July 17, 2009

Pursuant to the authority vested in the State Hospital Review and Planning Council and the Commissioner of Health by Public Health Law Sections 2803, 3612, and 4010, Title 10 (Health) of the Official Compilation of Codes, Rules and Regulations of the State of New York, is amended, to be effective upon filing with the Secretary of State, as follows:

Part 66 is amended to add Subpart 66-3, as follows:

Title: Subpart 66-3 – Health care facility personnel - influenza vaccination requirements

Sec.

66-3.1 Definitions

66-3.2 Health care facility – personnel influenza vaccination requirements

66-3.3 Health care facility requirements, existing personnel

66-3.4 Health care facility requirements, new personnel

66-3.5 Documentation

66-3.6 Exceptions

66-3.7 Reporting Requirements

Section 66 - 3.1 – Definitions

(a) "Medically contraindicated" means a physician licensed to practice in the State of New York or a nurse practitioner certified to practice in the State of New York certifies that influenza vaccine(s) should not be administered to an individual because it would be detrimental to the

individual's health. Medical contraindication shall continue until such immunization is found no longer to be detrimental to the individual's health. Nationally recognized up-to-date guidance for medical contraindications and recommendations for vaccination(s) for influenza will be posted on the New York State Department of Health immunization page website and will be updated regularly.

(b) "Personnel" means all persons employed or affiliated with a healthcare facility, whether paid or unpaid, including but not limited to employees, members of the medical staff, contract staff, students, and volunteers, who either have direct contact with patients or whose activities are such that if they were infected with influenza, they could potentially expose patients, or others who have direct contact with patients, to influenza; provided, however, that the provisions of this subpart shall not apply to those individuals employed or affiliated with a facility that have neither direct contact with patients nor activities that could potentially expose patients or others who have direct contact with patients. This shall include, but not be limited to, any individual whose (i) job site is physically separated from patient care locations, and who has no direct contact with patients; and (ii) job activities would result in no more than infrequent and/or incidental direct contact with others who might have direct contact with patients; provided, that such direct contact is unlikely to transmit influenza. Examples include, but are not limited to, administrative, data entry, and building or property maintenance functions that meet the criteria of items (i) and (ii).

(c) "Health Care Facilities" include general hospitals as defined in section 2801 of the Public Health Law, diagnostic and treatment centers as defined in section 751.1 of part 751 of this Title, certified home health agencies, long term home health care programs, acquired immune

deficiency syndrome (AIDS) home care programs and licensed home care services agencies as defined in section 3602 of the Public Health Law, and hospices as defined in section 4002 of the Public Health Law.

Section 66 - 3.2 – Health care facility - personnel influenza immunization requirements

Every health care facility in this state shall notify all personnel of the requirement and require that personnel be immunized against influenza virus(es) as a precondition to employment and on an annual basis. Such influenza vaccination(s) must be in accordance with the national recommendations in effect at the time of vaccination(s), unless the commissioner has determined that there is not an adequate supply of vaccine. If the commissioner determines the vaccine supplies are not adequate given the numbers of personnel to be vaccinated or vaccine(s) are not reasonably available, the commissioner may suspend the requirement(s) to vaccinate and/or change the annual deadline for such vaccination(s), as established in this subpart.

Section 66 - 3.3 – Health care facility requirements, existing personnel

Each health care facility must provide or arrange for influenza vaccination(s), at no cost to its personnel, either at the facility or elsewhere. Personnel may choose to receive influenza vaccination(s) from a source other than that arranged for by the facility and provide documentation to the facility as described in Section 66 – 3.5. Annual influenza vaccination(s) and the documentation thereof shall take place no later than November thirtieth of each year.

66 - 3.4 – Health care facility requirements, new personnel

Personnel newly entering into service at a facility after November thirtieth but before April first of each year shall have his or her status for influenza vaccination(s) determined by the facility and, if found to be deficient, the facility shall provide or arrange for the necessary vaccination(s) at no cost to the new personnel. Instead of obtaining influenza vaccination(s) from the facility, personnel may choose to receive influenza vaccination(s) from a source other than that arranged for by the facility and provide documentation as described in Section 66 – 3.5.

