruption**- State stock antiviral medications can be used to meet immediate health care entity needs due to supplier disruption or unavailability.

Assumptions Used to Determine Distribution Mechanisms

1. There is a limited supply of state stock antiviral medication.
2. The number of receiving entities, including end-user pharmacies must be limited to avoid depleting resources with initial shipment.
3. DSHS will work chain retail pharmacies to serve as many counties as possible since the chain pharmacies have their own distribution systems, minimizing the strain on the DSHS RSS. In counties without a pharmacy chain, DSHS will work with independent pharmacies that serve those counties.
4. DSHS assumes the cost to ship antiviral medications from DSHS to the chain pharmacy distribution center or from DSHS to the independent pharmacy store.
5. In chain pharmacy, independent pharmacy, and FQHC/CHC settings, healthcare providers act as the gatekeeper to determine which individuals receive a state stock prescription based on need. Clinical guidance regarding antiviral medications is available on the DSHS website at www.texasflu.org.

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Three Mechanisms for Distributing State Stock

The state stock antiviral medication is stored in a secured receiving, staging and storing (RSS) site from which distributions are made. The DSHS RSS will send shipments of state stock antiviral medications directly to the following entities:

1. **Health Service Regions (HSRs):** Supplies to be used for outbreak control by the health service region and local health departments. Supplies will also be used to meet small needs that may arise due to supplier breakdowns and outbreak control in entities such as hospitals. If the distribution to these locations becomes an overwhelming task for HSRs, the DSHS RSS will take over responsibility for direct shipments to these entities.
2. **Chain and Independent Retail Pharmacies:** DSHS will partner with chain and independent pharmacies to serve the uninsured and underinsured across the state. The DSHS RSS will ship to the central distribution center of DSHS contracted chain pharmacies, which in turn supply all selected stores in their organization which hold state stock. The DSHS RSS will also ship directly to selected independent pharmacies that hold state stock.
3. **Federally Qualified Health Center (FQHC) and Community Health Center (CHC) distribution centers:** Each distribution center will provide medications to multiple CHC/FQHC clinic sites to meet the needs of their patient population without the patient needing to take the extra step of taking the prescription to a retail pharmacy to be filled. CHC/FQHCs are not expected to serve non-CHC/FQHC patients.

Overview of the Texas Antiviral Distribution Network

Process for Dispensing State Owned Antiviral Medications through Chain Pharmacies

The following is the process the Texas Department of State Health Services (DSHS) will use to dispense state antiviral medications through private retail chain pharmacy systems during novel H1N1 influenza virus response efforts.

Assumptions

1. The antiviral medications in the state stockpile (“state stock”) are intended to meet gaps that may not be addressed through normal channels and in particular the needs of the uninsured or underinsured populations.
2. Healthcare providers will follow the guidance for clinicians posted on the DSHS website (www.texasflu.org) for determining when to provide antiviral medications. This document will be updated regularly as needed.
3. Healthcare providers will follow guidance they receive from DSHS and through professional associations to determine who is specifically eligible for state stock antiviral medications.
4. Healthcare providers will write a prescription that identifies the patient needs their prescription dispensed from state stock. Information about how to write a prescription for state stock will be communicated to healthcare providers through DSHS and professional associations.
5. Healthcare providers will refer a patient who needs state stock antiviral medication to a DSHS contracted pharmacy. Healthcare providers will be informed of the DSHS contracted pharmacies in their area that carry state stock antiviral medication. Healthcare providers will receive this communication from DSHS and state and county professional associations.

Initial Supply of State Stock Antiviral Medications to Chain Pharmacies

1. DSHS will determine which pharmacy chains will be participating and which counties each pharmacy chain will serve. Pharmacy chains will designate one distribution site to receive shipments for all of their pharmacies in the state that will have state stock.
2. The DSHS RSS (Receiving, Staging, and Storing) site will ship state stock antiviral medications to each participating retailer's pharmacy distribution center via private supplier or state vehicle at the cost to DSHS. Initial stocking level to be shipped to each distribution center will be determined by DSHS based on geography, usage of private stock in that area, amount of illness in the area, and amount of state stock available.
3. In turn, the retailer's pharmacy distribution center will ship antiviral to their pharmacy stores via their normal distribution process at their cost. The initial stocking level per store will be based on usage of private stock, amount of illness identified in the target area, and the amount of state stock available. This decision will be made jointly by DSHS and the pharmacy chain representative.

Process for Dispensing State Owned Antiviral Medications through Chain Pharmacies (Continued)

Re-supply of State Stock Antiviral Medications to Chain Pharmacies

1. Retail pharmacy store re-supply will be through the retailer's normal pharmacy ordering process/re-supply system.
2. When a retailer's pharmacy distribution center needs re-supply, the DSHS RSS will ship to the pharmacy distribution center when the request is received. The DSHS RSS will ship via private carrier or state vehicle to the distribution center at the cost to DSHS.
3. The retailer's pharmacy distribution center in turn will ship through their normal distribution system to their participating pharmacies in selected counties.
4. The retailer's pharmacy distribution system will accommodate shipments between pharmacies within their company if needed, per the usual company process for doing so.

Intended Use of State Stock Antiviral Medications in Chain Pharmacies

1. State stock antiviral medications are intended to serve the uninsured and underinsured who otherwise could not afford the cost of the antiviral medication they have been prescribed.
2. The use of state stock is reserved only for clients who present a healthcare provider's prescription that identifies the client as needing to have his/her prescription dispensed from the state stock.
3. If a patient with a regular prescription for antiviral medication states he/she cannot afford private stock price, a pharmacist at a DSHS contracted pharmacy can choose to dispense from state stock.
4. Pharmacies are allowed to charge a \$10 administrative fee to offset their costs on prescriptions filled by state stock. However, if a patient cannot afford the charge the fee must be waived.

