

Pursuant to the authority vested in the State Hospital Review and Planning Council and the Commissioner of Health by sections 206(1)(e), 2500, 2803(2), 2803(4), 2803(8), 2803-j(3), 2805-j, 2805-m of the Public Health Law and section 366-g of the Social Services Law, a new section 400.22 of Part 400 of Subchapter A of Chapter V of Title 10 (Health) of the Official Compilation of Codes, Rules and Regulations of the State of New York is hereby added, to be effective upon publication of a Notice of Adoption in the New York State Register in hospitals and freestanding birthing centers in New York State outside of New York City, and to hospitals and freestanding birthing centers in New York City on January 1, 2007, to read as follows:

The table of contents for Part 400 is amended to read as follows:

PART 400

ALL FACILITIES-GENERAL REQUIREMENTS (Statutory authority: Public Health Law, Sections 2800, 2803)

Sec.

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400.22 Statewide perinatal data system

A new section 400.22 is added to Part 400 to read as follows:

Section 400.22 Statewide perinatal data system. (a) All hospitals and freestanding birthing centers which provide care and services to parturient women and/or neonates shall participate in the Statewide Perinatal Data System by providing required information in accordance with this section. Facilities contributing data to the system

may only access data from the system in accordance with this section and other applicable laws and regulations.

(b) As used in this section the following terms shall have the following meanings:

(1) The statewide perinatal data system (SPDS) shall mean the electronic maternal and newborn data collection and analysis system established and maintained by the Department of Health which includes the data elements, organized in modules, which comprise the New York State Certificate of Live Birth for births occurring in New York State outside of New York City, or the New York City Certificate of Live Birth for births occurring in New York City, and other data elements which relate to maternal and newborn health and care in hospitals and free-standing birthing centers.

(2) The core module shall be the New York State Certificate of Live Birth, a data set consisting of elements specified by the Commissioner of Health and collected for all parturient women and newborns in New York State outside of New York City; and for births occurring in New York City, the core module shall be the New York City Certificate of Live Birth, a data set consisting of elements specified by the New York City Commissioner of Health and Mental Hygiene and collected for all parturient women and newborns in New York City.

(3) The supplemental module shall mean a set of data supplied by the patient consisting of data elements specified by the Commissioner of Health in consultation with the Commissioner of the New York City Department of Health and Mental Hygiene. Supplemental module data elements shall be related to quality of prenatal care and maternal factors that may be related to birth outcomes.

(4) The high risk obstetric module shall mean a data set consisting of data elements that provide clinically-relevant information on pregnant women who are

referred to obstetricians for specialty care in the antepartum period or who are transported to a higher level facility for delivery or care in the antepartum, intrapartum or postpartum period. Elements will be as specified by the Commissioner of Health in consultation with the Commissioner of the New York City Department of Health and Mental Hygiene concerning all pregnant women identified as having high risk pregnancies, inclusive of maternal transports to higher levels of care. The data elements shall supplement core module data, providing additional data on clinical risk status and interventions for high risk births.

(5) The high risk neonatal module (NICU module) shall mean a data set consisting of data elements that provide clinically-relevant information on the neonate at the time of entry to the neonatal intensive care unit. The elements will be as specified by the Commissioner of Health in consultation with the Commissioner of the New York City Department of Health and Mental Hygiene and data will be collected on all neonates entering all special care and intensive care nurseries for longer than four hours. The high risk neonatal module shall also include information on all newborns who die in the delivery room, in transit to the neonatal special or intensive care unit, and in the neonatal special or intensive care units. The data elements shall supplement core module data, providing additional data on clinical risk status and interventions for high risk newborns.

(6) The newborn Medicaid eligibility module shall consist of the Medicaid Client Identification Number (CIN) and other Medicaid-specific information as specified by the Commissioner of Health, and shall be available solely to authorized Office of Medicaid Management staff and departmental staff authorized to help maintain the SPDS files and the programming required thereby.

(7) De-identified patient data shall mean data from which individual patient names have been expunged and other identifiers have been modified so that there is no reasonable basis to believe that individual patients can be identified by using such data except by the facility which provided the patient care and services.

(8) Quality improvement shall mean any use or analysis of SPDS data that identifies for further investigation any poor outcomes potentially amenable to intervention (sentinel events), trends by hospital, hospital level or region, potential problem areas or any issues with quality of care; and further, may lead to improvement of the care provided by the regional perinatal center, its affiliate hospitals or regional perinatal system providers through development of initiatives designed to address the potential problems identified, or to improve the quality of the data collected via the SPDS.

