MEMORANDUM

City of Philadelphia
Date: 8/28/07

TO: Romulo L. Diaz Jr., City Solicitor

FROM: Jeanne Reedy, Administrative Services Director, Records Dept.

SUBJECT: Proposed Amendment to Philadelphia Department of Public Health's Regulations Governing the Immunization and Treatment of Newborns, Children and Adolescents

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The above Amendment promulgated by the Health Department was received in the Department of Records on 7/26/07 for filing and advertising.

Inasmuch as there were no requests for hearings, this Amendment became effective midnight 8/27/07.

Cc: Carmen I. Paris, MPH, Health Commissioner
Caroline Johnson, MD, Director, Division of Disease Control

CITY OF PHILADELPHIA
DIVISION OF SOCIAL SERVICES
DEPARTMENT OF PUBLIC HEALTH
OFFICE OF THE COMMISSIONER

MEMORANDUM **DATE: July 24, 2007**

TO: Joan T. Decker, Commissioner, Department of Records

FROM: Carmen I. Paris, MPH, Health Commissioner CIParis

SUBJECT: **PROPOSED AMENDMENT TO PHILADELPHIA DEPARTMENT OF PUBLIC HEALTH'S REGULATIONS GOVERNING THE IMMUNIZATION AND TREATMENT OF NEWBORNS, CHILDREN AND ADOLESCENTS**

In accordance with Section 8-407(a) of the Philadelphia Home Rule Charter, I enclose herewith the public hearing documents in regard to proposed Amendments To Regulations Governing The Immunization and Treatment of Newborns, Children and Adolescents.

The following procedural actions were taken.

Approved by Board of Health	July 18, 2007
Approved by Law Department	July 19, 2007

It is requested that the attached Department of Public Health Regulations for Regulations Governing The Immunization and Treatment of Newborns, Children and Adolescents be filed for final action by the Department of Records.

Should you require anything additional in this matter, please contact Caroline Johnson, MD, Director, Division of Disease Control, 215-685-6740.

CIP/ktg
attachment

cc: Caroline Johnson, MD, Director, Division of Disease Control

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CITY OF PHILADELPHIA DEPARTMENT OF PUBLIC HEALTH	PASSED: BOARD OF HEALTH: July 18, 2007 LAW DEPARTMENT: July 19, 2007 RECORDS DEPARTMENT _____

REGULATIONS GOVERNING THE IMMUNIZATION AND TREATMENT OF NEWBORNS, CHILDREN AND ADOLESCENTS

WHEREAS, The Board of Health recognizes the need to protect newborns, children and adolescents from preventable diseases; and

WHEREAS, Newborn, childhood and adolescent 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, the Health Code authorizes the Board of Health to establish lists of reportable diseases and conditions and to require health care providers and laboratories identifying these reportable diseases and conditions designated by the Board, to report the occurrence of diseases and conditions to the Department; and

WHEREAS, Monitoring of immunization coverage levels is essential for the prevention and containment of disease outbreaks and for identifying newborns, children, and adolescents who are in need of immunizations; and

WHEREAS, the Philadelphia Health Department's Immunization Database must contain all immunizations administered to Philadelphia newborns, children, and adolescents in order to be effective; and

WHEREAS, the Board recognizes the need to ensure that accurate and up-to-date immunization information is available to health care providers in Philadelphia;

WHEREAS, it is necessary to update and consolidate certain existing regulations of the Department regarding immunizations and the reporting of immunizations; **NOW, THEREFORE,**

SECTION 1. The Board of Health hereby rescinds the following regulations:

A. *Department of Regulations for Required Immunization for School Attendance* (approved by Board of Health on July 23, 1981; became law August 27, 1981)

B. *Regulations for Immunization of Child Care Center Attendees* (approved by Board of Health on December 19, 1990; became law March 6, 1991)

C. Untitled Regulation Regarding Reporting of Immunizations to the Immunization Database (approved by Board of Health on June 2, 1992; became law August 19, 1994)

D. *Regulations for Two Doses of Measles-Containing Vaccine for School Entry* (approved by Board of Health on January 30, 1996; became law March 28, 1996)

E. *Regulations Governing the Control of Communicable and Noncommunicable Diseases and Conditions* (Regarding the reporting of immunizations given) (approved by Board of Health March 10, 1998; became law May 27, 1998)

