Novel H1N1 MASS VACCINATION PLAN

September 22, 2009

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OVERVIEW

INTRODUCTION

For more than five years, the United States has been planning for a potential response to an avian pandemic influenza virus. Planning scenarios have included the following assumptions: 1) that the pandemic influenza strain would be severe and deadly; 2) a vaccine would not be available for some time, and once it did become available, the supply would be insufficient to vaccinate large numbers of people; and 3) that daily activities would be disrupted significantly, people would not be able to work and infrastructure such as healthcare, public safety, and utilities would be threatened.

Although the novel H1N1 virus outbreak that began in the spring of 2009 has not been severe, it is a serious disease especially for individuals with certain risk factors. A vaccine has been developed and is currently in clinical trials. Vaccine for novel H1N1 is expected to be available in limited quantities beginning in early-October, 2009.

Texas will depend on all healthcare providers to ensure that the novel H1N1 vaccine is available to everyone who wishes to be vaccinated. Healthcare providers include, but are not limited to physicians, physician assistants, nurses, nurse practitioners, and community vaccinators in various settings such as doctors' offices, clinics, hospitals, pharmacies, schools and work settings.

GOAL

The goal of the mass vaccination plan is to vaccinate all persons in Texas who choose to be vaccinated against the novel H1N1 influenza.

OBJECTIVES

1. Minimize death and severe disease in high-risk populations
2. Maintain adequate health care and emergency medical services
3. Ensure timely vaccination
4. Vaccinate all persons who wish to be vaccinated after an initial effort to vaccinate priority groups
5. Track and monitor vaccination adverse events
6. Ensure accountability in the ordering, distribution, and administration of the novel H1N1 vaccine

ASSUMPTIONS

Planning assumptions for the implementation of the novel H1N1 vaccination program include:

- Eventually there will be enough vaccine for every man, woman, and child over six months of age who would like to receive the vaccine.
- Not all of the vaccine will be available at the same time, but rather, will become available over a period of time.
- Until everyone has had the opportunity to obtain vaccine, certain individuals in our society will have priority over others to receive vaccine first. The list of priority groups may change as the disease progresses over time.
- The federal government will be providing vaccine at no cost to persons in the United States. Health insurance companies, Medicaid, and Medicare will likely reimburse providers for administering the vaccine to eligible individuals; others may be charged an out-of-pocket administration fee.
- The Centers for Disease Control and Prevention (CDC) will coordinate the distribution of the vaccine at the federal level.
- The Texas Department of State Health Services will manage and coordinate the allocation and distribution of the vaccine in Texas.
- Public health and private healthcare providers, including non-traditional providers like mobile mass vaccinators and schools, will partner together to implement the vaccination program to ensure that all Texans have access to vaccine.
- Children between 6 months and 9 years of age: Two doses of the H1N1 vaccine
- All persons 10 years of age and older: One dose of the H1N1 vaccine
- Because the situation is fluid and ever-changing, all partners need to remain flexible.
- H1N1 vaccination will co-occur with seasonal flu vaccination and administration of antivirals.

STAKEHOLDERS

The successful implementation of the novel H1N1 vaccine will require the cooperation and collaboration of public and private sectors, to include public and private healthcare providers, businesses, schools, and higher education throughout Texas. The novel H1N1 vaccine will not be available through the usual purchasing and ordering mechanisms used for seasonal flu vaccine as all novel H1N1 vaccine distribution will be coordinated through the Texas Department of State Health Services (DSHS).

DSHS is working with stakeholders statewide in key aspects of the vaccine implementation, including education and dissemination of important information as the situation unfolds.

VACCINE MANUFACTURING INFORMATION

There are five manufacturers of the novel H1N1 influenza vaccine. They include Sanofi-Pasteur, GlaxoSmithKline, CSL Biotherapies Ltd., Novartis, and MedImmune.

Both live attenuated and inactivated novel influenza A (H1N1) 2009 monovalent vaccine formulations will be available initially. The vaccine will be made available in multi-dose vials, prefilled syringes and nasal sprayers. It is anticipated that there will be sufficient preservative-free vaccine in single dose syringes for young children and pregnant women.

FDA-approved H1N1 vaccines undergo the same rigorous FDA manufacturing oversight, product quality testing, and lot release procedures that apply to seasonal influenza vaccines. H1N1 vaccines are licensed by the FDA and are manufactured using processes which have a long record of producing safe seasonal influenza vaccines.

VACCINE EMERGENCY USE AUTHORIZATION (EUA)

If an emerging public health threat is identified for which no licensed or approved product exists, the Project BioShield Act of 2004 authorizes the Food and Drug Administration Commissioner to issue an Emergency Use Authorization promising countermeasures to be disseminated quickly to protect the safety of the U.S. population.