(9) Target area for a community-based organization under contract to the New York State Department of Health shall mean the organization's specified area of operation and/or influence as noted in their current contract.

(c) Participation in the statewide perinatal data system (SPDS).

(1) All hospitals and freestanding birthing centers that provide perinatal health care services shall participate in the statewide perinatal data system. All live births shall be entered into the state perinatal data system. For births occurring in New York City, the core module shall be implemented on January 1, 2007.

(2) Each hospital and freestanding birthing center shall submit core module data to the agency responsible for collecting birth records. In addition, all hospitals shall submit data from the supplemental module, the high risk obstetric module, and the Medicaid eligibility module, and, if the hospital has a neonatal special or intensive care

unit, from the high risk neonatal module as well, to the department in a form and manner prescribed by the department. The hospital shall be responsible for retaining signed consent forms, if any, for at least six years. The hospital will only transmit data as required under the regulations and any additional data for which it has consent, when consent is needed. Data elements in the system shall address the following:

(i) mother's Medicaid information to be used only to determine newborns' Medicaid eligibility;

(ii) public health surveillance of birth outcomes; and

(iii) improvement of prenatal, obstetric, and newborn care for mothers and infants.

(3) New York City Department of Health and Mental Hygiene will continue to exercise oversight of the use and release of the New York City Birth Certificate and the information contained therein. Nothing contained herein shall abridge the authority of the New York City Department of Health and Mental Hygiene to maintain the New York City Vital Records System. Nothing contained herein shall abridge the authority of the New York State Department of Health to maintain the New York Vital Records System outside of New York City.

(4) Access to SPDS data shall be limited to staff authorized by the Department of Health, and in the case of core module data for births occurring in hospitals and freestanding birthing centers located in New York City, staff authorized by the New York City Department of Health and Mental Hygiene, in the following settings for the purposes specified. Identifying SPDS information may be disclosed to authorized staff when and to the extent the disclosure is consistent with the Public Health Law, and for core module data from New York City consistent with applicable New York City law and regulations, and necessary to conform to an identified requirement of the Public Health Law or one of

its implementing regulations and when that disclosure is not otherwise prohibited or restricted by or inconsistent with the Public Health Law or its implementing regulations.

(i) Authorized staff of a facility shall have access to data submitted to the SPDS by that facility, with the exclusion of the Medicaid eligibility module; use of data shall conform with facility policies regarding use of confidential data.

(ii) A regional perinatal center shall have access to de-identified data submitted to the SPDS by its perinatal affiliates, with the exclusion of the Medicaid eligibility module, with a unique identifier that can be linked to identifying information only by the originating hospital for reference in evaluation of patient outcomes as specified in section 721.9 of this Title. De-identified data may also be used to monitor regional trends.

(iii) A comprehensive prenatal/perinatal services network or other community-based organization under contract to the Department of Health may be given access to available selected aggregate core and supplemental module data about births within its target area with all patient and provider identifiers eliminated. The level of aggregation and/or the geographic area targeted must ensure that no patients or providers are able to be identified from the data provided. Data shall be used only in furtherance of the organization's role in assessing and improving perinatal health in their target area, as specified in their contract with the Department.

(iv) Staff authorized by the Department of Health shall have access to individual-level perinatal data system data reported by hospitals and freestanding birthing centers except in the case of core module data for births occurring in hospitals and freestanding birthing centers located in New York City, where staff access to core module data will be authorized by the New York City Department of Health and Mental Hygiene. For births occurring in hospitals and freestanding birthing centers located in New York City, SPDS

data, including core and supplemental modules, shall be available to the New York City Department of Health and Mental Hygiene.

(v) Regional perinatal centers, affiliate hospitals and freestanding birthing centers with access to the data in the statewide perinatal data system (“SPDS”) shall not use the data for purposes other than quality improvement as defined in these regulations.

SPDS data is confidential and must be appropriately secured by the regional perinatal centers, affiliate hospitals and freestanding birthing centers and shall not be redisclosed, except to the department or its authorized agents or contractors.

(d) The Commissioner shall waive for up to one year, upon request from the New York City Department of Health and Mental Hygiene on behalf of the facilities located within that vital records registration district, the data collection requirements of this section under the following circumstances:

(1) An application for a waiver must be submitted that:

(i) is received at least three months before the effective date of the SPDS in the registration district;

(ii) identifies the financial, administrative or other hardship which necessitates the request;

(iii) describes the measures to be taken to eliminate the hardship and the anticipated completion date of those measures; and

(iv) assures continued access by hospitals to data comparable to that required in this section prior to implementation of SPDS.