

Perinatal Services

Effective date: 1/16/17

Pursuant to the authority vested in the Commissioner of Health by section 2505-A of the Public Health Law, section 405.21 of Title 10 (Health) of the Official Compilation of Codes, Rules and Regulations of the State of New York is amended, to be effective 90 days after publication of Notice of Adoption in the New York State Register, to read as follows:

Subdivision (f) (3) Section 405.21 is amended to read as follows:

(f) (3) Education and orientation of the mother who is planning to raise the baby.

(i) The hospital shall provide instruction and assistance to each maternity patient who has chosen to breastfeed and shall provide information on the advantages [and disadvantages] of breastfeeding and possible impacts of not breastfeeding to women who are undecided as to the feeding method for their infants. At a minimum:

(a) the hospital shall designate at least one person who is thoroughly trained in breastfeeding physiology and management to be responsible for ensuring the implementation of an effective breastfeeding program. At all times, there should be available at least one staff member qualified to assist and encourage mothers with breastfeeding;

(b) written policies and procedures shall be developed, updated, implemented, and disseminated annually to staff providing maternity or newborn care to assist and encourage the mother to breastfeed which shall include, but not be limited to:

(1) prohibition of the application of standing orders for anti_lactation drugs;

(2) placement of the newborn skin-to-skin for breastfeeding immediately following delivery, unless contraindicated;

(3) restriction of the newborn's supplemental feedings to those indicated by the medical condition of the newborn or of the mother;

(4) provision for the newborn to be fed on demand;

(5) pacifiers or artificial nipples may be supplied by the hospital to breastfeeding infants to decrease pain during procedures, for specific medical reasons, or upon the specific request of the mother. Before providing a pacifier or artificial nipple that has been requested by the mother, the hospital shall educate the mother on the possible impacts to the success of breastfeeding and discuss alternative methods for soothing her infant, and document such education;

[provision for distribution of discharge packs of infant formula only upon a specific order by the attending practitioner or at the request of the mother;]

(6) prohibition of the distribution of marketing materials, samples or gift packs that include breast milk substitutes, bottles, nipples, pacifiers, or coupons for any such items to pregnant women, mothers or their families;

(7) prohibition of the use of educational materials that refer to proprietary product(s) or bear product logo(s), unless specific to the mother's or infant's needs or condition; and

(8) prohibition of the distribution of any materials that contain messages that promote or advertise infant food or drinks other than breast milk.

(c) the hospital shall provide an education program as soon after admission as possible which shall include but not be limited to:

(1) the importance of scheduling follow-up care with a pediatric care provider within the timeframe following discharge as directed by the discharging pediatric care provider;

(2) the nutritional and physiological aspects of human milk;

(3) the normal process for establishing lactation, including care of the breasts, common problems associated with breastfeeding and frequency of feeding;

(4) the potential impact of early use of pacifiers on the establishment of breastfeeding;

[(4)] (5) dietary requirements for breastfeeding;

[(5)] (6) diseases and medication or other substances which may have an effect on breastfeeding;

[(6)] (7) sanitary procedures to follow in collecting and storing human milk;

[(7)] (8) sources for advice and information available to the mother following discharge; and

(d) for mothers who have chosen formula feeding or for whom breastfeeding is medically contraindicated, hospitals shall provide individual training in formula preparation and feeding techniques.

Subdivision (f) (5) of Section 405.21 is amended to read as follows:

(f) (5) Discharge planning. The discharge of mother and newborn shall be performed in accordance with section 405.9 of this Part. In addition, prior to discharge, the hospital shall determine that:

(i) sources of nutrition for the infant and mother will be available and sufficient and if this is not confirmed, the attending practitioner and an appropriate social services agency shall be notified;

(ii) follow-up medical arrangements [for mother and infant], consistent with current perinatal guidelines and recommendations, have been made for mother and newborn;

(iii) the mother has been informed of community services, including the Special Supplemental Nutrition Program for Women, Infants and Children (WIC), and shall make referrals to such community services as appropriate.

[(iii)] (iv) the mother has been instructed regarding normal postpartum events, care of breasts and perineum, care of the urinary bladder, amounts of activity allowed, diet, exercise, emotional response, family planning, resumption of coitus and signs of common complications;

[(iv)] (v) the mother has been advised on what to do if any complication or emergency arises;

[(v)] (vi) the newborn has had a documented and complete physical examination and verification of a passage of stool and urine;

[(vi)] (vii) the means of identification of mother and newborn are matched. If the newborn is discharged in the care of someone other than the mother, the hospital shall ensure that the person or persons are entitled to the custody of the newborn; and

[(vii)] (viii) the newborn is stable; sucking and swallowing abilities are normal. Routine medical evaluation of the neonate's status at two to three days of age shall have been conducted or arranged[as well as newborn]. Newborn screening shall be conducted at time of discharge, provided discharge is greater than 24 hours after the birth, or between the third and fifth day of life, whichever occurs first, in accordance with Part 69 of this Title.