Section 66 - 3.5 - Documentation

The health care facility shall document the annual vaccination(s) against influenza virus of all personnel in their personnel files, including the date, site of administration, type of vaccine, dose, manufacturer and lot number of the vaccine, reactions if any, vaccine information statement given, and the name of the person administering the vaccines. If any personnel receive influenza vaccination(s) from other than facility staff, the facility shall document in the personnel file the date, type of vaccine, dose and name of the person administering the vaccine.

Section 66 – 3.6 - Exceptions

No personnel shall be required to receive an influenza vaccine if the vaccine is medically contraindicated for that individual. Nationally recognized up-to-date guidance for medical contraindications and recommendations for vaccination(s) for influenza will be posted on the New York State Department of Health immunization page website and will be updated regularly. The facility shall, on a case-by-case basis, evaluate what steps those who are not vaccinated pursuant to this section must take to reduce the risk of transmitting influenza to patients.

Section 66 - 3.7 - Reporting Requirements

Each facility shall collect aggregate data on personnel influenza vaccination(s) status for the period beginning April first and ending March thirty-first of each year and report that data to the department by May first of the same year in a manner determined by the commissioner. Required data will include, but not be limited to, number of personnel immunized by occupation, total number of personnel by occupation, and reason(s) personnel did not receive vaccine.

Subparagraph (v) of paragraph (10) of subdivision (b) of Section 405.3 of Part 405 is added to read as follows:

(v) documentation of preemployment and annual vaccination(s) against influenza, in accordance with Part 66 of this Title.

Paragraph (6) of subdivision (d) of Section 751.6 is added to read as follows:

(6) documentation of preemployment and annual vaccination(s) against influenza, in accordance with Part 66 of this Title.

Paragraph (5) of subdivision (c) of Section 763.13 is added to read as follows:

(5) documentation of preemployment and annual vaccination(s) against influenza, in accordance with Part 66 of this Title.

Paragraph (6) of subdivision (d) of Section 766.11 is added to read as follows:

(6) documentation of preemployment and annual vaccination(s), in accordance with Part 66 of this Title.

Paragraph (6) of subdivision (d) of Section 793.5 is added to read as follows:

(6) documentation of preemployment and annual vaccination(s) against influenza, in accordance with Part 66 of this Title.

REGULATORY IMPACT STATEMENT

Statutory Authority:

The authority for the promulgation of the regulatory changes adding Subpart 66-3 and amending Sections 405.3, 751.6, 766.11 and 793.5 of Title 10 is contained in Sections 2803 (2), 3612 and 4010 (4) of the Public Health Law (PHL). PHL section 2800 places the comprehensive responsibility for the development and administration of the state's policy with respect to Article 28 facilities with the State Department of Health. PHL Section 2803(2) authorizes the State Hospital Review and Planning Council (SHRPC) to adopt and amend rules and regulations, subject to the approval of the Commissioner, to implement the purposes and provisions of PHL Article 28, and to establish minimum standards governing the operation of health care facilities. PHL Section 3612 authorizes the SHRPC to adopt and amend rules and regulations, subject to the approval of the Commissioner, with respect to certified home health agencies, providers of long term home health care programs and providers of AIDS home care programs. PHL Section 4010 (4) authorizes the SHRPC to adopt and amend rules and regulations, subject to the approval of the Commissioner, with respect to hospice organizations.

Legislative Objectives:

The legislative objective of PHL Article 28 includes the protection of the health of the residents of the State by assuring the efficient provision and proper utilization of health services, of the highest quality at a reasonable cost. PHL Article 36 states a public commitment to the appropriate provision and expansion of services rendered to the residents of the State by certified home health agencies, to the maintenance of a consistently high level of services by all home care services agencies, to the central collection and public accessibility of information

concerning all organized home care services, and to the adequate regulation and coordination of existing home care services. PHL Article 40 declares that hospice is a socially and financially beneficial alternative to conventional curative care for those afflicted by terminal illness. In recognition of the value of hospice and consistent with State policy to encourage the expansion of health care service options available to New York State residents, it is the intention of the Legislature that hospice be available to all who seek such care and that it become a permanent component of the State's health care system. Immunizing staff of these providers against influenza will promote the health and safety of the patients they serve and support efficient provision of services.