Several vaccines containing an adjuvant are being studied, but probably will not be available initially. These vaccines would require an Emergency Use Authorization (EUA). Additional guidance will be provided if adjuvanted vaccines are made available.

TIMING OF VACCINE AVAILABILITY

The CDC has informed States that planning for the availability of the novel H1N1 vaccine should be based on the concept that there will be enough vaccine to vaccinate every man, woman, and child six months of age and older who would like to receive the vaccine.

At this time the CDC expects the following number of vaccine doses will be available nationally in October. These are planning estimates and it is possible that they may change.

National Availability

Early October	15, 670,000
Mid October	29,530,000
Late October	18,600,000
Total October	63,800,000

CDC will allocate vaccine in accordance with population and has informed Texas that the State's share is 7.605% of the national total. On this basis, DSHS estimates that the vaccine quantities available to Texas will be:

Per the 22 August, 2009 CDC Communication to Association State and Territorial Health Officials (ASTHO)

Texas' Availability would be:

Early October	1,191,704
Mid October	2,245,757
Late October	1,414,530
Total October	4,851,991

Not all vaccine formulations will be available simultaneously. For example, a vaccine type indicated for children less than 36 months of age may not be available until late October. Some vaccine types have limiting indications (e.g. not recommended for those of certain ages or with certain conditions). DSHS will take these factors into consideration in determining how best to distribute vaccine.

CDC'S ADVISORY COMMITTEE ON IMMUNIZATION PRACTICES (ACIP) PRIORITY GROUPS FOR NOVEL H1N1 VACCINATION

The CDC's ACIP prioritization of populations is based on epidemiological and clinical data related to the spring 2009 novel H1N1 epidemic.

PRIORITY GROUPS (IN NO PARTICULAR ORDER)

- Pregnant women
- Household contacts and caregivers for children younger than six months of age
- Healthcare and emergency medical services personnel
- All people six months through 24 years of age
- Persons 25 years through 64 years of age who have health conditions associated with higher risk of medical complications from influenza disease

Once the groups listed above have had the opportunity to receive vaccine, healthy individuals 25 years of age and older (including senior citizens) will be offered vaccine, subject to availability.

SUB-GROUP PRIORITIES (IN NO PARTICULAR ORDER)

If there is initially a limited supply of vaccine, the Advisory Committee on Immunization Practices (ACIP) (as of 29 July 2009) recommends the following subset of the initial priority groups receive vaccination until vaccine availability increases:

- Pregnant women
- Household contacts and caregivers for children younger than six months of age
- Healthcare and emergency medical services personnel who have direct contact with patients or infectious material
- Children aged six months through 4 years
- Children and adolescents age 5 through18 years who have health conditions associated with higher risk of medical complications from influenza disease.

RISK COMMUNICATION

The Texas Department of State Health Services (DSHS) is currently developing a statewide flu public awareness campaign to include social media, outreach, media relations, paid media, webinars, Provider Toolkits, and educational videos.

A call center has been established to assist in communication. In coordination with the statewide 2-1-1 Texas Information and Referral Network (TIRN), a program of the Health and Human Services Commission (HHSC), DSHS can address calls from both the general public as well as medical providers

or other professional groups. This collaboration will result in the provision of public education and outreach at the local level and establish the infrastructure needed to address future emergencies. Frequently asked questions generated by the public will be used to identify any gaps or needs that can be addressed through a public awareness campaign.

DSHS VACCINATION STRATEGY

GOAL

The above strategy is based on the most current CDC vaccine forecast and is subject to change. The DSHS vaccination strategy was developed with the ACIP priority group recommendations in mind. A primary objective is to ensure that priority groups have the first opportunity to receive vaccine. DSHS will follow the recommendations of the ACIP and the CDC.

However, decisions for vaccine allocation during October when vaccine is in limited supply may be affected by the specific formulations that are being shipped from manufacturers thru CDC. During this phase of limited supply the sub-group priorities are:

- Pregnant women
- Household contacts and caregivers for children younger than six months of age
- Healthcare and emergency medical services personnel who have direct contact with patients or infectious material
- Children aged six months through 4 years
- Children and adolescents age 5 through 18 years who have health conditions associated with higher risk of medical complications from influenza disease

When additional vaccine becomes available in November, efforts will be focused on vaccinating the remaining priority groups.

In late November, when vaccine will likely be readily available, all others will be encouraged to seek vaccination.

