To: Joseph Dworzky, City Solicitor  Date: 08/23/94

From: Jeanne Reedy, Executive Assistant, Records Dept.

Subject: Proposed Regulations Regarding Reporting of
Preschool Immunizations, Serology on
Maternal/Cord Blood for Congenital Syphilis

The above Regulations, promulgated by the Department of
Public Health, were received in the Department
of Records on 07/20/94 for filing and advertising.

Inasmuch as there were no requests for hearings, these
Regulations became effective midnight, 08/12/94.

CC: Estelle B. Richman, Health Commissioner
MEMORANDUM

July 13, 1994

TO: V. Chapman-Smith, Commissioner
    Department of Records

FROM: Estelle B. Richman, Commissioner

SUBJECT: REGULATIONS FOR APPROVAL

Enclosed please find copies of two regulations approved by the
Board of Health and Law Department. It is my understanding that
these regulations need to be approved by the Records Department and
published for public response.

Will you please advise Kimberley Imperiale of my office (686-5006)
when the regulations can be considered legal. Thank you.

EBR: dl

cc: Susan Pingree, Chief of Staff
    Robert Levenson, Director, Division of Disease Control
    Charlotte Nicholas, Chief Deputy City Solicitor
    Kimberley Imperiale, Assistant Health Commissioner
    Marta Lippin, Records Department
WHEREAS, there has been a marked increase in reported early syphilis cases from 1985 (696 cases) to 1991 (4,736 cases) -- a more than six-fold increase; and

WHEREAS, there has been a simultaneous increase in reported congenital syphilis during the same period (5 cases in 1985 to 301 cases in 1991); and

WHEREAS, congenital syphilis causes stillbirth and significant morbidity and long-term sequelae to the newborn; and

PURSUANT to Section 5-301(b) of the Home Rule Charter and Sections 6-201, 6-202, 6-203, 6-208 and 6-402(4)(b) of the Philadelphia Code, the following Regulation is promulgated by the Board of Health to be added in the appropriate subsection to the:

I. REGULATIONS GOVERNING THE CONTROL OF COMMUNICABLE AND NON-COMMUNICABLE DISEASES AND CONDITIONS,
   8. Venereal Diseases,
      (f) Prenatal Examination,
          (3) Maternal/Cord Blood Serology for Congenital Syphilis; and

II. REGULATIONS FOR MATERNITY AND NEWBORN SERVICES,
   5. Care of Newborn Infants,
      (a) Delivery Room Care,
          (14) Examination of Infant,
The Regulation is to read as follows:

I. REGULATION GOVERNING THE CONTROL OF COMMUNICABLE AND
  NON-COMMUNICABLE DISEASES

8. Venereal Diseases
   (f) Prenatal Examination
   (1) Every physician and all other persons permitted by law to
       attend, treat or examine any pregnant woman for
       conditions relating to pregnancy during the time of
       gestation or at delivery, shall take or cause to be taken, a
       sample of blood of such woman at the time of first
       examination and again during the second and/or third
       trimester of gestation and shall submit such samples to
       an approved laboratory for an approved serological test
       for syphilis. All persons permitted by law to attend
       pregnant women, but not permitted by law to take blood
       samples, shall likewise cause samples of the blood of
       every such pregnant woman attended by them to be
       taken by a duly licensed physician or practitioner of the
       Commonwealth of Pennsylvania and to be submitted to
       an approved laboratory for an approved serologic test
       unless the woman dissents. If the pregnant woman
       objects, it shall be the duty of the physician or
       practitioner to explain to her the desirability of such
       tests.

   (2) In reporting every birth and fetal death, physicians and
       others required to make such reports shall state upon
       these certificates whether the above required blood tests
       were made, and if so, the dates of the tests but not the
       results of the tests. If the tests were not made, it shall
       be stated whether they were not made because, in the
       opinion of the physician or practitioner, the tests were
       not advisable or because the woman objected.

II. REGULATION FOR MATERNITY AND NEWBORN SERVICES

5. Care of Newborn Infants
   (a) Delivery Room Care
   (14) Examination of Infant
   (f) Maternal/Cord Blood Serology for Congenital Syphilis
   (1) Every physician or licensed birth attendant who delivers a newborn
       whether alive or dead after 22 weeks gestation, shall acquire body
       blood from the mother and submit it to an approved laboratory for
       standard serological tests for syphilis. If at the time of birth, a
       sample of blood from the umbilical cord is obtained and tested for
       syphilis, the requirement to test the mother’s blood shall be waived,
       unless the cord blood test is determined to be positive;
Specimens shall be taken from the mother upon entry to the responsible institution for the purpose of delivery, or if a specimen taken from the cord, it shall be taken immediately after birth. Blood from the mother in response to a positive cord blood test must be drawn and submitted for testing within 24 hours of receipt of the cord blood test result.

The date and time of maternal and/or cord blood collection and the test results of such specimens shall be recorded in the infant's permanent health record prior to discharge from the institution. The same information shall be entered in the mother's permanent health record. Bloods submitted for testing must be marked clearly as Maternal/Delivery, Cord or Newborn in order to facilitate reporting to the Philadelphia Department of Public Health's (PDPHs) Sexually Transmitted Diseases (STD) Control Program within 24 hours of receipt of test results.

Approved laboratories shall perform standard quantitative serologic tests for syphilis titred to endpoint on all Maternal/Delivery, Cord, and Newborn specimens of blood received. All results must be reported to the responsible Physician/Licensed Birth Attendant within 24 hours of completion of testing. All positive results must be reported to the PDPH STD Control Program by telephone or FAX within 24 hours of completion of testing and must include an appropriate designation, i.e. Maternal/Delivery, Cord, Newborn.

The responsible Physician/Licensed Birth Attendant shall:

(a) collect, label, submit specimens and assure that test results are recorded as specified in the Regulation;

(b) report all suspected or confirmed cases of congenital syphilis by telephone to the PDPH STD Control Program within 24 hours of receipt of the test results; and

(c) work in cooperation with designated public health investigators to assure that diagnosis, therapy and any necessary follow-up meet current standards of care.

This Regulation will expire on June 30, 1997.