F. *Regulations Governing the Control of Communicable and Noncommunicable Diseases and Conditions -- Hepatitis B Immunization Requirement for Middle School Entry* (approved by Board of Health on March 10, 1998; became law May 27, 1998)

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SECTION 2. The Board of Health hereby adopts *Regulations Governing The Immunization and Treatment Of Newborns, Children And Adolescents* as follows:

City of Philadelphia

Department of Public Health

Regulations Governing the Immunization and Treatment of Newborns, Children and Adolescents

Approved:

BOARD OF HEALTH
LAW DEPARTMENT
RECORDS DEPARTMENT

CITY OF PHILADELPHIA
DEPARTMENT OF PUBLIC HEALTH

Regulations Governing the Immunization and Treatment of Newborns, Children and Adolescents

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1. DEFINITIONS

In these Regulations, the following definitions apply:

(a) *Advisory Committee on Immunization Practices (ACIP).* The Committee appointed by the Centers for Disease Control and Prevention (CDC) to develop written recommendations for the routine administration of vaccines to the pediatric and adult populations, along with schedules regarding the appropriate periodicity, dosage, and contraindications applicable to the vaccines.

(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) *Board.* The Board of Health of the City of Philadelphia.

(d) *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.

(e) *Child care group setting.* A home or facility in which four or more children who are not related to the operator receive child care.

(f) *Department.* The Department of Public Health of the City of Philadelphia, the Commissioner of the said Department, or any designated representative thereof.

(g) *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.

(h) *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.

(i) *Immunization status.* The number of dosages of specific vaccine antigens and their respective dates of administration, which are used to determine adequacy of immunization.

(j) *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.

(k) *Record of immunization.* A written document, such as a physician record or other document of similar reliability, reflecting the date and type of immunization.

(l) *School.* Public, private and parochial schools in Philadelphia, including special education, special classes, vocational programs, intermediate units and home education programs.

2. IMMUNIZATION REQUIREMENTS FOR ATTENDING SCHOOL

(a) *Required for School Entry Into Kindergarten or First Grade.* The following immunizations, whether administered as single vaccines or as components of US Food and Drug Administration approved combination vaccines, given in compliance with the minimum intervals and schedules required for each component vaccine, are required for entry into school and attendance at the kindergarten or first grade level:

(1) *Hepatitis B.* Three properly-spaced doses of hepatitis B vaccine or a history of hepatitis B immunity proved by laboratory testing.

(2) *Diphtheria.* Four or more properly spaced doses of diphtheria toxoid, which may be administered as a single antigen vaccine, in combination with tetanus toxoid or in combination with tetanus toxoid and pertussis vaccine. One dose must have been administered on or after the 4th birthday.

(3) *Tetanus.* Four or more properly spaced doses of tetanus toxoid, which may be administered as a single antigen vaccine, in combination with diphtheria toxoid or in combination with diphtheria toxoid and pertussis vaccine. One dose must have been administered on or after the 4th birthday.

(4) *Pertussis.* Four properly spaced doses of pertussis vaccine in combination with diphtheria and tetanus toxoids, or a physician's documentation of a medical contraindication to pertussis vaccine. One dose shall be administered on or after the 4th birthday.

(5) *Poliomyelitis.* Three or more properly spaced doses of any combination of oral polio vaccine or enhanced inactivated polio vaccine.

(6) *Measles (rubeola), Mumps, Rubella (german measles).* Two properly spaced doses of live attenuated vaccine, as the combination vaccine Measles, Mumps, Rubella (MMR) or as Measles, Mumps, Rubella, Varicella (MMRV), according to the routine recommended schedule, or a history of measles, mumps, and rubella immunity proved by serological evidence. The first dose of vaccine must have been given no sooner than 12 months of age, and the second dose at 4-6 years of age, with a minimum interval of 28 days between doses. Immunization with single antigen vaccines for measles,

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mumps, and rubella is also acceptable, provided two doses of each were administered at appropriate intervals.

(7) *Varicella (chickenpox).* One of the following:

(i) Two doses of varicella vaccine, administered as the single antigen Varicella (V) or as the combination vaccine Measles, Mumps, Rubella Varicella (MMRV). The first dose of vaccine must have been given no sooner than 12 months of age, and the second dose at 4-6 years of age, with a minimum interval of 3 months between doses.

(ii) A history of chickenpox immunity proved by laboratory testing or a written statement of history of chickenpox disease from a healthcare provider.