PROVIDER METHODOLOGY

Given the magnitude of the vaccination effort, public and private sectors must partner for this effort to be successful. All healthcare providers are strongly encouraged to vaccinate their clientele and staff per ACIP recommendations. Local, regional, and state public health will identify, engage, and register private-sector partners for vaccine administration. Public health will assess the gaps in the private and public capabilities for mass vaccination implementation and provide supportive activities as needed to meet the needs. The following strategies (list not exhaustive) will be used:

- Identifying, engaging, and enrolling private-sector partners for potential vaccine administration
- Administering vaccine at public health-organized clinics or other venues and point-of-dispensing (POD) sites organized on behalf of public health agencies
- Entering into agreements with vaccinators and others for mass vaccination
- Supporting logistical and administrative costs associated with vaccine administration sites
- Maintaining cold-chain capacity where needed
- Assuring vaccine safety monitoring and reporting
- Tracking vaccine and vaccine ancillary supplies
- Monitoring and reporting of vaccine doses administered
- Implementing communication strategies to reach the public, especially those priority groups included in the Advisory Committee on Immunization Practices (ACIP) recommendations
- Dispensing/distributing antiviral drugs
- Implementing community mitigation activities/measures
- Identifying medically vulnerable populations and providing access to vaccinations through mobile vaccination teams, home-based vaccination, institutional vaccination, outreach teams, or other similar means.
- Assuring adequate security at central receiving sites and/or vaccine administration sites
- Developing information technology (IT) infrastructure for tracking H1N1 personnel, contractors, contracts, inventory, grant funding, and other expenses
- Space rental, refrigeration, and transportation expenses related to distribution of vaccine from central receiving sites to vaccine administration sites

DSHS Health Service Regions and Local Health Departments will work with communities in their jurisdictions to determine the most appropriate way to address gaps in their jurisdiction according to priority groups for the administration of the H1N1 vaccine.

The state (DSHS) is responsible for:

1. Allocating and distributing novel H1N1 vaccine
2. Tracking doses administered and vaccine adverse reactions

Local Health Departments, and the Health Service Regions which are acting as Local Health Departments, are responsible for:

1. Coordinating H1N1 activities within their jurisdiction
2. Acting as vaccine safety nets for individuals who are uninsured / underinsured and do not have other places to go for vaccine.

HEALTHCARE PROVIDER PRE-REGISTRATION FOR NOVEL H1N1 VACCINE

Providers must pre-register by logging on to www.Texasflu.org and completing the Healthcare Provider Pre-Registration form. Registering providers must be or have an agreement with an individual licensed to prescribe medications in the State of Texas, or be on a federal military installation within the state. Providers are encouraged to complete this registration form online by September 13, 2009 to assist DSHS in statewide distribution planning. Providers may continue to register after that date but DSHS may not be able to guarantee access to the early vaccine allocations. All providers will be required to complete the CDC agreement form. DSHS expects that upwards of 10,000 providers will register to participate. Process steps are outlined in Appendix C.

DSHS will review the pre-registration forms submitted and will contact providers for clarification if necessary. Regional DSHS Immunization Program Managers will receive a list of providers who have registered, along with their contact information and estimated patient populations by priority group. These data will assist with planning efforts and will be shared with appropriate regional and local public health management, who will identify gaps in coverage and make efforts to recruit providers to fill those gaps.

DSHS will develop and implement a program to match professional license numbers from registration to the list of licensed professionals from the appropriate licensing entity to check that (1) the number is valid and in active status and (2) that the name matches that of the medical professional authorizing the registration.

HEALTHCARE PROVIDER REGISTRATION FOR NOVEL H1N1 VACCINE

All registered providers will be asked to complete and submit a Provider Agreement as required by CDC. Providers will be required to sign the agreement prior to receiving vaccine. All providers who receive novel H1N1 vaccine must agree to report doses administered information to DSHS. Providers who have questions or do not have access to the internet may contact the call center for assistance. Additional information on the registration process is located in Appendix D.

VACCINE ORDERING

DSHS is currently developing an online H1N1 ordering and reporting system that is scheduled for completion in mid October. Once completed, this system will; (1) notify providers when vaccine is available for order; (2) allow providers to order vaccine; (3) allow providers to adjust population estimates and other provider information; and (4) allow providers to report weekly aggregate doses administered data.

When DSHS receives notification from CDC regarding dose availability, DSHS will allocate vaccine, and providers will be notified via email to check the TexasFlu.org website for a pending order. Once logged

in, the site will identify the vaccine type and number of doses available for order. Providers must enter the number of doses of each vaccine type that they wish to order. Once the order is made and prior to clicking the submit button, providers will verify (1) their hours of operation, (2) their refrigeration capacity is sufficient to properly store the ordered vaccines; and (3) that vaccine temperatures are checked and maintained within acceptable ranges. Ordering is expected to be a simple and basic process, and is outlined in Appendix E. Providers without Internet access can place their order by contacting the call center.