Reporting Requirements

1. Inventory Updates: Each participating chain retailer will be asked to provide an inventory report every Tuesday at 10:00 a.m. to sns@dshs.state.tx.us listing the specific inventory of state stock in each pharmacy store and the overall state stock inventory at the distribution centers. DSHS will provide a template for this report. Note: this reporting schedule may be changed to a daily reporting schedule, if necessary.
2. Patient Updates: If the pharmacy store is currently a registered user of ImmTrac, the state immunization record for Texas, the pharmacy store will report dispensing of antiviral medications through ImmTrac. If the pharmacy store is not currently registered in ImmTrac, the pharmacy store will fill out ImmTrac reporting forms, found online at

<http://www.dshs.state.tx.us/immunize/immtrac/default.shtm>, and then fax the completed ImmTrac forms to DSHS where DSHS staff will enter the data into the ImmTrac database.

Process for Dispensing State Owned Antiviral Medications through Independent Pharmacies

The following is the process the Texas Department of State Health Services (DSHS) will use to dispense state antiviral medications through private retail independent pharmacies during novel H1N1 influenza virus response efforts.

Assumptions

1. The antiviral medications in the state stockpile (“state stock”) are intended to meet gaps that may not be addressed through normal channels and in particular the needs of the uninsured or underinsured populations.
2. Healthcare providers will follow the guidance for clinicians posted on the DSHS website (www.texasflu.org) for determining when to provide antiviral medications. This document will be updated regularly as needed.
3. Healthcare providers will follow guidance they receive from DSHS and through professional associations to determine who is specifically eligible for state stock antiviral medications.
4. Healthcare providers will write a prescription that identifies the patient needs their prescription dispensed from state stock. Information about how to write a prescription for state stock will be communicated to healthcare providers through DSHS and professional associations.
5. Healthcare providers will refer a patient who needs state stock antiviral medication to a DSHS contracted pharmacy. Healthcare providers will be informed of the DSHS contracted pharmacies in their area that carry state stock antiviral medication. Healthcare providers will receive this communication from DSHS and professional associations.

Initial Supply of State Stock Antiviral Medications to Independent Pharmacies

1. DSHS will determine which independent pharmacies will be participating based on where the independent pharmacies are located. For any county not served by a chain pharmacy, DSHS will work with all independent pharmacies in that county that wish to participate.
2. DSHS, via the DSHS Receiving, Staging, and Storing (RSS) site or via a pharmacy distributor will ship state stock antiviral medications to each participating independent via private supplier or state vehicle at the cost to DSHS. Initial stocking level to be shipped to each independent pharmacy will be determined by DSHS based on geography, usage of private stock in that area, amount of illness in the area, and amount of state stock available.

Re-supply of State Stock Antiviral Medications to Independent Pharmacies

1. When an independent pharmacy needs re-supply, the DSHS RSS or pharmacy distributor will ship directly to the independent pharmacy when request is received. The DSHS RSS will ship via private carrier or state vehicle to the independent pharmacy at the cost to DSHS.

Process for Dispensing State Owned Antiviral Medications through Independent Pharmacies (Continued)

Intended Use of State Stock Antiviral Medications in Independent Pharmacies

1. State stock antiviral medications are intended to serve the uninsured and underinsured who otherwise could not afford the cost of the antiviral medication they have been prescribed.

2. The use of state stock is reserved only for clients who present a healthcare provider's prescription that identifies the client as needing to have his/her prescription dispensed from the state stock.
3. If a patient with a regular prescription for antiviral medication states he/she cannot afford private stock price, a pharmacist at a DSHS contracted pharmacy can choose to dispense from state stock.
4. Pharmacies are allowed to charge a \$10 administrative fee to offset their costs on prescriptions filled by state stock. However, if a patient cannot afford the charge the fee must be waived.

Reporting Requirements

1. Inventory Updates: Each participating independent pharmacy will be asked to provide an inventory report every Tuesday at 10:00 a.m. to sns@dshs.state.tx.us listing the specific inventory of state stock in the pharmacy store. DSHS will provide a template for this report. Note: this reporting schedule may be changed to a daily reporting schedule, if necessary.
2. Patient Updates: If the pharmacy store is currently a registered user of ImmTrac, the state immunization record for Texas, the pharmacy store will report dispensing of antiviral medications through ImmTrac. If the pharmacy store is not currently registered in ImmTrac, the pharmacy store will fill out ImmTrac reporting forms, found online at <http://www.dshs.state.tx.us/immunize/immtrac/default.shtm>, and then fax the completed ImmTrac forms to DSHS where DSHS staff will enter the data into the ImmTrac database.

Process for Dispensing State Owned Antiviral Medications through Federally Qualified Health Centers and Community Health Centers

The following is the process the Texas Department of State Health Services (DSHS) will use to dispense state antiviral medications through Federally Qualified Health Centers (FQHCs) and Community Health Centers (CHCs) during novel H1N1 influenza virus response efforts.

Assumptions

1. The antiviral medications in the state stockpile ("state stock") are intended to meet gaps that may not be addressed through normal channels and in particular the needs of the uninsured or underinsured populations.
2. Healthcare providers will follow the guidance for clinicians posted on the DSHS website (www.texasflu.org) for determining when to provide antiviral medications. This document will be updated regularly as needed.
3. Healthcare providers will follow guidance they receive from DSHS and through professional associations to determine who is specifically eligible for state stock antiviral medications.
4. Healthcare providers will write a prescription that identifies the patient needs their prescription dispensed from state stock. Information about how to write a prescription for state stock will be communicated to healthcare providers through DSHS and professional associations.
5. Healthcare providers will refer a patient who needs state stock antiviral medication to a DSHS contracted pharmacy. Healthcare providers will be informed of the DSHS contracted pharmacies in their area that carry state stock antiviral medication. Healthcare providers will receive this communication from DSHS and professional associations.

