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BOARD OF HEALTH: August 13, 2009 LAW DEPARTMENT: July 22, 2009 RECORDS DEPARTMENT: Sept. 21, 2009

# REGULATIONS GOVERNING THE IMMUNIZATION OF ADULTS

**WHEREAS,** The Board of Health recognizes the need to protect adults from preventable diseases; and

**WHEREAS,** Immunizations are an effective method of reducing morbidity and mortality caused by vaccine-preventable diseases; and

**WHEREAS,** Title 6 of The Philadelphia Code, entitled "Health Code," authorizes the Board to require the immunization of any person against any communicable disease for which immunization is effective; and

**WHEREAS**, as of this date, three-fourths of existing state and regional immunization registries in the United States contain immunizations administered throughout the lifespan, and more than half of the aforementioned registries require the reporting of immunizations by health care providers through legislation, rule, or Regulation; and

**WHEREAS**, implementing an adult immunization registry requirement is an important and effective strategy for health care providers to manage their patients' care and help ensure continuity of health services; and

**WHEREAS**, requiring the reporting of immunizations administered to adults is a logical extension of the existing requirement for health care providers in Philadelphia to report immunizations administered to individuals under 19 years of age; and

WHEREAS, the ability to document immunizations administered to individuals of all ages in an Immunization Registry accessible to authorized health care providers and public health authorities is an essential tool for managing public health emergencies as well as routine health services; and

**WHEREAS,** the ability to monitor federal and local assets distributed in the form of vaccine is important for good public stewardship of and accountability for such resources; and

**WHEREAS,** the epidemiology of disease from the novel Influenza A (H1N1) virus first detected in April 2009 is being closely monitored by public health officials, and candidate

vaccines are being developed in anticipation of the need for widespread vaccination against this virus in the fall of 2009; and

WHEREAS, the Department of Health and Human Services' Pandemic Influenza Plan declares that state and local health departments "should be prepared to collect data on vaccine effectiveness, vaccine supply and distribution, vaccine coverage, and vaccine safety" to ensure optimal and appropriate use of a new pandemic influenza vaccine; and

**WHEREAS**, any information system that would be used in pandemic response would ideally be integrated with existing systems regularly utilized by the Department's immunization program for general public health practice, being of sufficient capacity to manage the volume of data generated in a pandemic mass vaccination setting;

**NOW, THEREFORE,** the Board of Health promulgates the following *Regulations Governing The Immunization of Adults*:

#### 1. **DEFINITIONS**

In these Regulations, the following definitions apply:

- (a) Adult. An individual 19 years of age and older.
- (b) *Authorized user*. Any person or entity authorized to provide or receive information from an Immunization Registry, which may include health care providers, parents and guardians, schools and childcare facilities, managed care organizations, and local government health departments and their agents.
- (c) *Coverage rate*. The percent of a given population immune to a specific communicable disease, or combination of diseases, as a result of vaccination or disease history.
- (d) *Department*. The Department of Public Health of the City of Philadelphia, the Health Commissioner, or any designated representative thereof.
- (e) *Health care facility*. A facility providing health services, including, but not limited to, a general, chronic disease, or other type of hospital; a private medical practice; a home health care agency; a hospice; a long-term care nursing facility, a cancer treatment center; an ambulatory surgical facility; a birth center; and an inpatient drug and alcohol treatment facility, regardless of whether such health care facility is operated for profit, nonprofit or by an agency of the government.
- (f) *Health care provider*. An individual who is authorized to practice some component of the healing arts by a license, permit, certificate or registration issued by a

Commonwealth of Pennsylvania licensing agency or board.