The ordering system is currently under development and there is a possibility that vaccine may become available before the system is operational. In the interest of distributing vaccine as quickly as possible, providers have the option of receiving an initial order without prior approval. During pre-registration, providers are being asked to consider available refrigeration space and to indicate the maximum number of doses they would like to receive for an initial order.

ALLOCATION AND DISTRIBUTION

ALLOCATION

Initially, when vaccine supply is limited, vaccine will be allocated to providers according to the data provided at pre-registration on the number of people they expect to vaccinate in each of the groups recommended to receive vaccine. Once the vaccine supply is robust enough to meet demand, providers will receive the vaccine according to their need and will be able to place orders without limitations. (See Appendix A)

DISTRIBUTION

DSHS will ship vaccine to the provider who will administer it regardless of how many doses that provider orders or needs.

DSHS will use two distributors to ship the novel H1N1 vaccine to Texas providers. DSHS has determined that the services of the national distributor McKesson must be supplemented with another state contracted distributor in order to meet the distribution needs of the state.

Process steps for allocation and distribution are outlined in Appendix A and Appendix B shows the distribution flow. (See Appendix B)

VACCINE ADMINISTRATION

Texas' plan calls for dispensing to be accomplished by a wide variety of provider types, including but not limited to: hospitals and other healthcare facilities, private physicians, pharmacies, large employers, federal and state agencies, local public health departments, federally qualified health centers and other community health centers. Each of these entities may dispense according to plans and procedures already developed for the entity to optimize effectiveness and efficiency. For example, local and regional public health departments have written and exercised mass vaccination plans (including plans that emphasize social distancing, such as drive-thru dispensing plans) as part of SNS and pandemic influenza planning initiatives.

Although these plans may differ in format, they all include the following elements:

1. Procedure for preparing vaccines, including drawing up vaccine from a multi-dose vial.
2. Administration of an intramuscular injection.
3. Nasal spray dosing and administration.
4. Infection control practices for immunization clinics, including standard precautions.
5. Immunization after-care guidelines.
6. Guidelines for documentation related to vaccine administration.
7. Protocols for management of adverse reactions following immunization, including management of anaphylaxis.
8. Characteristics of a mass vaccination site/facility/clinic, including: supplies needed for mass vaccination, protocols for crowd management, and procedures for orderly and safe client flow.
9. Clinic staff roles and responsibilities.

REIMBURSEMENT

CDC will provide the novel H1N1 vaccine as well as vaccine administration supplies, such as syringes, needles, sharps containers, alcohol wipes, and immunization cards free of charge to providers and vaccine recipients. Further information on vaccine administration fee reimbursement through various third party payers will be disseminated as soon as it is available. Providers will not charge for the vaccine, but may need the CPT code for an EMR or in billing for the vaccine administration.

DOSES ADMINISTERED REPORTING

All providers who receive novel H1N1 vaccine must agree to report doses administered information to DSHS. The online reporting system will allow providers to report aggregate doses administered information weekly by dose one or two, and by various age groups (CDC specifications).

All vaccinations will be reported using ImmTrac see Appendix G for more information.

Both ordering and reporting should be a quick and basic process, and an online training will be available at www.Texasflu.org once the system is operational, to guide providers through the process as outlined in Appendix F.

IMMTRAC REPORTING

ImmTrac is the statewide immunization registry and disaster preparedness tracking and reporting system. Providers who pre-registered or register after September 13th for H1N1 vaccine will also indicate if they have an ImmTrac Provider Number (PFS). Providers who do not have this number will be contacted and registered for ImmTrac. A registration form is necessary to complete and return to DSHS. See Appendix G for more information.

Once a provider is registered, the contact person(s) is then notified via e-mail of their ImmTrac User ID and their ImmTrac Provider Number (PFS). The newly registered provider is then mailed a new provider packet with information regarding ImmTrac and any training that is available. A standard follow-up procedure is in place to ensure that the new provider has the information they need for access and to answer any questions they may have. The registration process and requirements for computer infrastructure is listed in Appendix G.