Initial Supply of State Stock Antiviral Medications to Chain Pharmacies

1. All FQHCs and CHCs in Texas are encouraged to participate in the antiviral distribution network. DSHS will work with the Texas Association of Community Health Centers (TACHC) to recruit health centers.

2. TACHC and DSHS will confirm participating centers and will determine which health centers serve as distribution centers. Each health center that is a distribution center will distribute state stock antiviral medications to other health centers in the region.
3. The DSHS RSS (Receiving, Staging, and Storing) site will ship state stock antiviral medications to each FQHC/CHC that is designated as a distribution center via private supplier or state vehicle at the cost to DSHS. Initial stocking level to be shipped to each distribution center will be determined by DSHS based on geography, usage of private stock in that area, amount of illness in the area, and amount of state stock available.
4. In turn, each FQHC/CHC designated as a distribution center will ship state stock antiviral medications to all health centers served by that distribution center at their cost. The initial stocking level per health center will be based on usage of private stock, amount of illness identified in the target area, and the amount of state stock available. This decision will be made jointly by DSHS and TACHC.

Process for Dispensing State Owned Antiviral Medications through Federally Qualified Health Centers and Community Health Centers (Continued)

Re-supply of State Stock Antiviral Medications to Chain Pharmacies

1. FQHC/CHC re-supply will be done by ordering from the FQHC/CHC designated as the regional distribution center.
2. When health center designated as the regional distribution center needs re-supply, the DSHS RSS will ship to the regional distribution center when request is received. The DSHS RSS will ship via private carrier or state vehicle to the distribution center at the cost to DSHS.
3. The health center regional distribution center in turn will ship to the FQHCs/CHCs served by that regional distribution center.

Intended Use of State Stock Antiviral Medications in Chain Pharmacies

1. State stock antiviral medications are intended to serve the uninsured and underinsured who otherwise could not afford the cost of the antiviral medication they have been prescribed.
2. FQHCs and CHCs serve only their enrolled clinic patients.
3. The use of state stock is reserved only for clients who present a healthcare provider's prescription that identifies the client as needing to have his/her prescription dispensed from the state stock.
4. If a patient with a regular prescription for antiviral medication states he/she cannot afford private stock price, a pharmacist at a DSHS contracted pharmacy can choose to dispense from state stock.
5. Pharmacies are allowed to charge a \$10 administrative fee to offset their costs on prescriptions filled by state stock. However, if a patient cannot afford the charge the fee must be waived.

Reporting Requirements

1. Inventory Updates: Each FQHC/CHC will be asked to provide an inventory report every Tuesday at 10:00 a.m. to sns@dshs.state.tx.us listing the specific inventory of state stock in each health center. An FQHC/CHC that is the regional distribution center will need to provide an inventory report listing the health center's state stock and the overall state stock inventory at the distribution center. DSHS will provide a template for this report. Note: this reporting schedule may be changed to a daily reporting schedule, if necessary.
2. Patient Updates: If the FQHC/CHC is currently a registered user of ImmTrac, the state immunization record for Texas, the health center will report dispensing of antiviral medications through ImmTrac. If the FQHC/CHC is not currently registered in ImmTrac, the health center will fill out ImmTrac reporting forms, found online at <http://www.dshs.state.tx.us/immunize/immtrac/default.shtm>, and

then fax the completed ImmTrac forms to DSHS where DSHS staff will enter the data into the ImmTrac database.

Process for Dispensing State Owned Antiviral Medications through Health Service Regions

The following is the process the Texas Department of State Health Services (DSHS) will use to dispense state antiviral medications through DSHS Health Service Regions (HSRs) during novel H1N1 influenza virus response efforts.

Assumptions

1. The antiviral medications in the state stockpile (“state stock”) that are distributed to HSRs are intended to meet three needs: serving uninsured or underinsured populations, public health measures such as outbreak control, and stop-gap measures if routine supply channels breakdown.
2. HSRs will be provided antiviral medication from the state stock early in the course of a flu response event.
3. HSRs are licensed as Class D Pharmacies.

Initial Supply of State Stock Antiviral Medications to Health Service Regions

1. Every DSHS HSR received a regional cache of state stock in the spring of 2009.
2. DSHS HSRs received these shipments from the DSHS RSS (Receiving, Staging, and Storing) site.

Re-supply of State Stock Antiviral Medications to Health Service Regions

1. When a HSR needs re-supply, the RSS will ship to the HSR when a request is made through the state ordering system (TIMS). The RSS will ship via private carrier or state vehicle to the HSR.

Intended Use of State Stock Antiviral Medications in Health Service Regions

1. State stock antiviral medications in HSRs can be used for outbreak control measures in the HSR.
2. State stock antiviral medications in HSRs can be used for Local Health Departments (LHD’s) in outbreak control measures.
3. State stock antiviral medications in HSRs can be provided to hospitals as a stop-gap measure if private stock is depleted and routine supply channels break down. Depending on the severity of the outbreak and duration of time when private stock is depleted and routine supply channels are broken, the RSS may take over supplying hospitals directly.
4. State stock antiviral medications in HSRs can be provided to EMS or healthcare providers to use as prophylaxis if needed and if ordered by prescription by health professionals from those entities.
5. In special circumstances, and understanding delegation orders from the Regional Medical Director, state stock antiviral medications in HSRs can be used to meet the needs of the uninsured and underinsured in counties with no retail pharmacies.

Process for Dispensing State Owned Antiviral Medications through Health Service Regions (Continued)

Reporting Requirements

1. Inventory Updates: Each HSR will be asked to provide an inventory report on a weekly basis to sns@dshs.state.tx.us listing the specific inventory of state stock in the HSR, including any stock at LHDs within the HSR. DSHS will provide a template for this report. Note: this reporting schedule may be changed to a daily reporting schedule, if necessary.

2. Patient Updates: The HSR, and any LHDs that have HSR stock, will report dispensing of antiviral medications patient into ImmTrac, the state immunization record for Texas.