Needs and Benefits:

The State Department of Health strongly advocates that all health care personnel (HCP) should receive annual influenza vaccination(s). This recommendation was communicated in two letters from the Commissioner (dated October 2006 and September 2007), and a health advisory (dated December 14, 2007), sent to hospitals, long term care facilities, providers and local health departments. PHL Article 21-A, the Long Term Care Resident and Employee Immunization Act, currently requires that all long-term care facilities, adult homes, adult day healthcare facilities, and enriched housing programs offer influenza vaccine to all employees and residents. Further amendments to PHL Article 21-A have been introduced to require all HCP under its purview to receive annual influenza vaccination(s).

The intent of this regulation is to coordinate the influenza vaccination requirements for personnel in Article 28, Article 36, and Article 40 entities to be the same; however, each type of

entity has a separate set of regulations that apply to them. In order to avoid the need to revise multiple regulations in the event of future changes to Subpart 66-3, the regulations for each type of provider entity will refer to one central set of requirements in Part 66. The authority for the Part 66-3 regulation, as applying to the affected types of facilities, rests with the State Hospital Review and Planning Council.

Each year, influenza causes significant morbidity and mortality in the United States, especially among the vulnerable populations in hospitals and long term care facilities. Common symptoms include the sudden onset of headache, high fever, cough, sore throat, fatigue and body aches. Complications of influenza may include bacterial or viral pneumonia; dehydration; the worsening of chronic medical conditions, such as congestive heart failure, asthma, or diabetes; or death. The risk for complications, hospitalization, and death from influenza are higher among persons 65 years of age or older, young children, and persons with chronic medical conditions. Influenza is the sixth leading cause of death among adults in the United States, killing an average of 36,000 Americans annually and causing more deaths than all other vaccine-preventable diseases combined.

Influenza viruses spread mainly from person to person when an infected individual coughs or sneezes. Most healthy adults, including HCP, may be able to infect others beginning 1-2 days before symptoms develop and up to 5 days after becoming sick. That means HCP may be able to pass on the disease to a patient before they are aware they are sick or they may continue to work while they are contagious.

Influenza Infections in Hospitals and Long Term Care Facilities. Tables 1 and 2 detail the burden of nosocomial influenza infections (i.e., influenza infections acquired in hospitals and long term care facilities) in New York State by using NYSDOH surveillance data from 2001 to 2006. During the 2005-06 influenza season, there were 205 confirmed outbreaks in New York State hospitals and long-term care facilities. There were 1,896 suspected and confirmed cases of influenza associated with these reported outbreaks. As shown in Tables 1 and 2, the number of outbreaks and cases varies significantly year to year depending on the severity of that year's influenza season.

Table 1: Confirmed Influenza Outbreaks in New York State Hospitals and LTCFs

	2000-01	**2001-02**	**2002-03**	**2003-04**	**2004-05**	**2005-06**	**2006-07**	**Total**
Number of outbreaks reported to NYSDOH	31	173	24	199	451	205	70	1153

Source: NYSDOH surveillance data

Table 2: Morbidity from Nosocomial Influenza Infections in New York State

	2000-01*	2001-02	2002-03	2003-04	2004-05	2005-06	2006-07	Total
Number of patients/residents reported ill (suspected and confirmed) with nosocomial influenza in hospitals and LTCFs	359	2814	403	3535	8675	2603	**663**	**19,052**
Number of staff reported ill (suspected and confirmed) with nosocomial influenza in hospitals and LTCFs	55	889	146	1105	2124	702	**158**	**5,179**

Source: NYSDOH surveillance data

*Nosocomial data is only available from January 1, 2001 forward.

Role of HCP in Influenza Transmission. Influenza transmission and outbreaks in hospitals and nursing homes are well documented. HCP can acquire influenza from infected patients or the community and transmit influenza to patients and other staff. Many HCP develop no or only mild symptoms of the disease and, therefore, do not realize they have influenza and can transmit the disease to patients. Since influenza can be transmitted 1-2 days before the onset of symptoms, patients are at risk even if HCP do stay at home while ill.