VACCINE SAFETY

GENERAL GUIDELINES

All providers administering the novel H1N1 vaccine should adhere to the following guidelines to ensure safe administration:

- Providers are required to follow ACIP recommendations published in the August 21, MMWR, Use of Influenza A (H1N1) 2009 Monovalent Vaccine, www.cdc.gov.mmwr/preview/mmwrhtml/rr58e0821a1.html.
- Providers should begin giving vaccine as soon as it is received.
- We will follow CDC dosage recommendations: www.fda.gov/BiologicsBloodVaccines/Vaccines/ApprovedProducts/ucm181950.htm
- Healthcare providers should ensure that a reminder/recall system is in place.
- Simultaneous administration of inactivated vaccines against seasonal and novel influenza A (H1N1) viruses is permissible if different anatomic sites are used. However, simultaneous administration of live, attenuated vaccines against seasonal and novel influenza A (H1N1) virus is not recommended.
- CDC will provide to states vaccine cards to dispense to patients. Providers should give each patient an immunization record card as supplied by the CDC. The card will contain space to

document influenza vaccination location, date, vaccine type, lot number and dose. The card will be pre-populated with key information regarding an adverse event and how to report clinically significant adverse events to VAERS.

- Providers should give each patient a copy of the H1N1 Influenza Vaccine Information Statement (VIS). Once CDC releases the VIS, Texas will add an addendum. When available providers may order online at www.immunizetexasorderform.com.
- Specific information is required to be recorded in the medical record anytime a vaccine is administered. The required information includes the following:
  - Vaccine manufacturer
  - Lot number
  - Vaccine administration site
  - Date of the Vaccine Information Statement (VIS)
  - Date of the vaccination
  - Signature of the person administering the vaccine
  - Address where the vaccine was administered

Every year, seasonal flu infects between 5 percent and 20 percent of a given population resulting in approximately 250,000 to 500,000 deaths globally. Unlike seasonal flu, emerging research indicates older children and young adults are more likely to be infected with the novel H1N1 virus.

The novel H1N1 vaccine is made the same way as the seasonal influenza vaccine, a method that has been tested and proven safe for years. The only difference between the vaccines is the virus strain. The new H1N1 vaccine is being rigorously tested before it will be dispensed to the public.

TEXAS POISON CONTROL NETWORK

During the normal course of business, the Texas Poison Center Network (TPCN) will be on the alert for adverse event calls related to novel H1N1 influenza vaccine. The health professionals at the poison centers will provide treatment recommendations or refer calls to the local emergency department as appropriate. In addition, the DSHS Immunization Branch will receive notification of TPCN H1N1 related calls; an e-mail will be sent to a DSHS Immunizations' H1N1 designated mailbox. When TPCN staffs follow-back with emergency departments, they will inquire as to whether the event was reported to DSHS; if not, they will encourage the hospital staff to complete a Vaccine Adverse Event Reporting System (VAERS) form and submit it to DSHS.

VACCINE ADVERSE EVENT REPORTING SYSTEM (VAERS)

VAERS is the front-line monitoring system for collecting and analyzing voluntary reports of adverse events following novel H1N1 vaccination. VAERS is a federal vaccine safety surveillance system co-

managed by CDC and the Food and Drug Administration. VAERS is a key mechanism to identify potential vaccine safety concerns.

Healthcare providers are encouraged to report clinically significant adverse events after novel H1N1 vaccine or any vaccine to VAERS. A report should be submitted even if the reporter is not certain that the vaccine caused the event. Anyone can submit a VAERS report, including healthcare providers, vaccine providers, public health officials, vaccine manufacturers, and persons vaccinated or their caregivers.

VAERS reports may be reported two ways:

1. Directly to VAERS via the Internet at https://secure.vaers.org, by fax at 1-877-721-0366 (toll-free), or by mail at VAERS, P.O. Box 1100, Rockville, MD, 20849-1100

2. Directly to the Texas DSHS via fax at: 1-866-624-0180 (toll-free), or by mail at: DSHS, Immunization Branch, MC 1946, P.O. Box 149347, Austin, TX 78714-9347

A DSHS VAERS clinical team has been established to respond to vaccine safety concerns and will serve as a safety resource for healthcare providers and the general public. The Vaccine Safety Coordinator/VAERS Coordinator will serve as the primary liaison between the State and the CDC.