Prescribing and Dispensing State Owned Antiviral Medications

Last Updated 8/12/2009 Email sns@dshs.state.tx.us for more information

Sample Letter Inviting Pharmacies to Participate in the Texas Antiviral Distribution Network

TEXAS DEPARTMENT OF STATE HEALTH SERVICES

P.O. Box 149347
Austin, Texas 78714-9347
1-888-963-7111

DAVID L. LAKEY, M.D. TTY: 1-800-735-2989 COMMISSIONER www.dshs.state.tx.us

July 21, 2009

To Texas Federation of Drug Stores Community Pharmacies:

The Texas Department of State Health Services is developing a Texas Antiviral Distribution Network as one of the primary mechanisms for distribution of the state's emergency cache of antiviral medications. The purpose of this network is to ensure access to antiviral medications for the uninsured and underinsured. Please take a moment to review the enclosed contract and consider participating in this important initiative. Community pharmacies will play a very important role in the Texas Antiviral Distribution Network and will be a key partner in effectively distributing antivirals to Texans.

Background Information

If the H1N1 influenza pandemic worsens this fall prior to the widespread availability of a new H1N1 vaccine, there may be a period of time when there will be a high demand for antiviral medications (such as Tamiflu and Relenza). Texas has access to a large cache of antiviral medications created from two sources: the Texas allotment of the federal Strategic National Stockpile (SNS) and from purchases made by the Texas Department of State Health Services. Antiviral medications will be released from the state's cache and used within the Texas Antiviral Distribution Network to increase access for uninsured and underinsured Texans. The state cache can only be used when a flu pandemic has been declared by the U.S. Department of Health and Human Services.

All Community Pharmacies Are Encouraged to Participate

All community pharmacies are welcome and encouraged to participate in the Texas Antiviral Distribution Network. Due to a limited supply of antiviral medications in the state cache, if an abundance of pharmacies serving the same geographic area agree to participate, the possibility exists that not all community pharmacy store locations in that particular area will be selected to serve that area. The main consideration for selecting which specific pharmacy stores within each community will

receive state stock will be geographic location, population demographics, and the distribution and severity of disease. The goal is to create a network that will enhance distribution and convenience to Texans through a balance of community and independent pharmacy partners. Again, all community pharmacies are welcome and encouraged to participate, and participation is on an opt-in basis. All participating community pharmacies will be required to sign a contract with the Texas Department of State Health Services to enter the network.

Distribution of Antiviral Medications

The distribution of state stock antiviral medications will be accomplished using the traditional medical model. Patients will obtain prescriptions from prescribing medical providers and then take the prescriptions to participating pharmacies in order to receive medications from the state's antiviral cache. Only patients who have valid prescriptions specifying state stock antiviral medications will be eligible for the program. The antiviral medications from the state cache will be distributed to participating pharmacies in much the same way as you replenish your inventory currently. The Texas Department of State Health Services will retain ultimate control of when and how much inventory is released from the state's antiviral cache.

Conditions of Participation for Pharmacies

- The participating pharmacies will receive the antiviral medications from the state's antiviral cache at no charge.
- These antiviral medications will be dispensed at no charge to patients who present valid prescriptions specifying state stock antiviral medications.
- An administration fee, maximum of \$10 per prescription, may be charged by the dispensing pharmacy. However, the pharmacy must be willing to waive this fee if the patient expresses they are not able to pay this fee.
- The main criteria for selection of pharmacies will be geographic location and population demographics. Participating pharmacies must be willing to have state cache antiviral medications only in the specific store locations selected by the Texas Department of State Health Services.
- State stock antiviral medication is not permitted to leave the State of Texas under any circumstances. All distribution and delivery routes must remain within the State of Texas.
- Maintain the state stock inventory of antivirals physically separate from the community pharmacy's inventory. State stock cannot be used in place of Contractor stock at any time. The community pharmacy may use its stock to substitute for state stock, but no reimbursement will be available for this action.
- Maintain the state stock of antivirals in a safe and secure location during distribution, storage, and dispensing.
- Participating pharmacies will need to submit reports about quantities of state stock antiviral medication dispensed and on-hand. The frequency of these reports will vary based on the need for information corresponding to the severity of the pandemic. The Texas Department of State Health Services will work with each community pharmacy partner individually to streamline reporting and to ensure that the community pharmacy's usual reporting method can be used whenever possible.
- Communication channels will remain open between the Texas Department of State Health Services and all participating pharmacies.
- Confidentiality: All information provided by the Texas Department of State Health Services regarding state stock antiviral medications is strictly confidential. This includes, but is not limited to, any information about state stock antiviral medication supply, storage, distribution, and dispensing. All information provided by participating community pharmacies (i.e. levels of state stock dispensed

and on-hand, distribution channels, etc.) will remain strictly confidential. This information will only be shared with key emergency response professionals and will be done so under strict confidence.

Opt-In Process

Because of the possibility that we could be faced with a pandemic surge event this fall, we would appreciate your prompt consideration. If you are interested in participating in the Texas Antiviral Distribution Network and would like to learn more, please email us at sns@dshs.state.tx.us by close of business on Monday, July 27th, 2009 to express your interest.

After receiving statements of interest, the Texas Department of State Health Services will hold a conference call for all interested community pharmacies on Wednesday, July 29th, from 12:30:1:30pm CST. Conference call details will be sent to all community pharmacies who express interest in participating (via contacting sns@dshs.state.tx.us by July 27th). The Texas Department of State Health Services will also schedule one-on-one phone calls or meetings with each chain pharmacy interested in participating to discuss additional details as needed.

Thank you for reviewing this information about the Texas Antiviral Distribution Network. Community pharmacies will serve a critical role in helping their communities during this influenza response, and the Texas Antiviral Distribution Network can help ensure that all Texans, particularly our uninsured and underinsured community members, have access to the antiviral medications they need. We appreciate your interest in working with us during this H1N1 influenza response effort, and we look forward to working together to protect the health of Texans.