A few studies provide estimates of the incidence of influenza-like illness among HCP. According to the CDC, "In one serosurvey of HCP, 23% had documented serologic evidence of influenza infection after a mild influenza season; however, of these, 59% could not recall having influenza, and 28% could not recall any respiratory infection, suggesting a high proportion of asymptomatic illness." In addition, multiple studies have also shown that HCP continue to work despite being ill with influenza, increasing exposure of patients and coworkers. When HCP

come in to work while ill, whether it is because they do not want to lose sick time or pay or out of a sense of obligation, influenza virus can be transmitted to patients and other staff.

Studies have shown that influenza outbreaks in health facilities are associated with low vaccination rates among HCP and that, conversely, high vaccination rates among HCP are associated with fewer outbreaks. One study looked at the yearly incidence of lab-confirmed influenza illness among both staff and patients over 12 influenza seasons in an acute care facility, from 1999-2000. As the influenza vaccine rate climbed from 4% to 67%, the proportion of influenza cases decreased among hospitalized patients from 32% to 0, and among staff from 42% to 9%.

Influenza outbreaks in long-term care facilities are common and can cause severe outcomes in the vulnerable resident populations. Older adults in nursing homes often have multiple chronic or acute conditions that make them particularly susceptible to the complications of influenza disease. The intimate and constant care that is required by residents from the HCP who care for them allows for ready transmissibility from symptomatic or asymptomatic infected staff members. In addition, because influenza vaccination(s) is/are less effective among frail and elderly patients, outbreaks can occur in facilities where a high proportion of residents or patients are immunized. High vaccination levels of HCP are needed to protect patients, making influenza vaccination(s) of HCP an important patient safety issue.

A Scottish study compared mortality rates between long-term care hospitals that offered influenza vaccination to HCP, where 51% were vaccinated, and hospitals that did not, where

only 5% were vaccinated. The result was nearly a 40% reduction in all-cause mortality among the patients cared for by HCP in the hospitals with higher levels of HCP influenza vaccination.

Yet, despite the documented and positive effects of immunizing HCP against influenza on patient outcomes, HCP absenteeism, and reducing influenza infection among staff, and incentives to promote vaccination(s) of HCP, 30–50% continues to remain unvaccinated.

In 2000, New York State enacted Public Health Law Article 21-A requiring long-term care facilities to offer influenza vaccine to all residents and HCP and to document refusal of the vaccine. As seen in NYSDOH survey data, while the overall vaccination of residents has improved to 80% or greater in most facilities, the response among HCP has been poor (less than 45%).

CDC and National Recommendations. Recognizing the need to protect hospital patients and long-term care facility residents, the Centers for Disease Control and Prevention (CDC) has recommended influenza vaccination(s) for health care personnel (HCP) since 1981.

In November 2003, 24 leading organizations endorsed a policy to make annual influenza vaccination(s) among HCP an important goal for public health and safety. These organizations included the Society for Hospital Epidemiology of America, the American Medical Association, the American Academy of Family Practitioners, the American Academy of Pediatrics, and the American Nurses Association.

In February 2006, the Healthcare Infection Control Practices Advisory Committee (HICPAC) and the Advisory Committee on Immunization Practices (ACIP) jointly recommended that all HCP be vaccinated annually against influenza.

In January 2007, the Infectious Disease Society of America called for a mandatory requirement for all HCP to receive influenza vaccination yearly.

Costs for the Implementation of and Continuing Compliance with these Regulations to the Regulated Entity

The cost to regulated entities to vaccinate personnel should be modest. Personnel in hospitals, diagnostic and treatment centers, home care services agencies and hospices all must undergo a health assessment to ensure that such personnel are free from a health impairment which is a potential risk to patients or which may interfere with the performance of his/her duties. Personnel are also required to have a certificate of vaccination against measles and rubella unless medically contraindicated and be tested for tuberculosis as condition of employment or affiliation. It should be noted that measles and rubella are one-time vaccinations, while influenza vaccination(s) is/are given annually. Many, if not most, facilities recognize the importance of their personnel receiving such vaccination(s) and already offer it to them, usually at no charge. Influenza vaccine is one of the least expensive vaccines and the average price in the private sector ranges from approximately $9.75 to $19.70 per dose.

