

Administration of Vitamin K to Newborn Infants

Effective date: 6/10/14

Pursuant to the authority vested in the Public Health and Health Planning Council and the Commissioner of Health by Section 225 of the Public Health Law, Section 12.3 of Title 10 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 a Notice of Adoption in the New York State Register, to read as follows:

12.3 Precautions to be observed for the prevention of hemorrhagic diseases and coagulation disorders of the newborn and infants related to vitamin K deficiency.

It shall be the duty of the attending physician, licensed midwife, registered professional nurse or other licensed medical professional attending the newborn to assure administration of a single [parenteral] intramuscular dose of 0.5 - 1.0 mg of [natural] vitamin [K¹;] K1 oxide (phytonadione) within [one hour] six hours of birth in accordance with current standards of medical care.

REGULATORY IMPACT STATEMENT

Statutory Authority:

Paragraph (4) of Section 225 of the Public Health Law gives the Public Health and Health Planning Council authority to promulgate this regulation with the approval of the Commissioner of Health.

Legislative Objectives:

The proposed rule expands the time window for the administration of vitamin K to newborn infants to remove a barrier to mothers completing the first breastfeeding prior to routine procedures, such as vitamin K administration.

Needs and Benefits:

Current hospital regulations (10 NYCRR § 12.3) require administration of Vitamin K to the newborn within one hour of birth. This short time period has been identified as a barrier in ensuring that new mothers and their infants have the recommended 30- 60 minutes of uninterrupted time for mother-infant skin-to-skin contact to complete the first breastfeeding before routine procedures occur, such as vitamin K administration. There are no medical reasons to require that vitamin K be administered to newborns within one hour of birth. This proposed rule expands the time window for administration of vitamin K to newborns from within one hour to within six hours of birth, which is consistent with the 2012 American Academy of Pediatrics Policy Statement and with the position statement of the Canadian Pediatric Society, Fetus and Newborn Committee (originally issued 1997). A public health goal of the New York State Department Health is to

increase exclusive breastfeeding, and removing this barrier may help promote and support early initiation and exclusive breastfeeding during the birth hospitalization.

Costs:

Costs to the State Government:

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

Costs to Local Government:

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

Costs to Private Regulated Parties:

The proposed rule would have very minimal costs for hospitals. Minimal costs for hospitals may include the cost of changing the hospital policy and procedures for administering vitamin K to newborn infants and the costs of training staff to inform them of the change. Vitamin K will continue to be administered to newborn infants in the same manner and the same dose as is done currently under 10 NYCRR §12.3. The proposed rule will simply change the current regulation to allow for greater flexibility.

Costs to the Regulatory Agency:

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

Local Government Mandates:

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

Paperwork:

The rule imposes no new reporting requirements, forms, or other paperwork upon regulated parties. Hospitals were and will continue to be required to document the administration of vitamin K.

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:

The Department considered other possible time frames. Extending the window for the administration of vitamin K to newborns from within one hour to within six hours was consistent with the recent recommendation of the 2012 American Academy of Pediatrics Policy Statement and with the position statement of the Canadian Pediatric Society, Fetus and Newborn Committee (originally issued 1997).

Federal Standards

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

Compliance Schedule:

The proposed effective date will be upon publication of a Notice of Adoption in the State Register.

Contact Person:

Katherine Ceroalo
New York State Department of Health
Bureau of House Counsel
Regulatory Affairs Unit
Corning Tower Building, Room 2438
Empire State Plaza
Albany, New York 12237
518-473-7488
518-473-2019-FAX
REGSQNA@health.state.ny.us

REGULATORY FLEXIBILITY ANALYSIS
FOR SMALL BUSINESS AND LOCAL GOVERNMENTS

Effect of Rule:

The provisions of these regulations will apply to the 228 general hospitals in New York State, including 18 general hospitals operated by local governments. Three general hospitals in the State are considered small businesses. These small business hospitals will not be affected differently from any other hospital.

Compliance Requirements:

Compliance requirements are applicable to those three hospitals considered small businesses as well as the 18 hospitals operated by local governments. Compliance will require: (a) reviewing and changing written policy for the administration of vitamin K to newborn infants; and (b) training applicable providers and staff about the change in the timeframe for administering vitamin K.

Professional Services:

Professional services are not anticipated to be impacted as a result of the following: (a) changing the timeframe for administration of vitamin K to newborn infants; and (b) training providers and staff about the change in the timeframe for administering vitamin K.