LIABILITY

The Public Readiness and Emergency Preparedness Act ("PREP Act") enacted as Division C of the Defense Appropriations Act for fiscal year 2006, Pub. L. No. 109-148, added new authorities to alleviate concerns about liability related to the manufacture, testing, development, distribution, administration and use of agents in a pandemic. Summary of the Act can be located at: www.hhs.gov/disasters/emergency/manmadedisasters/bioterorism/medication-vaccine-qa.html

SOURCES

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"Prevention and Control of Seasonal Influenza with Vaccines: Recommendations of the Advisory Committee on Immunization Practices (ACIP)", MMWR, July 31, 2009 / Vol. 58 / No. RR-8, 1-52 www.cdc.gov/mmwr/preview/mmwrhtml/rr5808a1.htm?s_cid=rr5808a1_e

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"2009 H1N1 Influenza Vaccination Guidance for State, Local, Tribal and Territorial Health Officials", www.cdc.gov/h1n1flu/vaccination/statelocal/

"Influenza A (H1N1) 2009 Monovalent", U.S. Food and Drug Administration, www.fda.gov/BiologicsBloodVaccines/Vaccines/ApprovedProducts/ucm181950.htm

APPENDIX A

PROCESS FOR VACCINE ALLOCATION AND DISTRIBUTION

VACCINE ALLOCATION

Process Steps: Allocation			
Step	**Process**	**Responsible Party**	**Timing**
1	When supplies are limited, DSHS will make decisions based on the following factors: o Vaccine availability o Priority groups o Population o Disease trends o Geographic morbidity/mortality o Federal guidelines o Distribution limitations	DSHS	Each time vaccine is received

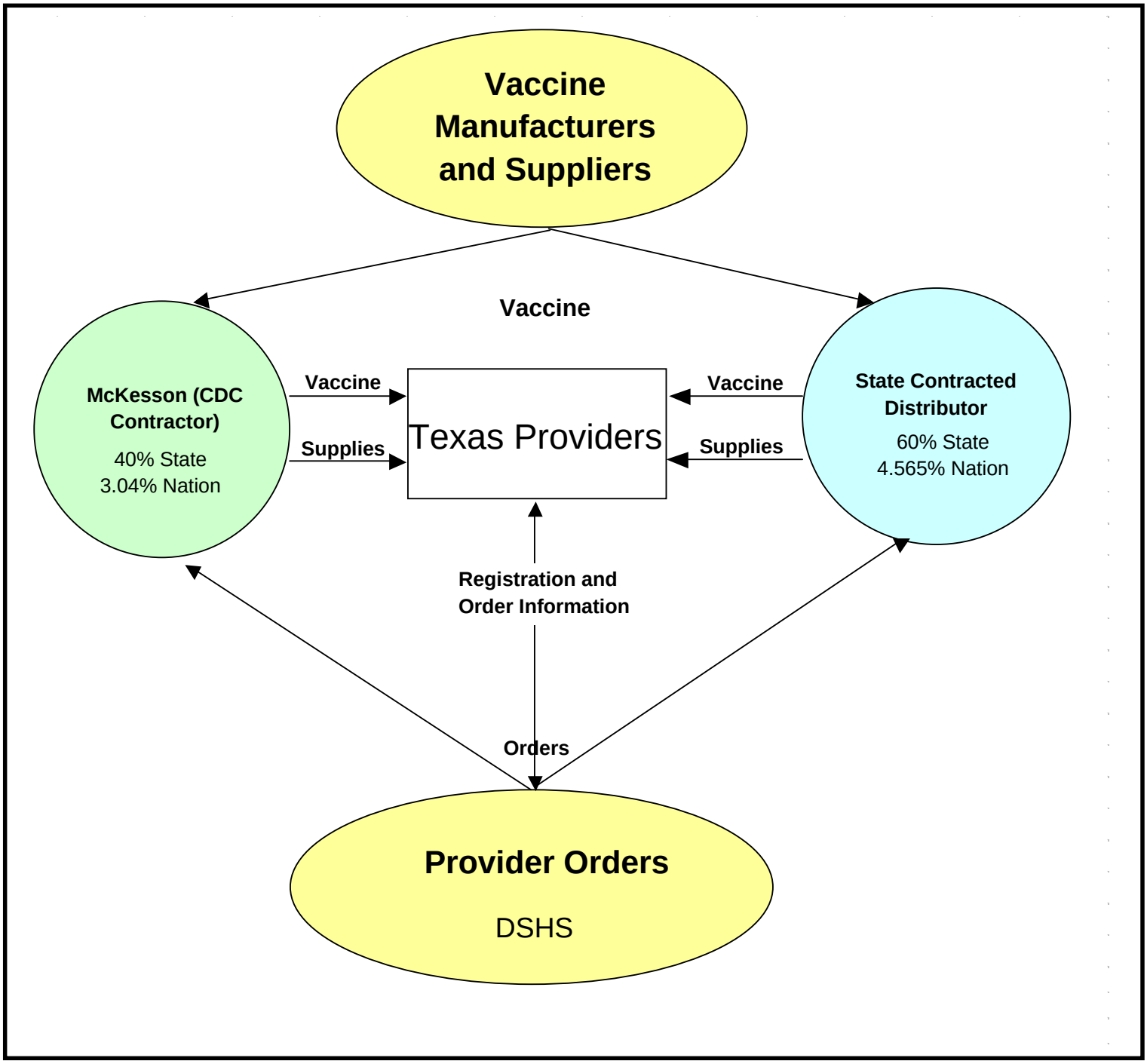
VACCINE DISTRIBUTION

Process Steps: CDC to State of Texas Distribution			
Step	**Process**	**Responsible Party**	**Timing**
1	CDC will send vaccine to the distributor and notify the state when vaccines are available for order.	CDC	As vaccines are received