REGULATORY IMPACT STATEMENT

Statutory Authority:

Section 2505-a(4) of the Public Health Law (PHL) authorizes the Commissioner to make regulations reasonably necessary to implement the Breastfeeding Mother's Bill of Rights.

Legislative Objectives:

PHL § 2505-a(4) established the Commissioners authority to implement the Breastfeeding Mother's Bill of Rights and the principles enumerated therein. The Breastfeeding Mother's Bill of Rights gives women the right to be informed of the benefits of breastfeeding and have their health care provider and maternal health care facility encourage and support breastfeeding.

Needs and Benefits:

Part 405 of Title 10 of the New York Codes Rules and Regulations (10 NYCRR) outlines the minimum standards for hospitals, which includes provisions for perinatal services (405.21). The Department's proposal seeks to amend the perinatal services minimal standards to make them consistent with the evidence-based practices recommended in the *Ten Steps to Successful Breastfeeding*, the Baby-Friendly Hospital Initiative, and breastfeeding policy positions of professional health care organizations and government entities. These revisions will increase the number of women who exclusively breastfeed during birth hospitalization.

The current regulations require the hospital to educate and orientate the mother planning to raise the baby. These revisions will expand the requirements regarding educating and orientating breastfeeding mothers. These additional requirements include: discussing with mothers the possible impacts to the health of the baby or herself associated with not breastfeeding; ensuring hospitals annually update and disseminate their written policies and

procedures to staff; encouraging “skin-to-skin” placement of the newborn immediately after delivery; prohibiting the distribution of marketing materials, samples or gift packs that include breast milk substitutes, bottles, nipples, pacifiers or coupons for any of these items; prohibiting educational materials that refer to proprietary products or product logos; prohibiting the distribution of materials that contain messages that promote or advertise infant food other than breast milk; and by only allowing dissemination of pacifiers when used to decrease pain during a procedure, for specific medical reasons, or upon the specific request from a mother. However, if a mother requests a pacifier, the hospital must first educate the mother on the possible impacts pacifier use may have to the success of breastfeeding and discuss alternative methods, and document such education. Furthermore, the proposed amendments require the hospital to include the potential impact of the early use of pacifiers on the establishment of breastfeeding, in the hospital’s education program for the mother who is planning to raise the baby.

The current regulation also sets forth requirements for the discharge of the mother and newborn from the hospital. The proposed amendments will now require follow-up medical arrangements to be made for mother and newborn, consistent with current perinatal guidelines and recommendations; and require informing the mother of community services available including the WIC program and making appropriate referrals to community services.

Costs:

Costs to the State Government:

The proposed rule does not impose any new costs on state government.

Costs to Local Government:

The proposed rule does not impose any new costs on local government.

Costs to Private Regulated Parties:

The proposed rule would have minimal costs for hospitals. Minimal costs for hospitals include the cost of changing hospital policy and procedures and the costs of informing and training staff of the changes. For hospitals that currently distribute marketing materials or formula to new mothers, the space required for storage of the materials may now be used for other purposes.

Costs to the Regulatory Agency:

The proposed rule does not impose any new costs on any regulatory agency.

Local Government Mandates:

The proposed rule imposes no mandates upon any county, city, town, village, school district, fire district, or other special district.

Paperwork:

The proposed rule imposes no new reporting requirements, forms, or other paperwork upon regulated parties.

Duplication:

There are no relevant rules or other legal requirements of the Federal or State governments that duplicate, overlap, or conflict with this rule.

Alternatives:

There were not significant alternatives to be considered during the regulatory process. There are no risks of harm to mothers and their infants by this proposal, no costs or burdens to hospitals to implement, no existing programs or statutes would need to be amended to achieve the desired result, no additional regulations would be required, and enforcement would remain the same.

Federal Standards

The proposed rule does not exceed any minimum standards of the federal government for the same or similar subject area.

Compliance Schedule:

The proposal will go into effect 90 days after the Notice of Adoption is published in the *New York State Register*.

Contact Person:

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REGULATORY FLEXIBILITY ANALYSIS
FOR SMALL BUSINESS AND LOCAL GOVERNMENTS

Effect of Rule:

The proposed rule will apply to the 125 hospitals providing maternity and newborn care services in New York State including four hospitals run by a local government (county) and one hospital defined as a small business. Hospitals that are a small business or operated by local government will not be affected in any way different from any other hospital.

Compliance Requirements:

Compliance requirements are applicable to those hospitals considered small businesses as well as the hospitals operated by local governments. Compliance will require: (a) reviewing and changing written policy; and (b) training applicable providers and staff about the changes in the perinatal services.

Professional Services:

Professional services are not anticipated to be impacted as a result of the changes to perinatal services to comply with accepted standards of care. These updated regulations will be consistent with evidence-based practices recommended in the *Ten Steps to Successful Breastfeeding*, the Baby-Friendly Hospital Initiative, and breastfeeding policy positions of professional health care organizations and government entities.

Compliance Costs:

Compliance costs associated with these regulations will be minimal and will arise as a result of: (a) changing written policy and procedures, and (b) informing staff about the changes to perinatal services.