Any additional costs to vaccinate all personnel should be more than offset by cost savings to the facility. Cost-effectiveness studies of adults aged <65 years indicate that vaccination(s) can reduce both direct medical costs and indirect costs from work absenteeism, resulting in 13%-

44% fewer health-care provider visits, 18%-45% fewer lost workdays, 18%-28% fewer days working with reduced effectiveness, and a 25% decrease in antibiotic use for influenza-like illness (ILI). HCP absenteeism can be a serious cause of staffing shortages during the influenza season at a time when emergency room visits and admissions due to influenza-related illness are greatly increased. The benefit of an immunized staff decreases direct and indirect costs to health care facilities.

Before 12/1/09, for inpatient hospital reimbursement, flu costs incurred prior to 12/1/09 may be the subject of a rate appeal per 10 NYCRR 86-1.17(a)(3). Section 86-1.17(a)(3) permits application for prospective revisions of certified rates and established revenue caps in the current year based on "[D]ocumented increases in the overall operating costs of a medical facility resulting from the implementation of additional or expanded programs, staff or services specifically mandated for the facility by the commissioner." After that time, the new hospital reimbursement system, PHL section 2807-c, subdivision 35 (added by section 2 of Part C, Chapter 58 of the Laws of 2009) permits very limited rate appeals, as noted in PHL 2807-c (35)(b)(x).

Reimbursement for certified home health agencies (CHHA) is set forth in 10 NYCRR 86-1.46. This is not impacted by the new subdivision 35. Consequently, CHHA rate appeals based on new DOH mandated services may continue to be available.

For long-term home health care programs, reimbursement is found in Subpart 86-5 of 10 NYCRR and section 86-5.14(a)(3) and permits the commissioner to consider applications for revision of certified rates which are based on "significant increases in the overall

operating costs of the long term home health care program resulting from the implementation of additional programs, staff or services specifically mandated for the program by the commissioner."

Diagnostic and treatment centers (D&TC) rates were scheduled to move to a new system (APGs) on March 1, 2009, but the transition has not occurred due to a delay in federal approval of state plan amendments. In the interim, 10 NYCRR 86-4.16(c) would continue to permit D&TC rate appeals based on new mandates.

Cost to State and Local Government:

The regulatory requirements are not expected to result in costs to state or local governments. Potential savings to Medicaid and other payors are expected by decreasing influenza cases. Among healthy persons aged 18-64 years, vaccination(s) can save an estimated $60-$4,000 per illness, depending on the cost of vaccination(s), the influenza attack rate, and vaccine effectiveness against influenza-like illness (ILI). In another economic analysis, vaccination(s) resulted in an average annual cost savings of $13.66 per person vaccinated; however, other analyses have not demonstrated cost savings. Among studies of healthy young adults, >70% of the costs prevented were associated with reductions in lost work productivity. The estimated annual direct cost of influenza infection in the United States is estimated to be between 3 and 5 billion dollars.

In the event that medical facilities and long-term home health care programs seek a timely medicaid rate change and it is approved, the state and local government may have to pay a proportion of the amount approved, with the federal government contributing the balance.

However, due to the medicaid cap imposed on the county share, it is impossible at this time to calculate whether local governments will in fact have to contribute any funds to meet this potential expense.

Cost to the Department of Health:

Minimal new costs to the New York State Department of Health {NYSDOH) will be incurred associated with enactment of these regulations. By decreasing HCP influenza disease and absenteeism, and the spread of influenza disease among patients, the quality of health care should be improved, as well as patient outcomes.

