Executive Order - Questions and Answers

1. What is the purpose of this Declaration and why was it issued now?

The Declaration is intended to provide the New York State Department of Health and local health departments throughout the state the flexibility needed to ensure that once vaccine supplies become more abundantly available, New York is able to quickly and efficiently vaccinate as many individuals as possible. We are now beginning to see the numbers of persons sick with the flu increase – we have seen several schools close and several deaths have been reported. While nationally vaccine availability has been limited to date, we anticipate that the supply will begin to increase significantly over the coming weeks. The Declaration puts in place the needed resources and flexibility to be able to respond quickly and efficiently.

In brief, this Emergency Declaration is effective for 6 months unless it is rescinded by the Governor at an earlier date; the suspensions of law in the executive order are effective for 30 days. The executive order puts in place the following to assure that State and local health departments have the resources and flexibility to quickly implement community-based flu vaccine programs. More specifically, this declaration allows for the following:

- An expanded number of trained health care personnel will be legally able to administer flu vaccine (seasonal and 2009 H1N1) in state and local health department sponsored flu vaccine programs or Points of Dispensing (PODs). In this way, multiple patients from multiple providers can be immunized at a single centralized site. This is a much more efficient mechanism for safe vaccination of large numbers of individuals. Physician assistants, specialist assistants, dentists, dental hygienists who have been issued a special anesthesia/analgesia certificate, pharmacists without a certificate authorizing them to administer vaccinations, podiatrists, midwives, and advanced emergency medical technicians have been authorized to immunize people at these vaccine program for 2009 H1N1 and seasonal influenza provided they first receive training approved by the Commissioner of Health. Nurses and pharmacists with a certificate authorizing them to administer vaccines are already authorized to do so under existing law.
- Specially trained physician assistants, in addition to licensed physicians and certified nurse practitioners, will be permitted to supervise state or locally sponsored flu vaccine programs without being under the direct supervision of a physician.
- Physicians and certified nurse practitioners will be allowed under this executive order to
 prescribe and order "non patient-specific" regimens authorizing vaccination by the health care
 workers who will be vaccinating individuals at large flu vaccine programs. Thus one order may
 be written for all individuals who are seen at a specific location for the purpose of being
 vaccinated against seasonal or 2009 HiN1 flu rather than requiring that each individual have a
 unique patient order for the vaccine.
- The executive order makes provisions that will allow schools to be used as vaccination sites for adults. These provisions will allow adults to be immunized in school-based health clinics that ordinarily serve children only and for state health department authorized part-time clinics to be

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operated by hospitals in elementary or secondary schools. School districts have the ability to allow use of their facilities for mass vaccination programs under existing law.

- Certified pharmacists will be permitted to immunize all individuals age 6 months and older and
 may immunize individuals under the non-patient specific order of a licensed physician or
 certified nurse practitioner from anywhere in New York State rather than only those physicians
 or nurse practitioners who practice in the same or an adjoining county as the pharmacy. This
 will increase the number of locations that a child or adult may be vaccinated.
- Registered nurses with current CPR certification may administer immunizations pursuant to a
 non-patient specific orders under existing law. The executive order will permit registered
 nurses trained but not certified in CPR to administer vaccinations at PODs, provided at least 2
 CPR certified staff are present on site.

2. How will vaccinations provided at PODS be reported? How will an individual's physician be made aware that the individual has been vaccinated?

PODs will be authorized to record the immunization of children and adults for 2009 H1N1 and seasonal influenza in the New York State Immunization Information System (NYSIIS) and the New York City Immunization Registry without consent. Providers in other settings in New York City will also be able to record 2009 H1N1 immunizations in the City Immunization Registry without consent. This will permit timely reporting to the federal government and effective monitoring for adverse events.

3. What provisions are made under the Executive Order to streamline and reduce paperwork and reporting for individuals vaccinated at PODs?

Pharmacists and registered nurses vaccinating individuals at PODS will not be required to keep a record of and report immunizations performed under a non-patient specific order to the patient's attending physician. Similarly, pharmacists administering immunizations at PODs will not be required to provide patients they immunize with information regarding the importance of having a primary care physician. Instead, vaccine records for individuals vaccinated at PODs will be maintained through the State and City immunization registries.

4. How will this executive order improve New York's 2009 H1N1 immunization program?

The executive order will increase the number of individuals who may legally vaccinate individuals and will expand the type and thus number of sites where state and local health departments may sponsor large community-based vaccine programs and in turn ensure that as many New Yorkers are vaccinated as quickly as possible, once vaccine supplies become more readily available.