Process Steps: Vaccine Distribution to Providers			
Step	**Process**	**Responsible Party**	**Timing**
1	After allocation decisions have been made, DSHS Immunization Branch will pull the orders into an electronic file and send orders to the appropriate distributor for execution.	DSHS	As vaccines arrive
2	Distributors will pick, pack, and ship the vaccine to the provider.	Distributor(s)	Daily
3	Provider receives vaccine ordered.	Distributor(s)	Periodically
4	DSHS expects to receive a periodic shipping report from vendors.	CDC, State Contracted Distributor	TBD
5	Ancillary supplies (syringes, needles, alcohol swabs, sharps containers, and immunization record cards) will be shipped in quantities to match vaccine.	TBD	TBD

APPENDIX B

DISTRIBUTION FLOW CHART



APPENDIX C

PROCESS FOR HEALTHCARE PROVIDER PRE-REGISTRATION

Process Steps: Pre-Registration

Step	Process	Responsible Party	Timing
1	Provider pre-registers online. If provider does not have Internet access, may phone the Call Center.	Provider	Anytime
2	Provider information downloaded in Austin onto an Excel spreadsheet.	DSHS	Frequency TBD
3	Data on the Excel spreadsheet is reviewed by DSHS Austin Vaccine Services staff.	DSHS	As received
4	If there are questions on the data, Call Center staff will contact the provider for clarification.	Call Center	As received
5	The professional license numbers from the pre-registration forms will be matched to the list of licensees from the appropriate board to verify that the number exists and matches that of the person registered.	DSHS	As received
6	An email will be sent to each provider acknowledging receipt of the pre-registration form.	DSHS	After pre-registration
7	DSHS Austin Immunization Branch staff will produce a list of providers to date (by HSR and LHD) and provide to HSR on a regular basis. Information to be provided to regional immunization program managers includes a list of providers who have registered, along with their contact information and estimated patient populations, by priority group.	DSHS	Frequency TBD
8	Regional Immunization Program Managers will share the information with appropriate management in their region, including Local Health Departments. This information may assist regional management and LHD management in identifying potential gaps and targeting recruitment.	HSR	As received

APPENDIX D

PROCESS FOR HEALTHCARE PROVIDER REGISTRATION FOR NOVEL H1N1

Providers may sign electronically by entering the authorized provider's name and medical license number

Process Steps: Registration			
Step	**Process**	**Responsible Party**	**Timing**
1	Provider has completed pre-registration process	Provider	
2	When DSHS receives the CDC Provider Agreement Form, a new link will be added to TexasFlu.org for providers to sign. (process in development)	DSHS	When received
3	Providers will log on to the system and "sign" and submit to DSHS (new online form to be developed).	Provider	Prior to receiving vaccine

PROCESS FOR NON ELECTRONIC PROCESS FOR NOVEL H1N1 PRE-REGISTRATION, REGISTRATION AND FINAL REGISTRATION

Providers without access to the internet should contact the call center for assistance. Ordering will be managed through a similar process, combining fax and telephone support to assist providers who cannot access the internet.

Process Steps: Non-Electronic Process			
Step	**Process**	**Responsible Party**	**Timing**
Pre-registration			
1	Provider contacts Call Center to pre-register.	Provider	Operational Hours (subject to change)
2	Fax the Pre-registration form to the provider to complete.	Call Center Staff	During or immediately after phone call.
3	Once the pre-registration form is returned, Call Center staff will complete the pre-registration form online for the provider, following the instructions for ordering and reporting above.	Call Center Staff	Within 24 hours if possible

Final Registration			
4	Provider contacts Call Center to sign Provider Agreement.	Provider	Prior to receiving vaccine
5	Fax the Agreement form to the provider to sign and complete.	Call Center Staff	During or immediately after phone call.
6	Once the signed Agreement form is returned, Call Center staff will sign the agreement online for the provider.	Call Center Staff	Within 24 hours if possible