Sincerely,

Sample Contract for Pharmacies Participating in the Texas Antiviral Distribution Network

Contract

Recitation/Background

The Department of State Health Services (DSHS) is an agency of the government of the State of Texas. Among its duties is the preparation for the possibility of an H1N1 pandemic during the coming months (2009/2010), _____ (Pharmacy) is a corporation properly licensed to do business in the state of Texas, operating retail pharmacies in Texas. As it is in the mutual interest of DSHS and Pharmacy to properly and efficiently distribute Antivirals in this state, they have entered into the following agreement.

Agreement

Pharmacy will receive for distribution a stock of antivirals from DSHS deemed appropriate for the distribution area assigned to Pharmacy.

Pharmacy will be allowed to distribute the antivirals through normal pharmacy operations subject to the following conditions.

- Pharmacy will receive the antiviral medications from the state's antiviral cache at no charge.

- These antiviral medications will be dispensed at no charge to patients who present valid prescriptions specifying state stock antiviral medications.
- A dispensing fee, maximum of \$10 per prescription, may be charged by the dispensing Pharmacy. However, the Pharmacy must be willing to waive this fee if the patient expresses they are not able to pay this fee.
- The main criteria for selection of pharmacies will be geographic location and population demographics. Pharmacy must be willing to have state cache antiviral medications only in the specific store locations selected by the Texas Department of State Health Services. The area covered by this agreement is _____. Pharmacy shall not distribute the antivirals covered by this agreement outside of this area. Changes to this service area may only be made with the written permission of DSHS.
- State stock antiviral medication is not permitted to leave the State of Texas under any circumstances. All distribution and delivery routes must remain within the State of Texas.
- Pharmacy shall maintain the state stock inventory of antivirals physically separate from the Contractor's inventory. State stock cannot be used in place of Contractor stock at any time. The Contractor may use his stock to substitute for state stock, but no reimbursement will be available for this action.
- ☐ Pharmacy shall maintain the state stock of antivirals in a safe and secure location during distribution, storage, and dispensing.
- Pharmacy shall submit reports about quantities of state stock antiviral medication dispensed and on-hand. The frequency of these reports will vary based on the need for information corresponding to the severity of the pandemic. DSHS shall work with each community Pharmacy partner individually to streamline reporting and to ensure that the community Pharmacy's usual reporting method can be used whenever possible.
- Communication channels will remain open between DSHS and all participating pharmacies.
- Confidentiality: All information provided by the Texas Department of State Health Services regarding state stock antiviral medications is strictly confidential under Health and Safety Code §161.0213 and other provisions of state law. This includes, but is not limited to, any information about state stock antiviral medication supply, storage, distribution, and dispensing. All information provided by participating community pharmacies (i.e. levels of state stock dispensed and on-hand, distribution channels, etc.) will remain strictly confidential, subject to the provisions of state law. This information will only be shared with key emergency response professionals and will be done so under strict confidence.

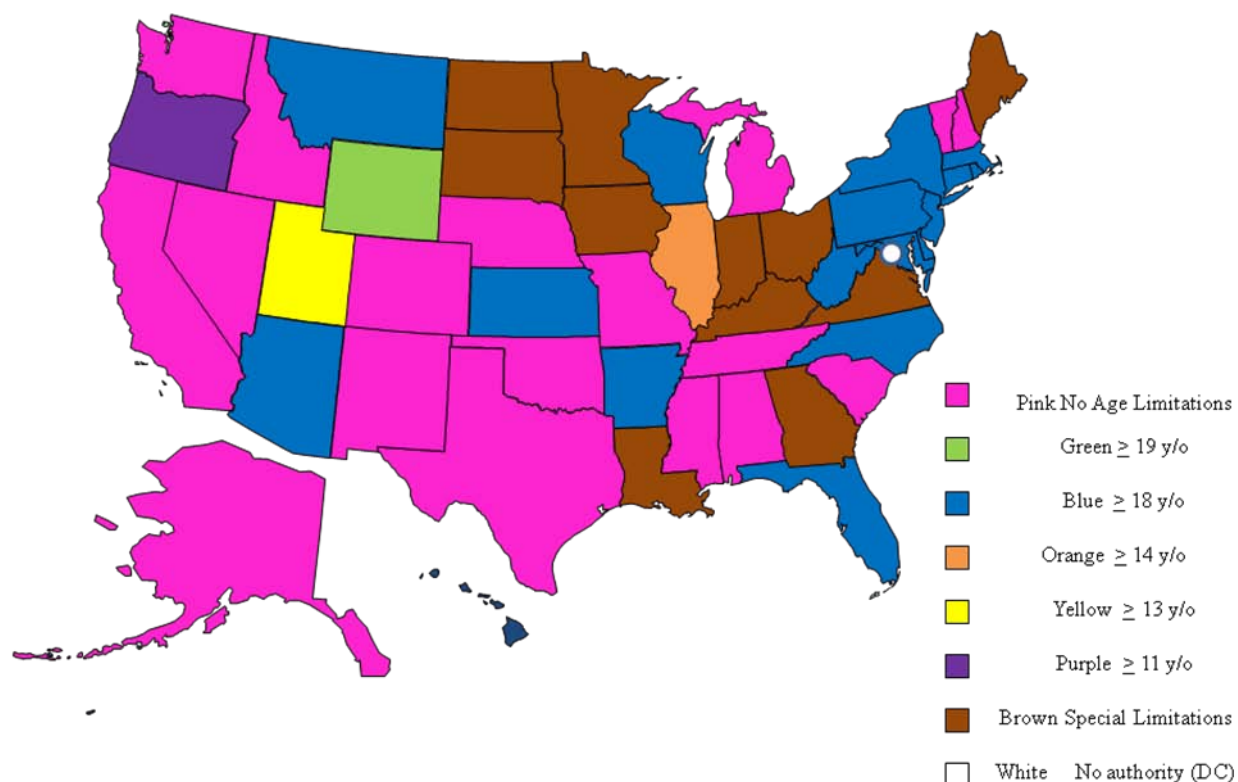
If, in the opinion of DSHS the Pharmacy fails to adhere to the conditions above, Pharmacy shall immediately return all undistributed antivirals to DSHS. Failure to adhere to these conditions may disqualify Pharmacy from participating in this and future pharmaceutical distribution efforts. DSHS reserves the right to pursue other remedies allowed by law for failure to adhere to these conditions.