NYSDOH has dedicated multiple resources to promote voluntary HCP vaccination(s) programs in public health and private arenas, including hospitals, clinics, and local health organizations over the past decade. As previously mentioned, the standard for care in New York State is that all HCP should receive annual influenza vaccination(s). This recommendation was sent to all New York State hospitals, long-term care facilities, providers and local health departments, via two Commissioner letters (dated October 2006 and September 2007), and a Health Advisory (December 14, 2007). Other initiatives to promote this practice have included educational materials, toolkits, a department-wide workgroup, outreach to healthcare partners, and public service announcements. These initiatives will continue.

Any additional costs will be associated with increased oversight of compliance with the regulatory requirements. NYSDOH already collects data from long-term care facilities on an annual basis to monitor compliance with PHL Article 21-A. Long-term care facilities must submit an annual report (DOH form 4193) to NYSDOH by May 1 providing information on the

number of residents and employees who received and the number who did not receive influenza and pneumococcal vaccine during the previous year. This form will be modified to capture data from additional health care facilities. Additional costs will mostly involve the additional data collection, analysis, written reports and follow-up with facilities.

Local Government Mandates:

There are no local government mandates in New York State related to this proposal, except as they apply to providers operated by local government entities.

Paperwork:

PHL Article 21-A, the New York State Long-Term Care Resident and Employee Immunization Act, requires nursing homes, adult care facilities, enriched housing facilities, and adult day health care programs in New York State to document their vaccination efforts and to submit an annual report to NYSDOH. The facility annual report was historically completed using DOH form 4193. This form is now available on the Health Provider Network (HPN). The form will be modified to capture hospitals, diagnostic and treatment centers, home care and hospice programs. Those entities covered by these regulations will be required to submit vaccination information using the Health Commerce System. All reporting will be accomplished using the internet only.

Duplication:

This proposal does not duplicate any state or federal regulation.

Alternative Approaches:

Voluntary programs to increase HCP influenza vaccination rates have not resulted in adequate vaccination levels. For the past decade, the New York State Department of Health has dedicated multiple resources to promote voluntary HCP vaccination programs in public health and private arenas, including hospitals, clinics, and local health organizations. Initiatives have included educational materials, toolkits, a department-wide workgroup, outreach to healthcare partners, and public service announcements. However, these programs have failed to substantially increase HCP vaccination rates.

On April 1, 2000, Article 21-A, the Long-Term Care Resident and Employee Immunization Act, was added to the Public Health Law. This law requires nursing homes, adult homes, enriched housing programs, and adult day health care programs to provide or arrange for influenza vaccination(s) for all residents and employees every year. The law also requires these types of facilities to provide or arrange for pneumococcal vaccination(s) for all residents and employees for whom the vaccine is recommended according to guidelines issued by the Advisory Committee on Immunization Practices. Residents and employees may refuse vaccination(s) due to medical contraindication, religious objection, or by choice after being fully informed of the health benefits and risks of such action. These long-term care facilities must document vaccination status of residents and employees, including refusal of vaccination(s) and the reasons for refusal.

In 2001, NYSDOH began collecting data from long-term care facilities to monitor compliance with PHL Article 21-A. Long-term care facilities must submit an annual report

(DOH form 4193) to NYSDOH by May 1 providing information on the number of residents and employees who received and the number that did not receive influenza and pneumococcal vaccine during the previous year. Even the enactment of NYS PHL Article 21-A targeting long-term care facilities has failed to promote consistent HCP vaccination rates above 44%.

A requirement for vaccination(s) is not unique to influenza. Childhood vaccination rates vastly improved in the US, often exceeding 90–95%, once mandatory school-entry vaccination requirements were put into place. In health care settings, measles and rubella vaccination has also been successful in achieving nearly universal vaccination of health employees against these pathogens. Consequently, requiring influenza vaccination(s) for health care workers would similarly be highly effective and, perhaps with additional education, widely accepted.

Federal Requirements:

There are no minimum standards established by the federal government for the same or similar subject areas.

Compliance Schedule:

This proposal will go into effect upon filing with the Secretary of State.