Economic and Technological Feasibility:

It is economically and technologically feasible for hospitals that are small businesses or operated by local governments to comply with this amended rule.

Minimizing Adverse Impact:

There are no adverse impacts anticipated. Hospitals will have a minimum of 90 days following adoption of these regulations to change their policy and protocols and three months to inform staff about the changes to perinatal services.

Small Business and Local Government Participation:

A copy of this notice of proposed rulemaking will be posted on the Department's website. The notice will invite public comments on the proposal and include instructions for anyone interested in submitting comments, including small businesses and local governments.

Cure Period:

Chapter 524 of the Laws of 2011 requires agencies to include a "cure period" or other opportunity for ameliorative action to prevent the imposition of penalties on the party or parties subject to enforcement when developing a regulation or explain in the Regulatory Flexibility Analysis why one was not included. This regulation creates no new penalty or sanction. Hence, a cure period is not required.

RURAL AREA FLEXIBILITY ANALYSIS

Types and Estimated Numbers of Rural Areas:

The proposed rule will apply to the 125 hospitals providing maternity and newborn care services in New York State, including the 38 hospitals located in rural areas of the State defined as counties with less than a population of 200,000.

Reporting, Recordkeeping, Other Compliance Requirements and Professional Services:

Compliance requirements are applicable to those hospitals located in rural areas. Compliance will require: (a) reviewing and changing written policy; and (b) informing applicable staff about the change in perinatal services. Professional services will not be impacted as a result of these regulations.

Costs:

There are minimal costs to report. The costs are associated with staff time to change written hospital policy and procedures and to train staffed regarding these changes in perinatal services.

Minimizing Adverse Impact:

There are no adverse impacts anticipated. Hospitals will have a minimum of 90 days following adoption of these regulations to change their policy and protocol and three months to inform staff about the changes in perinatal services.

Rural Area Participation:

A copy of this notice of proposed rulemaking will be posted on the Department's website. The notice will invite public comments on the proposal and include instructions for anyone interested in submitting comments, including small businesses and local governments.

JOB IMPACT STATEMENT

No Job Impact Statement is included because the Department has concluded that the proposed regulatory amendments will not have a substantial adverse effect on jobs and employment opportunities. The basis for this conclusion is that these amendments merely assist the State in the application of the Breastfeeding Mother's Bill of Rights, pursuant to Section 2505-a of the Public Health Law.

ASSESSMENT OF PUBLIC COMMENT

Public comments were submitted to the New York State Department of Health (DOH) in response to the proposed changes to Title 10 NYCRR section 405.21, requiring updates to the minimum standards for hospitals regarding perinatal services. The Department received comments from two health care organizations, one hospital, and one city health department. These comments and DOH's responses are summarized below.

COMMENT: A comment suggested that the prohibition of the distribution of formula discharge packs should also pertain to obstetrical practices.

RESPONSE: These regulations, including the prohibition in the distribution of marketing materials, samples and gift bags to pregnant women, mothers and their families, apply to general hospitals, general hospital extension clinics and freestanding birthing centers providing perinatal services. Private obstetrical practices, however, are outside the Department's legislated authority.

COMMENT: A comment suggested the elimination of "dietary requirements for breastfeeding," or changing the word "requirements" to "suggestions" in section 405.21(f)(3)(i)(c)(5).

RESPONSE: In its Dietary Guidelines, the United States Department of Agriculture (USDA) states that: "When you are pregnant or breastfeeding, you have special nutritional needs." See

<http://www.choosemyplate.gov/moms-breastfeeding-nutritional-needs>. DOH believes that using the term “requirements” accomplishes the intent of the above guidance.

COMMENT: A comment suggested that information on the advantages of breastfeeding and possible impacts of not breastfeeding should be offered to all maternity patients, not just to those who are undecided.

RESPONSE: DOH encourages all women to be educated about the advantages of breastfeeding and possible impacts of not breastfeeding during prenatal care visits. However, the decisions of pregnant women who have been admitted to the hospital for delivery, and who have already decided to not breastfeed, should be respected.

COMMENT: A comment suggested that the regulations should specify that “skin-to-skin” placement applies in the case of both vaginal births and births by cesarean section, unless contraindicated.

RESPONSE: The regulations do not specify the method of delivery, but rather that all newborns should be placed skin-to-skin for breastfeeding immediately following delivery, unless contraindicated. DOH believes that the regulations provide sufficient clarity that skin-to-skin contact should occur after a birth by cesarean section.

COMMENT: A comment suggested that the Supplemental Nutrition Assistance Program (SNAP) be added to section 405.21(f)(5)(iii), in addition to the reference to the Special Supplemental Nutrition Program for Women, Infants, and Children (WIC).

RESPONSE: The regulations require mothers to be informed of community services. A specific reference to WIC is included because WIC targets pregnant and postpartum women, infants and children. Referrals to additional community services, including SNAP, are also encouraged. Furthermore, the WIC program is required to make referrals to SNAP, if an individual is eligible for SNAP but not enrolled.