To the extent allowed by state law, Pharmacy shall be considered a "volunteer performing a homeland security activity at the request or under the direction of an employee of a state agency" and entitled to the civil liability consideration afforded by Government Code §421.061.

Texas Department of State Health Services Texas Antiviral Distribution Network Tool Kit Last Updated 8/12/2009 Email sns@dshs.state.tx.us for more information

Appendix D: Pharmacist Authority, Age of Patient Limitations¹⁷

Pharmacist Authority to Administer Influenza Vaccines Age of Patient Limitations



¹⁷ American Pharmacists Association. September 2009.

State	Extent of Administration Authority ¹⁸	Administration Authorized By*	Patient Age	Allowable Vaccines/ Drugs	Other	Allowed Route(s)
Alabama	Vaccines: Full	Standing order or Rx	Any	Any vaccine		Any
Alaska	Vaccines: Full	Protocol as part of collaborative agreement	Any	Any vaccine		Any
Arizona	Vaccines: Partial (Vaccine Legislation Approved/signed 7-10-09, Effective 9-30-09, 11-2009 RPh will begin)	BOP approved protocol (no rx needed)	≥ 18	CDC Recommended Adult Vaccines, CDC's International Travel Vaccines, Epinephrine and diphenhydramine		Any
Arkansas	Vaccines: Partial	Protocol, standing order. Rx or other order	≥ 18	Any vaccine		Any
California	Vaccines: Full	Protocol	Any	Any vaccine		Any
Colorado	Vaccines: Full	Protocol	Any	Any vaccine		Any
Connecticut	Vaccines: Limited	Protocol or Rx	≥18	Influenza		Any
Delaware	Vaccines: Partial	Protocol for injectables. Any by Rx.	≥18	Any vaccine		Injection or oral
District of Columbia Potential rule under consideration	Vaccines: Limited	If ≥ 18, protocol, standing order or Rx flu or pneumo only; other vaccines Rx & protocol from same MD (If <18, protocol with patient's physician - check)	Any? 18 and over?	Influenza and emergency anaphylactic treatment		Any
Florida	Vaccines: Limited	Protocol from supervisory M.D.	≥ 18	Influenza		Any

¹⁸ **General Extent of Pharmacist Immunization Administration Authority (all vaccines)**

Full/Nearly Full: Gives pharmacists full or nearly full authority to administer any vaccine to patients of any age via any route of administration under a *protocol or standing order*

Partial/Limited: Gives pharmacists only partial or limited authority to administer vaccines by: requiring a patient-specific *prescription*, restricting the *types of vaccines*, restricting the patient's *age*, or other *significant restrictions*

Operational Framework – Appendix D

Georgia	Vaccines: Partial (but see legislation pending)	Rx, patient -specific collaborative agreement or facility protocol	< 13 influ only with protocol & Rx ; 13-17 influ only w/ parent/legal guardian consent	Influenza, Epi	Any
Hawaii	Vaccines: Partial	Protocol, order or collaborative agreement	≥18	Any vaccine	Injection, oral or intranasal
Idaho	Vaccines: Full	Rx or pharmacist-specific agreement with physician	Any	Any vaccine	Any
Illinois	Vaccines: Partial	For outpatients, protocol or Rx. For inpatients, per hospital policy	≥14	Any vaccine	Injection, oral, topical and inhalation
Indiana	Vaccines: Limited	Protocol or Rx for influenza or other vaccine in declared emergency; Rx o/w for all others	> 18 y/o; and 14-17 year olds w/ parent or guardian consent	Any vaccine	Any
Iowa	Vaccines: Limited	Protocol or Rx for influenza and pneumonia. Rx for all others	≥ 18 for influenza or pneumo-coccal on protocol. Any age for Rx	Any vaccine	Any
Kansas	Vaccines: Partial	Protocol or Rx	≥ 18	Any vaccine	Any
Kentucky	Vaccines: Partial	Protocol or Rx	≥18 for protocols. Any age if by Rx	Any vaccine	Any
Louisiana	Vaccines: Partial	Patient- specific "authority to administer," collaborative agreement for practitioner's patients, or per Dept. of Health authority	Any if per "authority to administer." ≥16 if per collab. agreement	Any vaccine	Any
Maine (not till 9-12-09)	Vaccines: Full	Protocol, standing order or Rx for all IZ except for influenza (must submit protocol to the Board no later than 20 calendar days after the effective protocol date)	≥ 9 for influenza; ≥18 for IZ rx and protocol	Influenza, intranasal influenza, pneumococcal, shingles, herpes zoster, tetanus-diphtheria-pertussis, booster tetanus-diphtheria	Any
Maryland	Vaccines: Limited	Protocol for influenza. Rx for pneumococcal or zoster	≥18	Influenza, pneumococcal pneumo and zoster	Injection or inhalation