(b) *Required for School Attendance.* The following immunizations, whether administered as single vaccines or as components of US Food and Drug Administration approved combination vaccines, given in compliance with the minimum intervals and schedules required for each component vaccine, are required as a condition for attending school at grade levels 2 through 12:

(1) *Diphtheria.* Three or more properly spaced doses of diphtheria toxoid, which may be administered as a single antigen vaccine, in combination with tetanus toxoid or in combination with tetanus toxoid and pertussis vaccine.

(2) *Tetanus.* Three or more properly spaced doses of tetanus toxoid, which may be administered as a single antigen vaccine, in combination with diphtheria toxoid or in combination with diphtheria toxoid and pertussis vaccine.

(3) *Poliomyelitis.* Three or more properly spaced doses of either oral polio vaccine or enhanced inactivated polio vaccine. If a child received any doses of inactivated polio vaccine administered prior to 1988, a fourth dose of inactivated polio vaccine is required.

(4) *Measles (rubeola).* Two properly spaced doses of live attenuated measles vaccine, given as a single antigen vaccine, or as a combination vaccine Measles, Mumps, Rubella (MMR) or Measles, Mumps, Rubella, Varicella (MMRV), according to the routine recommended schedule, or a history of measles proved by serological evidence. The first dose of vaccine must have been given no sooner than 12 months of age, and the second dose at 4-6 years of age, with a minimum interval of 28 days between doses.

(5) *German measles (rubella).* One dose of live attenuated rubella vaccine administered as a single antigen vaccine, or as a combination vaccine Measles, Mumps, Rubella (MMR) or Measles, Mumps, Rubella, Varicella (MMRV), or a history of rubella proved by serological evidence.

(6) *Mumps*. One dose of live attenuated mumps vaccine, administered as a single antigen vaccine, or as a combination vaccine Measles, Mumps, Rubella (MMR) or Measles, Mumps, Rubella, Varicella (MMRV), or a history of mumps proved by serological evidence, or a physician diagnosis of mumps disease indicated by a written record signed by the physician or the physician's designee.

(7) *Varicella (chickenpox)*. One of the following:

(i) One dose of varicella vaccine, administered at 12 months of age or older.

(ii) A history of chickenpox immunity proved by laboratory testing or a written statement of history of chickenpox disease from a healthcare provider or parent.

(c) *Exemption from Immunization Requirements for School Entry or Attendance.*

(1) Medical exemption. Children need not be immunized if a physician or the physician's designee provides a written statement that immunization may be detrimental to the health of the child. Such a statement must comply with the list of valid vaccine contraindications as established by the Advisory Committee for Immunization Practices (ACIP). When the physician determines that immunization is no longer detrimental to the health of the child, the child shall be immunized according to this regulation.

(2) Religious exemption. Children need not be immunized if the parent, guardian or emancipated child objects in writing to the immunization on the grounds of prohibition based on religious belief or on the basis of a strong moral or ethical conviction similar to a religious belief.

(3) Exclusion of exempt students in situations of disease epidemic. In the event the Department declares that there is an epidemic of a vaccine preventable disease, any child who is enrolled in a public, private, or parochial school and who has been exempt from one or more immunization requirement for any of the causes authorized herein shall be temporarily excluded from attendance at the school. An enrollee so temporarily excluded shall be authorized to return to school upon the lifting of the epidemic declaration by the Department.

3. IMMUNIZATION REQUIREMENTS FOR CHILDCARE SETTINGS

(a) *Vaccination requirements.* Each child enrolled in a child care group setting shall be immunized in accordance with most current standards established by the Advisory Committee on Immunization Practices (ACIP), as presented in their *Recommended Childhood and Adolescent Immunization Schedule*.

(b) *Caregiver responsibilities.* For each child enrolled in a childcare group setting, the person in charge of the group setting shall ensure that a record of immunization is provided for each child enrolled in the childcare group setting by a healthcare provider, or designee, setting forth the vaccines the child has received and their dates of administration (month, day and year). The person in charge of the group setting shall ensure that the records are updated on a regular basis. The immunization status of each enrolled child shall be available for review by the Department, upon request.

(1) The caregiver at a child care group setting may not accept or retain a child 2 months of age or older at the setting, for more than 60 days, without verification of satisfaction of a child's age-appropriate immunization requirements, or the caregiver has received written documentation of satisfaction of one of the exemptions set forth in section 3(c).