Contact Person:

Ms. Katherine E. Ceroalo
NYS Department of Health
Bureau of House Counsel, Regulatory Affairs Unit
Corning Tower Building, Room 2438
Empire State Plaza
Albany, NY 12237
(518) 473-7488
(518) 473-2019 –FAX
REGSQNA@health.state.ny.us

REGULATORY FLEXIBILITY ANALYSIS

FOR SMALL BUSINESS AND LOCAL GOVERNMENTS

Effect of Rule:

Any facility defined as a hospital pursuant to PHL Article 28, as a home care services agency by PHL Article 36, or hospice by PHL Article 40 will be required to comply. Small businesses (defined as 100 employees or less), independently owned and operated, affected by this rule will include: 3 hospitals, 237 diagnostic and treatment centers, 91 nursing homes, 252 certified home health agencies, and approximately 900 licensed home care services agencies. There are 50 certified hospices in New York State; most of them would fit into the category of a small business, but definitive data concerning their small business status is not available.

Compliance Requirements:

All facilities must document the preemployment and annual vaccination(s) for influenza virus, subject to the availability of an adequate supply of the necessary vaccine and subject to exemptions for medical contraindications.

Professional Services:

Facilities will need to provide or arrange for influenza vaccination(s) of personnel. Most facilities currently offer influenza vaccinations to their personnel on a voluntary basis. It is not anticipated that facilities will need to hire additional staff to meet this mandate.

Compliance Costs:

The cost to facilities to meet this mandate is estimated to be minimal. It is anticipated that any costs incurred to vaccinate HCP will be offset by savings in direct medical costs by reducing influenza infection among HCP and patients, as well as savings in indirect costs associated with HCP absenteeism.

Economic and Technological Feasibility:

This proposal is economically and technically feasible.

Minimizing Adverse Impact:

There are no alternatives to the proposal to require influenza vaccination(s) of all HCP.

Small Business and Local Government Participation:

Outreach to the affected parties has been conducted. Such parties include professional organizations representing physicians, nurses, and other health care personnel, as well as general hospitals, diagnostic and treatment centers, home care agencies and hospices.

The organization representing county health officers, NYSACHO, has also been briefed. Organizations that represent the affected parties are given notice of this proposal by its inclusion on the agenda of the Codes and Regulations Committee of the State Hospital Review and Planning Council (SHRPC).

Presentations by Department staff were also given at the full Public Health Council and State Hospital Review and Planning Council meetings to brief Council members on this

upcoming proposal. The public, including many affected parties, have been in attendance at these meetings.

RURAL AREA FLEXIBILITY ANALYSIS

Pursuant to section 202-bb of the State Administrative Procedure Act (SAPA), a rural area flexibility analysis is not required. These provisions apply uniformly throughout New York State, including all rural areas.

The proposed rule will not impose an adverse economic impact on rural facilities defined within PHL Articles 28, 36, or 40. It will require additional documentation, record-keeping and other compliance requirements on public or private entities, but it is not expected to adversely affect rural areas.

JOB IMPACT STATEMENT

A Job Impact Statement is not included in accordance with Section 201-a (2) of the State Administrative Procedure Act (SAPA), because it will not have a substantial adverse effect on jobs and employment opportunities.

EMERGENCY ADOPTION JUSTIFICATION

Transmission of influenza disease from health care personnel to patients is a serious and significant patient safety issue because influenza disease is a leading cause of morbidity and mortality among hospitalized patients and those admitted to other types of health care facilities. This fact, plus the new threat posed to health and safety by the novel H1N1 influenza A strain that is circulating in New York State, puts a need for emergency regulations requiring that all health care personnel (HCP) be immunized against influenza annually into focus for the upcoming influenza season. Yearly, a significant threat to the health of patients, HCP themselves, and local communities exists that will be magnified in the upcoming season by the ongoing pandemic. The sooner that the emergency regulations are in place the sooner lives will be saved and other complications of influenza disease avoided.

Each year, influenza causes significant morbidity and mortality in the United States, especially among the vulnerable populations in hospitals and other health care facilities. Complications of influenza may include bacterial or viral pneumonia; dehydration; the worsening of chronic medical conditions, such as congestive heart failure, asthma, or diabetes; or death. The risk for complications, hospitalization, and death from influenza are higher among persons 65 years of age or older, young children, and persons with chronic medical conditions. Influenza is the sixth leading cause of death among adults in the United States, killing an average of 36,000 Americans annually and causing more deaths than all other vaccine-preventable diseases combined.