Operational Framework – Appendix D

Massachusetts	Vaccines: Limited	MDPH-approved Model Standing Order for Influenza. Rx for all others	≥ 18	Influenza, HepA&B, Hib, HPV, Immune Globulin, IPV, MMR, Meningo- coccal, MCV4, Pneumonia, Td/DT/Tdap, Varicella	Any
Michigan	Vaccines: Full	Protocol, local health dept. authorization or Rx	Any	Any vaccine	Any
Minnesota	Vaccines: Partial	Protocol or standing order	≥10 for influenza. ≥18 for all others	Any Vaccine	Any
Mississippi	Vaccines: Full	Protocol or Rx	Any	Any vaccine	Any
Missouri	Vaccines: Partial	Protocol for Influenza to >12 yrs. Rx for influenza <12 yrs. and any other vaccine	Any	Any vaccine	Any
Montana	Vaccines: Partial	Protocol via collaborative agreement	≥18	Any vaccine	Any
Nebraska	Vaccines: Full	Protocol or Rx	Any	Any vaccine	Any
Nevada	Vaccines: Full	Protocol or Rx	Any	Any vaccine	Injection or Intranasal if by Rx. Any route if per protocol.
New Hampshire	Vaccines: Partial	Protocol or Rx	Any	Influenza	Any
New Jersey	Vaccines: Partial (pending final rules approval)	Protocol, Rx or as part of govt.- sponsored program	≥18	Any vaccine, plus diphenhydramine and epinephrine	Injection, inhalation or oral
New Mexico	Vaccines: Full	Pharmacist qualified for "prescriptive authority" per collaborative agreement and Board protocol	Any	Board list of 20+ vaccines, plus any other if qualified for Prescriptive Authority or per state health dept.	Any
New York	Vaccines: Limited	Protocol or Rx from prescriber (MD,RN)within defined geographic area	≥18	Influenza and pneumonia and treatment for anaphylaxis	Any
North Carolina	Vaccines: Limited	Protocol, standing order, collaborative agreement or Rx.	≥18	Influenza, pneumonia, zoster and emergency meds by protocol or Rx. Any vaccine by patient-specific collab. agreement if a qualified "Clinical Pharmacist Practitioner"	Any

Operational Framework – Appendix D

North Dakota	Vaccines: Partial	Protocol or Rx	≥18 for injectable vaccines. Any age for all others	Any vaccine	Any
Ohio	Vaccines: Limited	Protocol	≥14 for influenza. ≥18 for all other vaccines	Influenza, pneumonia, hepatitis A & B, tetanus, meningitis, diphtheria, pertussis, diphenhydramine and epinephrine	Any
Oklahoma	Vaccines: Partial	Rx (rule change pending to drop patient- specific requirement - do not need rx from PCP, still need agreement/contract)	Any	Any vaccine	Any
Oregon	Vaccines: Full	State-approved protocol	≥11 for all vaccines	20 vaccines that have State-approved protocols (May 2009 added Meningococcal, Tdap, Varicella, HPV, and expanded influenza)	Any
Pennsylvania	Vaccines: Partial	Protocol or Rx	≥18 + 1 day for inject- able vaccines. Any age for all others	Any vaccine	Any
Puerto Rico	Vaccines: None	N/A	N/A	N/A	N/A
Rhode Island	Vaccines: Partial	Protocol or Rx	≥ 18	Any vaccine	Any
South Carolina	Vaccines: Nearly Full	Protocol or Rx	Any	Any vaccine	Any
South Dakota	Vaccines: Limited	Influenza by protocol or Rx. Zostavax by Rx	Influenza ≥18; Zostavax ≥60	Influenza and Zostavax	Any
Tennessee	Vaccines: Full	Protocol or Rx	Any	Any vaccine	Any
Texas	Vaccines: Nearly Full	Protocol, standing order or Rx, but if patient <14, protocol must be patient-specific	Any	Any vaccine	Any
Utah	Vaccines: Partial	Protocol or Rx	≥13	Influenza, HZ, Hep A&B, Papilloma, MMR, Meningococcal, Tdap/Td, Pneumonia, Varicella, others w/ Bd. approval, Epinephrine and Diphenhydramine	Any
Vermont	Vaccines: Full	Protocol, collaborative agreement or Rx	Any (but will CHANGE to ≥ 18 when rules finalized 10/1/09)	Any vaccine	Any

Operational Framework – Appendix D

Virginia	Vaccines: Full	Protocol, Rx or patient-specific collaborative agreement	Influenza only: ≥ 6 mon with no contraindications to vaccines & under direction & immediate supervision of RN or MD; Standing Orders ok	Any vaccine	Any
Washington State	Vaccines: Full	Protocol	Any	Any vaccine	Any
West Virginia	Vaccines: Limited (under rules expected to become final in early 2009 and reflected here)	State statute	≥18	Influenza and pneumonia, diphenhydramine and epinephrine	Any
Wisconsin	Vaccines: Partial	Protocol	≥18	Any vaccine	Any
Wyoming	Vaccines: Partial	Prescriptive authority for "healthy" adult. Rx for "high risk" adult	≥19	Influenza, HepA&B, Meningococcal, MMR, HPV, Pneumonia, Td, Tdap, Varicella, Zoster and epinephrine	Any
* Rx = Requires patient-specific prescription Protocol/standing order = From licensed physician. Need not be patient-specific					

Appendix E: Template Executive Order

NOTE: This template is to serve as a guide for the content and issues that may need to be addressed in a formal order; however, state requirements and official powers for an executive order differ. Each state will need to work within their individual powers and requirements.

Template Executive Order to be issued and signed by each state [governor/authorized official] pursuant to the authority contained in _____ Code sections _____, the [S/THD/authorized official] hereby issues the following order:

Public Health Order: The _____ of the State of _____ hereby issues the following order in response to the 2009 H1N1 virus outbreak in the State of _____. To protect the citizens and increase access to needed vaccination in a timely manner, the [S/THD/authorized official] is therefore authorized to take the necessary steps to utilize all necessary health care professionals and medical resources. This order provides for the suspension of applicable existing regulations related to the involvement of services by pharmacists in the State of _____:

Order issued to: All _____ licensed health care providers (pharmacists, physicians, nurses), hospitals, clinics, pharmacies, local boards of health, public health agencies, and [insert any other applicable groups]

Conditions of Order: The order only applies to activities related to the prevention and control of the 2009 H1N1 virus in the State of _____. You are hereby ordered to immediately comply with the following to protect the public health and prevent and control the spread of 2009 H1N1:

1. Pharmacists who are recognized as having qualifications in the state as an immunizing pharmacist shall be permitted to administer available 2009 H1N1 virus vaccine in accordance with the pharmacist's certification and to current guidance issued by the Centers for Disease Control and Prevention (CDC).
2. The authority to pharmacists for the activities listed in number 1 above is granted by this order.