APPENDIX E

PROCESS FOR VACCINE ORDERING

Process Steps: Vaccine Ordering			
Step	**Process**	**Responsible Party**	**Timing**
1	Providers will go online to TexasFlu.org to order vaccine.	Providers	After receipt of email
2	Providers will be allowed to go online to adjust patient estimates and other provider information.	Providers	Anytime after database is functional
3	DSHS will notify providers via email to check the website for a pending order. The site will identify the vaccine type and number of doses available for order.	DSHS	Automatic within allocation process
4	Providers must enter the number of doses of each vaccine type they wish to order. Before submitting the order the provider will be asked to verify the following: o Hours of operation o Ability to properly store the ordered vaccines o Vaccine temperatures will be checked and maintained within acceptable ranges	Provider	At the time of order
5	Upon placing an order, provider will receive confirmation on the screen of the vaccine types and quantities ordered.	Provider	At the time of order

APPENDIX F

PROCESS FOR AGGREGATE DOSES ADMINISTERED REPORTING

ELECTRONIC PROCESS

Process Steps: Doses Administered Reporting			
Step	**Process**	**Responsible Party**	**Timing**
1	Providers will go online and enter the aggregate number of doses administered for the week by dose 1 or 2, and by various age-groups (specified by CDC).	Provider	Weekly
2	Providers can see a history of prior doses administered entries by date.	System	Anytime after database is functional

APPENDIX G

PROCESS FOR IMMTRAC CLIENT REPORTING

Providers can use the methods described below to report immunizations and antivirals to ImmTrac.

H1N1 VACCINE AND ANTIVIRAL REPORTING

1. **Direct Online Entry**

   Providers can report immunizations administered by directly entering the data through the ImmTrac web application (Disaster Mode).

   - Using the user ID and password received during the registration process, the provider must log on to the ImmTrac application.
   - Once in the system, a Smart Search should be conducted to ensure that the client is not already an ImmTrac participant.
   - If the client is not found in ImmTrac, the provider can add the individual as a **disaster-only client.**
     - Information such as the client's name, date of birth, gender and address (including city and county) is required.

2. **Electronic Import Process**
   a. Standard import data file specification **(novel H1N1 vaccine and anti-viral reporting)**
      - Electronic import of immunization data is available to providers who are currently entering data into client encounter or electronic medical records software.
      - Some electronic medical records systems will support generation of a data extract file that can be imported to ImmTrac.
      - Please ask your IT staff or software vendor to contact ImmTrac at ImmTrac@dshs.state.tx.us to obtain the *ImmTrac Electronic Transfer Standards for Providers*

   b. Delimited file format with required data fields **(novel H1N1 vaccine and anti-viral reporting)**
      - To obtain the required data fields providers should contact ImmTrac at ImmTrac@dshs.state.tx.us

3. **Data Entry into Spreadsheet**
   a. An MS Excel spreadsheet can be made available to providers that wish to submit novel H1N1 vaccine and antivirals in a standardized format.
      - The spreadsheet can be uploaded through the ImmTrac web application or to the ImmTrac secure FTP server.
      - Contact ImmTrac at ImmTrac@dshs.state.tx.us to obtain the Excel spreadsheet.

4. **Disaster Consent Form (Paper Reporting)**
    a. Providers that do not have Internet capabilities must complete the Disaster Information Retention Consent Form (#F11-12956-P).
        - The demographic data portion of the form must be completed and returned to ImmTrac whether or not it was signed by the patient.
        - Fax completed form to ImmTrac at (1) 866-624-0180.

MINIMUM COMPUTER SYSTEM REQUIREMENTS AND RECOMMENDATIONS

Internet Access (HTTPS)

- Windows 95/98/ME/NT/2000 (Microsoft Windows XP/Vista - recommended)
- Internet Access (broadband recommended)
- Internet Explorer 5.5 or greater with 128 bit encryption
- Internet Explorer Security Settings set to default
- Internet Explorer Cookie Settings set to accept and retain cookie files
- Internet Explorer text set to "medium" or "small"
- Adobe Acrobat Reader 4.5 or higher (most recent version recommended)
- E-Mail Address for site/access location and Point of Contact (highly recommended)

** *Mozilla Firefox, Netscape, Safari and all other browsers are not supported.*

Computer

- Monitor set at 800X600 resolution or greater
- CPU clock set to correct date/time
- Display Properties (DPI) set to "normal" (recommended)

Electronic Data Submission

- Option 1: Data Submission via ImmTrac Web – HTTPS Internet Explorer 5.5 or greater with 128-bit encryption
- Option 2: FTP Data Submission – FTP AUTHSSL with 128-bit encryption

** *Macintosh, Linux/Unix and all other open-source software are not supported.*