5. What protections are there for individuals who are vaccinated at these sites?

This executive order describes limited circumstances under which the specified types of health care providers will be authorized to administer vaccine. This executive order is limited to seasonal and 2009

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H1N1 vaccination, is effective for a 30-day period and requires that the individuals authorized to administer vaccine may only do so once they have receive training in the following: techniques, indications, precautions, contraindications, infection control practice and the use of personal protective equipment. This training must meet a basic level of competence to administer vaccine as determined by the Commissioner of Health after consultation with the Commissioner of Education.

6. What types of health care providers will be authorized to vaccinate at these sites?

The following health care providers, when appropriately trained, will be authorized to participate in school and community-based flu vaccine programs:

 Physician assistants, specialist assistants, dentists, dental hygienists who have been issued a special anesthesia/analgesia certificate, pharmacists without a certificate of administration, podiatrists, midwives, and advanced emergency medical technicians. Nurses and pharmacists with a certificate of administration are already authorized to participate in these types of activities under existing law.

7. Under this executive order will anyone be required to be immunized?

No. There is nothing included in the declaration that requires anyone to be immunized without their express consent or the consent of someone legally authorized to consent for them.

8. Can this executive order be renewed?

Yes. Executive Law § 29-a(2) authorizes suspension of law and regulation in a declared state disaster emergency for a maximum of 30 days, and permits the Governor to extend the suspension for additional periods not to exceed 30 days.

9. How does Governor Paterson's Declaration differ from the President Obama's recent declaration?

President Obama's recent declaration is designed to help hospitals respond more quickly to surging numbers of pandemic H1N1 cases and pertains to certain requirements under Medicare, Medicaid and the State Child Health Insurance Program and to certain provisions of the Health Insurance Portability and Accountability Act (HHIPAA) Privacy Rule. While the President's declaration is similar to Governor Paterson's declaration in that the intent is to assure the federal government and the state have the flexibility needed to respond efficiently and effectively as the pandemic progresses. The President's declaration in no way impacts individual health care worker laws and regulations regarding how and where they may practice — which is the basis of Governor Paterson's Declaration.

10. Are there any provisions made in the executive order to ensure that cost is not a barrier to vaccination for New Yorkers?

Yes. The executive order very specifically states that vaccine provided at these large vaccination sites must be provided without charge to the individual who is being vaccinated. It may be possible for insurers to be billed an administration fee, when appropriate, but no individual may themselves be charged a fee for the vaccination.

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11. Does or will this declaration impact the availability of flu vaccine?

No. H1N1 vaccine availability is a function of production capacity by the various companies that have been authorized by the FDA to manufacture H1N1 vaccine. What the executive order provides is the flexibility needed so that New York is prepared to accept and use vaccine when in fact it becomes more readily available in greater quantities.

12. Will immunization records from these large scale vaccine programs be confidential?

Yes. This order does not change any existing provisions for the security or confidentiality of immunization information that is maintain in either New York State' Immunization Registry (NYSIIS) or in the New York City Citywide Immunization Registry (CIR).

13. Under what authority can the Governor issue this type of declaration?

The Governor may declare a disaster emergency by executive order whenever he finds that a disaster has occurred, or may be imminent, to which local governments are unable to respond adequately. Executive Law § 28(1). "Disaster" is defined as the occurrence or imminent threat of widespread or severe damage, injury, or loss of life or property resulting from any natural or man-made causes, including, but not limited to, epidemic. Executive Law §20(2)(a).

14. Have other States issued similar declarations?

Yes. New York joins nine states that have taken emergency action or are in the process of declaring a public health emergency related to the H1N1 outbreak this fall. Similar declarations have been issued by:

- Massachusetts, which recently passed an <u>emergency regulation</u> authorizing their Commissioner
 of Public Health to issue an order designating people who may administer H1N1 vaccine and
 under what conditions;
- Louisiana, where an "Emergency Order and Protocol for the Administration of Influenza vaccination by pharmacists;
- North Carolina is allowing retired nurses to vaccinate under the supervision of an RN;
- Minnesota recently amended their statute to extend the authority of the commissioner of heath to respond to local requests to expand the categories of persons authorized to administer vaccine;
- Maine has issued a proclamation of civil emergency to respond to the potential dangers of H1N1 influenza and to facilitate a statewide vaccination campaign;
- Nebraska proclaimed a state of emergency in April 2009, which remains in effect this fall to respond to H1N1 influenza;
- Wisconsin is operating under a declared Public Health Emergency, which directs the Wisconsin Department of Health Services to take all necessary and appropriate measures to prevent and respond to H1N1 influenza;

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- Ohio issued an emergency proclamation allowing 17,000 Ohio EMTs to administer the H1N1
 vaccine to Ohioans and to allow the transfer of antiviral medications and supplies to Ohio
 communities;
- Illinois is in the process of declaring an emergency to have extra personnel for vaccinating priority groups and expanding the scope of practice

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