If you have any questions regarding this Order, please call [insert phone number].

Effective date of order: [insert dates]

Executed by: _____
[S/THD/authorized official] Date

[governor/authorized official] Date

Appendix F: Template Agreement

I. Introduction

This Agreement is entered into as of _____, 2009 by and between _____ (hereinafter “Health Department”) and _____ (hereinafter “Pharmacy”). This Agreement establishes a relationship of cooperation for administration of the 2009 H1N1 vaccine, including all appropriate aspects therein.

Pharmacy locations covered under this Agreement include: _____

II. Requirements

As part of this Agreement, each party will agree to the activities outlined below.

Pharmacy agrees to:

1. Commitment
 - a. Provide pharmacists and staffing (as able) to administer vaccinations in accordance to the CDC H1N1 Vaccine Provider Agreement requirements and in accordance with this Agreement with the Health Department
 - b. Designate and train staff responsible for administering vaccine.
 - c. Provide primary and secondary points of contact to the Health Department, including emergency contact information.
 - d. Provide projections to the Health Department of the Pharmacy’s capacity and expected model of vaccine administration plan.
 - e. Abide by a mutually agreed upon communication schedule.
2. Vaccine Receipt and Storage
 - a. Receive vaccine and ancillary supplies at designated site(s), as registered with the Health Department.
 - b. Notify the authorized delivery agent of any discrepancies between the order and delivery.
 - c. Follow storage and handling instructions in accordance with the package insert provided with the vaccine and in accordance with the CDC’s Vaccine Storage and Handling Toolkit (<http://www2a.cdc.gov/vaccines/ed/sh toolkit/default.htm>.)
 - d. Secure vaccines and supplies.
 - e. Report unused vaccine to the Health Department and transfer or dispose of unused vaccine in accordance with applicable standards and regulation.
3. Vaccine Administration
 - a. Administer vaccine according to accepted practice, following the ACIP priority recommendations and under the guidance of the Health Department. Administration should be in accordance with the recommended immunization schedule, dosage, and contraindications, unless there are exceptions based on medical judgment or state law.
 - b. Provide a vaccine information sheet and immunization card to each vaccine recipient.
4. Vaccine Documentation and Reporting
 - a. Provide documentation of vaccines administered as required in the CDC H1N1 Vaccine Provider Agreement and in accordance with the Health Department.
 - b. Maintain and make available all vaccine administration records for three years and comply with all necessary patient information confidentiality requirements as necessary.
 - c. Report any adverse reactions using the Vaccine Adverse Events Reporting System (VAERS).
5. Vaccine and Administration Compensation
 - a. Not charge for the vaccine or supplies.

- b. Charge for the administration of the vaccine to the appropriate entity up to the established regional Medicare rate (or Medicaid where applicable).
- c. Provide vaccine free of charge, when feasible, to patients who have no method of payment.
- d. Refer patients to the Health Department if they cannot pay and Pharmacy cannot provide vaccine free of charge.

Health Department agrees to:

- 1. Keep Pharmacy apprised of expected delivery dates to the best of its ability.
- 2. Provide novel H1N1 vaccine and ancillary supplies (needles, syringes, sharps containers, alcohol swabs, and patient immunization cards) in accordance with the federally-funded distribution system.
- 3. Establish a reporting system for vaccine dose administration.
- 4. Update Pharmacy on appropriate information (vaccine availability, changes in priority groups, etc.) in a timely manner and serve as a point of information regarding the campaign.
- 5. Provide primary and secondary points of contact to the Pharmacy, including emergency contact information.
- 6. Abide by a mutually agreed upon communication schedule.

III. Indemnification

Pharmacy agrees to defend, indemnify and hold harmless the Health Department (including its officers, agents and employees) from and against any and all claims, demands, liabilities and costs incurred by the indemnified party, including reasonable attorney's fees, directly or indirectly arising out of or in connection with the indemnifying party's performance of any service or any other act or omission by or under the direction of the indemnifying party or its officers, agents or employees.

IV. Liability

Health Department and Pharmacy will be independently liable for the use and provision of assets, in accordance with applicable liability law. The parties expressly agree that no provision of this agreement is in any way intended to constitute a waiver by the state or the pharmacy of any immunities from suit or liability that the Health Department or the Pharmacy may have by operation of law.

Protection under Public Readiness and Preparedness Act is defined and limited by the existing HHS declarations, amendments and extensions of the declarations and the "emergency use authorizations" issued by the Food and Drug Administration.

V. Length of Agreement

This agreement shall be in effect for one (1) year.

VI. Discontinuation of Agreement

The Health Department or Pharmacy may terminate this agreement without cause upon giving the other party a 30-day notice. Upon termination, the Pharmacy shall return or dispose of any unused vaccine and supplies as directed by the Health Department. Both parties shall comply with all appropriate and agreed upon procedures for any vaccine administered prior to discontinuation.

VII. Notices

Any notices required to be given either by Health Department or Pharmacy to the other party under this Agreement shall be given in writing and sent to the other party at designated address.

VIII. Amendment

This Agreement shall not be supplemented, amended, or modified except on the express written agreement of the parties.

IN WITNESS WHEREOF, the Parties hereto have caused this Agreement to be executed by their duly authorized representatives as of the date set forth above

Authorized official signature

Authorized official signature

Health Department

Pharmacy

Name: _____

Name: _____

Title: _____

Title: _____

Date: _____

Date: _____