(2) Verifications of immunization status shall also specify any vaccination not given due to medical condition of the child and shall state whether the condition is temporary or permanent.

(3) If the caregiver receives a written verification explaining that timely vaccination did not occur due to a temporary medical condition, the caregiver shall exclude the child from the child care group setting after an additional 30 days unless the caregiver receives, within that 30-day period, written verification from a healthcare provider that the child was vaccinated or that the temporary medical condition still exists. If the caregiver receives a written verification that vaccination has not occurred because the temporary condition persists, the caregiver shall require the presentation of a new verification at 30-day intervals. If a verification is not received as required, the caregiver shall exclude the child from the child care group setting and not readmit the child until the caregiver receives a verification that meets the requirements of this section.

(4) The caregiver shall retain the written verification or objection referenced in paragraph (b) for 60 days following the termination of the child's attendance.

(c) *Exemptions.* Immunization requirements for childcare settings do not apply with respect to:

(1) Children who are known by the caregiver to attend a kindergarten, elementary school or high school in Philadelphia.

(2) A caregiver who does not serve as a caregiver for at least 40 hours during any one month period.

4. MEDICAL EVALUATION, IMMUNIZATION, AND TREATMENT OF MINORS

(a) *Minor's Consent to Examination and Treatment.* A person between the ages of 11 and 18 may give consent, without the approval or consent of another person, for medical and other health examination, treatment and services to determine the presence of or to treat a sexually transmitted disease and any other disease, infection or condition reportable pursuant to the Disease Prevention and Control Law of 1955 and the regulations adopted thereunder, provided such person is capable of providing informed consent. The health care provider may not be sued or held liable for implementing appropriate diagnostic measures or administering appropriate treatment to the minor if the minor has consented to such procedures or treatment.

(b) *Minor's Consent to* Immunization. A person between the ages of 11 and 18 may authorize his or her own immunization, without the approval or consent of another person, to prevent occurrence of a reportable disease, infection, or condition, provided such person is capable of providing informed consent. A parent or guardian does not need to be present at the time the vaccine is administered. Written consent by the minor is not required, but documentation that the vaccine information statement (VIS) was provided to the vaccine recipient, and the publication date of the VIS, is required. The health care provider may not be sued or held liable for providing such immunization to the minor if the minor has consented to such procedures or treatment.

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5. RESPONSIBILITY AND AUTHORITY FOR REPORTING IMMUNIZATION INFORMATION ON NEWBORNS, CHILDREN, AND ADOLESCENTS

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(a) *Responsibility for Reporting Immunization Information.* Any health care provider who treats or examines a newborn, child, or other person below the age of 19, and any head, superintendent or other person in charge of a health care facility that treats such persons, who has knowledge of administration of any immunization included in the current Advisory Council on Immunization Practices/American Academy of Pediatricians (ACIP/AAP) *Recommended Childhood and Adolescent Immunization Schedule* that are routinely administered to persons less than 19 years of age shall make a report of the immunization to the Department. The report shall be submitted in a content and manner as specified below and in accordance with additional parameters as may be established by the Department.

(b) *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.

(c) *Content of Reports.* All reports shall include the following information:

(1) Child's name (first, middle and last);

(2) Child's date of birth;

(3) Child's sex;

(4) Name of the child's legal guardian;

(5) Address of the child's legal guardian;

(6) Type of immunization;

(7) Date of vaccine administration (month, day, year);

(8) Name of the immunization provider;

(9) Any additional information as the Department may require in connection with a particular type of immunization or case.

6. IMMUNIZATION REGISTRY

(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) *KIDS Immunization Registry.* Reported data shall be housed in the KIDS Immunization Registry at the Department. The KIDS Immunization Registry shall provide authorized users with immunization histories, vaccination forecasting tools, and reporting capabilities.

(c) *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. Immunization information shall not be available for records marked to indicate a parent or legal guardian's decision not to participate in the KIDS Registry.

(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 newborns, children and adolescents for which the authorized user has professional responsibility and in accordance with the data use and confidentiality policies of the KIDS Registry.

(d) *Maintaining Immunization Data.*

(1)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.

2) The Department may choose, at its discretion, to maintain immunization data for adults in the Immunization Registry. Recording adult immunizations in the Registry will be applied when necessary in order to effectively carry out those programs of the Department designed to prevent and control disease and to monitor vaccine coverage rates.

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