- (g) *Immunization status*. The number of dosages of specific vaccine antigens and their respective dates of administration.
- (h) *Medical record*. An account compiled by physicians and other health professionals including a patient's medical history; present illness; findings on physical examination; details of treatment; reports of diagnostic tests; findings and conclusions from special examinations; findings and diagnoses of consultants; diagnoses of the responsible physician; notes on treatment, including medication, surgical operations, radiation, and physical therapy; and progress notes by physicians, nurses and other health professionals.
- (i) *Record of immunization*. A written document, such as a physician record or other document of similar reliability, reflecting the date and type of immunization.
- (j) Recommended Immunization. An immunization included in the current Recommended Adult Immunization Schedule approved by the Center for Disease Control's Advisory Committee on Immunization Practices, the American Academy of Family Physicians, the American College of Obstetricians and Gynecologists, and the American College of Physicians (ACIP/AAFP/ACOG/ACP) that is routinely administered to adults.

# 2. RESPONSIBILITY AND AUTHORITY FOR REPORTING ADULT IMMUNIZATION INFORMATION

- (a) Responsibility for Reporting Immunization Information. Any health care provider who treats, examines, or otherwise administers immunizations to adults, and any head, superintendent or other person in charge of a health care facility that treats such persons, shall report the following to the Department, in a content and manner as specified below and in accordance with additional parameters as may be established by the Department:
  - (1) administration of any Recommended Immunization;
  - (2) administration of a vaccine as part of pandemic or other public health emergency response.
- (b) Reporting of Pre-Regulation Immunizations. A provider may report to the Department, in such form as specified by the Department, the records of the immunizations administered to any adult before the date of the passage of this Regulation, if such information was not previously reported, and immunizations administered that are not required to be reported pursuant to subsection (a). The Department may also request that a provider submit such records to the Registry in such form as specified by the Department.
- (c) *Timing and Method of Reporting*. Reports of immunizations shall be made within 30 days of vaccine administration to the Department's Division of Disease Control, by mail to: Immunization Program, Division of Disease Control, Department of Public Health, 500 S. Broad Street, Philadelphia, PA 19146; or through secure transfer of electronic data in a manner as established by the Department.

- (d) Content of Reports. All reports shall include the following information:
  - a. Individual's name (first, middle and last);
  - b. Individual's date of birth;
  - c. Individual's sex;
  - d. Individual's address;
  - e. Type of immunization;
  - f. Date of vaccine administration (month, day, year);
  - g. Name of the immunization provider;
  - h. Any additional information as the Department may require in connection with a particular type of immunization or case.

#### 3. EXPANSION OF EXISTING CITYWIDE IMMUNIZATION REGISTRY

- (a) *KIDS Immunization Registry*. Reported data on adults shall be housed in the KIDS Immunization Registry at the Department, which shall serve as the City's central repository for data on immunizations administered to individuals from birth through death.
- (b) Other Authorized Immunization Registry Uses. The Registry may be used to manage and track vaccine administration and distribution, vaccine adverse events, immunization coverage rates and efficacy, as well as distribution of other select medications used in the prevention and control of communicable diseases, as the Department determines necessary to protect the health of the public.
- (c) The Department may choose, at its discretion, to maintain immunization data on newborns, children, and adolescents beyond their nineteenth birthday. Such records will be maintained for purpose of documenting prior immunization status and for assisting medical management of individuals in adulthood.

### 4. IMMUNIZATION REGISTRY PROVISIONS

- (a) Authority to Obtain Medical Information on Immunizations. The Health Commissioner, or designated representative, has the authority to obtain and store medical information, including photocopies of medical records and medical summaries, regarding immunizations governed by this Regulation without a signed authorization release from the patient or patient's representative.
- (b) Access to the Immunization Registry. Access to immunization information reported to the Department and maintained in the Immunization Registry shall be limited to authorized users as defined in this Regulation.
  - (1) Authorized users of the Immunization Registry must be approved by the Department and shall be authorized only as permitted by law.
  - (2) Authorized users of the Immunization Registry must agree to and sign the KIDS Registry Security and Confidentiality Agreement.

- (3) Patient information in the Immunization Registry shall be accessed by an authorized user only to ascertain and monitor immunization status of individuals for which the authorized user has professional responsibility and in accordance with the data use and confidentiality policies of the KIDS Registry.
- (4) Immunization information shall be made inaccessible for records marked to indicate a request by an adult, or their legal representative, not to participate in the KIDS Registry. The request shall be made in a form prescribed or otherwise authorized by the Department.