Recognizing the need to protect patients, the Centers for Disease Control and Prevention (CDC) has recommended influenza vaccination for HCP since 1981. In February 2006, the Healthcare Infection Control Practices Advisory Committee (HICPAC) and the Advisory

Committee on Immunization Practices (ACIP) jointly recommended that all HCP be vaccinated annually against influenza. In addition, the Infectious Disease Society of America, the Society of Hospital Epidemiologist of America, the American Medical Association, the American Academy of Family Practitioners, the American Academy of Pediatrics, the Association of Perioperative Nurses, the American Nurses Association, and multiple individual health care institutions have all supported and called for all HCP to receive influenza immunization yearly. Facilities that employ HCP have been strongly encouraged to provide vaccine to their staff by using evidence-based approaches that maximize the use of influenza vaccination.

Yet, despite the documented and positive effects of immunizing HCP against influenza on patient outcomes, HCP absenteeism, and reducing influenza infection among staff, and the fact that influenza transmission and outbreaks in healthcare facilities are well documented, national vaccination coverage rates among HCP continue to remain low, at around 42%. Even among health care centers utilizing highly organized and aggressive campaigns and incentives to promote immunization of HCP, 30–50% continue to remain unvaccinated. In 2000, New York State enacted Public Health Law Article 21A requiring long term care facilities to offer influenza vaccine to all residents and HCP and to document refusal of the vaccine. As seen in New York State Department of Health (NYSDOH) survey data, while the overall vaccination of residents has improved to 80% or greater in most facilities, the response among HCP has been poor.

Because of the serious consequences of nosocomial influenza outbreaks, as well as the impact on health care workers and the economic impact on health care systems, it is imperative that action be taken to ensure high health care worker vaccination rates. HCP absenteeism can result in serious staffing shortages during the influenza season, at a time when emergency room visits and admissions due to influenza-related illness are greatly increased. The benefit of an immunized staff decreases direct and indirect costs to health care facilities. The United States

and New York State are entering the 2009-2010 influenza season this Fall facing an emergency situation, with the potential circulation of both seasonal influenza viruses and the pandemic novel H1N1 influenza strain. Health care resources will be strained to the breaking point while addressing the burden of treating large numbers of patients ill with influenza. HCP need to be protected so that they will not become ill, transmit influenza to patients, their families and their communities, and also so that the health care system can be preserved and not collapse due to high degrees of HCP absenteeism. The urgency of this situation necessitates immediate emergency regulatory action to allow sufficient time for hospitals to arrange for the purchase and administration of influenza vaccine for the upcoming influenza season. This will also give health care facilities time to prepare for an extended novel H1N1 influenza vaccination campaign, in tandem with seasonal vaccination efforts.

Immunizing the staff of health care facilities against influenza will promote the health and safety of the patients they serve and support efficient provision of services during the pandemic. The NYSDOH has strongly and continuously advocated that all HCP should receive annual influenza vaccination(s). Annual influenza morbidity and mortality necessitates requiring influenza vaccination of all HCP in hospitals and other health care facilities on an emergency basis, so that lives can be saved. This is an even more urgent imperative during the current novel H1N1 influenza pandemic.

Summary of Key Points

- The burden of influenza disease is very high in health care facilities and will increase due to the current pandemic.

- Influenza vaccination of HCP is a patient and community safety issue and protects vulnerable hospitalized patients during seasonal influenza seasons and during the pandemic.
- HCP need to be vaccinated to control influenza in health care facilities even if patient vaccination rates are high.
- During the pandemic, it may be recommended that HCP receive influenza vaccination as the first line of protection of the public.
- Seasonal and pandemic influenza vaccination can be cost saving to health care facilities by decreasing absenteeism, improving patient outcomes, decreasing error rates, increasing quality of care, and decreasing personal and organizational expenditures.
- Voluntary programs to increase HCP influenza immunization rates have not resulted in adequate immunization levels.