

**DEPARTMENT OF HEALTH AND HOSPITALS
OFFICE OF PUBLIC HEALTH**

**EMERGENCY ORDER AND PROTOCOL
(Policy Memorandum No. _____)**

FROM: Jimmy Guidry, M.D., State Health Officer

SUBJECT: EMERGENCY ORDER AND PROTOCOL FOR THE ADMINISTRATION OF
INFLUENZA VACCINATION BY ELIGIBLE PHARMACISTS

PURPOSE/APPLICABILITY:

To set forth a procedure for the administration of influenza vaccinations by pharmacists credentialed by the Louisiana Board of Pharmacy to administer medications; to allow such pharmacists to administer influenza vaccinations by protocol rather than by a written physician prescription.

POLICY STATEMENT: This protocol is intended to ensure the safety, efficacy, and provision of influenza immunizations to meet the needs of the public welfare by decreasing the burden of influenza disease in the state of Louisiana.

EFFECTIVE DATES: The protocol set forth herein will be initially effective only until September 23, 2009, but may be further extended by subsequent order of the State Health Officer.

RATIONALE AND LEGAL AUTHORITY:

The impending 2009 influenza season will be severely challenging, since the Louisiana medical community will have to address both the seasonal flu and the H1N1 influenza virus, a novel flu strain for which most of the population does not have immunity. To effectively address both strains, each citizen will need to receive three separate vaccinations [two for H1N1 (given at separate times) and one for the seasonal flu]. The necessity of giving three separate vaccinations instead of the typical single vaccination will present unprecedented manpower and resource issues. Allowing pharmacists to administer vaccinations for seasonal flu by protocol will free-up other medical resources, and greatly assist the State in effectively managing this flu season. This additional assistance by pharmacists will effectively address otherwise critical shortages in manpower, will give the State a much needed head start in distributing and administering the H1N1 vaccine when it becomes available on or around October, 2009, and will help to ensure the success of the State's vaccination program as it relates to both strains.

Now therefore, pursuant to the powers vested in me by L.R.S. 40:1 *et seq.* [particularly L.R.S. 40:4(A)(13) and L.R.S. 40:5(2)], I, Jimmy Guidry, M.D., State Health Officer, do hereby issue the following emergency protocol:

Program Guidelines:

Pharmacists may administer influenza immunizations via this protocol only if they meet the minimum qualifications for the authority to administer as required by the Louisiana Board of Pharmacy. (Title 46, §521). Pursuant to this protocol, such pharmacists are authorized to administer influenza vaccinations to appropriate and eligible patients by injection or nasal-spray. **Pharmacists not credentialed to administer medications by the Louisiana Board of Pharmacy may not operate under or utilize this protocol.**

Pharmacists shall follow the Center for Disease Control recommendations for influenza immunization as determined by the Advisory Committee on Immunization Practices, and should follow the official State of Louisiana Immunization schedule and guidance for influenza vaccination as published by the Louisiana Office of Public Health Immunization Program manual.

Required Recordkeeping and Associated Tools:

In the course of influenza immunization, the pharmacist must collect demographic records of all patients receiving the vaccination. This information should include the patient name, date of birth, address, vaccination date, name and address of the pharmacist administering the immunization, name of vaccine, manufacturer, and lot number. All influenza immunizations administered shall be thus documented in the Louisiana Immunization Network for Kids Statewide database (“LINKS”). If the LINKS system is used, there is no need to maintain a paper copy in the pharmacy.

Pharmacists who administer influenza immunizations under this protocol must be familiar with the information on the LINKS system and complete a user agreement to obtain access for reviewing and entering immunization data into the LINKS system.

Informed Consent:

The parent, legal guardian, patient, or other person, as appropriate, must read and understand the influenza vaccine information statement/vaccine information pamphlet prior to the administration of each dose of vaccine being given. Under federal law, health care providers are not required to obtain the signature of the patient or parent or guardian acknowledging receipt of the vaccine information materials. To ensure that a record of the provision of the materials exists, the form requires the signature and title of the vaccine administrator. The pharmacy phone number where the individual receives the influenza vaccine must be given in case the patient has follow up questions after receipt of the immunization. Vaccines for Children (“VFC”) patients must also be screened for eligibility at each clinic visit.

If the parent or legal guardian accompanies the child to the pharmacy or if vaccine is given to an adult, the important influenza information statement/vaccine information pamphlet form for the vaccine to be administered shall be given to the responsible adult or adult patient. The adult should take the opportunity to read the statement or to have it read to him, be able to ask questions relating to the form and request additional information or clarification regarding influenza vaccination. In the same way, questions related to the VFC Program and LINKS can be discussed. If questions are raised, they must be answered to the satisfaction of the responsible adult or adult patient. Once questions have been answered and no further explanations are required, the pharmacist may then proceed with the influenza immunization.

If the parent or legal guardian cannot accompany the child to be immunized, any one of the following persons is authorized and empowered to consent to the vaccine or any related medical treatment:

- (a) Any parent, whether an adult or a minor, for himself/herself and for his/her child.
- (b) Any married minor, for himself/herself
- (c) Any person temporarily standing in loco parentis whether formally serving or not, for the minor under his/her care
- (d) Any female regardless of age or marital status, for herself when given in connection with pregnancy or childbirth.
- (e) Any adult, for his/her minor brother or sister.
- (f) Any grandparent for his/her minor grandchild.

In addition, under compelling circumstances and only after consulting the case with either the local or regional OPH medical director, OPH immunization consultants, or the OPH Immunization Program in New Orleans, a vaccination may be given to an unaccompanied minor without the need for any consent from a parent or guardian. In such a case, the signature of the minor receiving the influenza immunization should be obtained.

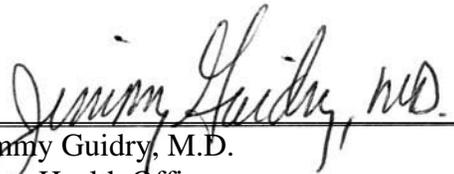
Any pharmacist administering vaccines or biologics according to this protocol must inform the patient, parent, legal guardian, or other responsible adult of common side-effects of the vaccine and steps that should be taken if these side-effects occur. The pharmacist must verify that the patient, parent, legal guardian, or other responsible adult has been made aware of any rare side effects by ensuring that the important influenza information statement/vaccine information pamphlet has been read. In addition, in the event of an adverse event, the telephone number of the pharmacy must be recorded in the space provided at the end of the important information statement/vaccine information pamphlet so that the patient, parent, legal guardian, or other responsible adult will know where to call.

Adverse Events and VAERS:

The pharmacy shall post in a prominent place an emergency plan to be implemented in case of an adverse event. Such plan shall include the phone number of the local EMS, and the role of the pharmacist and other participants. All adverse vaccine reactions must be reported using the Vaccine Adverse Event Reporting System form (VAERS-1) immediately (within 24 hours) upon

a patient's report or occurrence of adverse events following vaccination. VAERS is a cooperative program for vaccine safety of the Centers for Disease Control and Prevention (CDC) and the Food and Drug Administration (FDA). VAERS is a post-marketing safety surveillance program, collecting information about adverse events (possible side effects) that occur after the administration of U.S. licensed vaccines. Further information about VAERS can be found at <http://www.vaers.hhs.gov>.

Signed in Baton Rouge, Louisiana on September 10, 2009.



Jimmy Guidry, M.D.
State Health Officer