Compliance Costs:

Compliance costs associated with these regulations will be minimal and will arise as a

result of: (a) changing written policy and procedures for administering vitamin K to newborn infants; and (b) informing staff about the change in the timeframe for administering vitamin K to newborn infants. This will apply to those hospitals defined as small businesses.

Economic and Technological Feasibility:

It is economically and technologically feasible for small businesses to comply with these regulations.

Minimizing Adverse Impact:

There are no adverse impacts anticipated. This regulatory change increases the flexibility of administering vitamin K. Hospitals will have a minimum of 90 days following adoption of these regulations to change their policy and protocols for administering vitamin K to newborn infants and three months to inform staff about the change.

Small Business and Local Government Participation:

These regulations have been discussed with leadership from the Hospital Association of New York (HANY), the Greater New York Hospital Association (GNYHA), and the Iroquois Healthcare Alliance. These associations represent hospitals throughout the State of New York, including those that are small businesses and operated by local governments. These three associations were all supportive of this initiative.

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

Effect of Rule:

The provisions of these regulations will apply to general hospitals in New York State, including 47 general hospitals located in rural areas of the State. These hospitals will not be affected in any way different from any other hospital.

Compliance Requirements:

Compliance requirements are applicable to those hospitals located in rural areas.

Compliance will require: (a) reviewing and changing written policy for the administration of vitamin K to newborn infants; and (b) informing applicable staff about the change in the timeframe for administering vitamin K.

Professional Services:

Professional services will not be impacted as a result of these regulations.

Compliance Costs:

Compliance costs associated with these regulations will be minimal and will arise as a result of: (a) changing written policy and procedures for administering vitamin K to newborn infants; and (b) training staff about the change in the timeframe for administering vitamin K to newborn infants. This will apply to those hospitals located in rural areas of New York State.

Minimizing Adverse Impact:

There are no adverse impacts anticipated. This regulatory change increases the flexibility of administering vitamin K. Hospitals will have a minimum of 90 days following adoption of these regulations to change their policy and protocol for administering vitamin K to newborn infants and three months to inform staff about the change.

Rural Area Participation:

These regulations have been discussed with hospital associations that represent hospitals throughout the State, including those that are located in rural areas. These associations have been supportive of this initiative.

JOB IMPACT STATEMENT

No Job Impact Statement is required pursuant to section 201-a(2)(a) of the State Administrative Procedure Act. It is apparent, from the nature of the proposed amendment, that it will not have a substantial adverse impact on jobs and employment opportunities. Newborn infants are still required to have a single dose of vitamin K after birth. This medication will be provided in the same setting (hospital or birthing facility) by staff with similar credentials, and the procedure will take the same amount of time. The change in the regulation will just widen the time window which this medication may be given, from within 1 hour of birth to within 6 hours of birth.

Assessment of Public Comment

Public comments were submitted to the NYS Department of Health (DOH) in response to the regulation. The public comment period for this regulation ended on October 21, 2013. The Department received a total of nine comments from representatives of the provider community including private medical practitioners, the Academy of Breastfeeding Medicine, and the University at Albany School of Public Health.

Eight of the nine comments were similar and positive, stating that the adoption of these regulations is an obvious benefit to mother-newborn bonding. Summarized below is the Department of Health's response to the one comment that was not supportive:

COMMENT: One commenter cited and enclosed an article from the *AAP News* December 2008; 29(12). This is a newsletter of the American Academy of Pediatrics (AAP), and not a peer-reviewed journal. The newsletter usually summarizes other publications or policies, though no references are included. As the commenter pointed out, in this issue of *AAP News*, an article *Creating protocols for transitional care of the healthy, term newborn*, states:

Vitamin K – Within the first hour of delivery, give a single parental dose of natural vitamin K1 oxide (phytonadione) (0.5-1 mg) to prevent vitamin K-dependent hemorrhagic disease.

RESPONSE: The purpose of the proposed regulation change is to make it consistent with the more recent policy statement, issued in 2012, by the American Academy of Pediatrics (AAP): Policy Statement: Breastfeeding and the Use of Human Milk.

Pediatrics 2012; 129:e827. (accessed 12/13/2012 at:

<http://pediatrics.aappublications.org/content/129/3/e827.full.html>). This statement

specifically recommends a:

delay in administration of intramuscular vitamin K until after the first feeding is completed, but within 6 hours of birth,” and a delay in routine procedures (weighing, measuring, bathing, blood tests, vaccines, and eye prophylaxis) until after the first feeding is completed.

The more recent AAP Policy Statement recommendations (2012) should take precedence over the earlier AAP News article (2008).