



## Fast Track Proposed Regulation Agency Background Document

<b>Agency name</b>	Virginia Department of Health
<b>Virginia Administrative Code (VAC) citation</b>	12 VAC 5-410
<b>Regulation title</b>	Regulations for the Licensure of Hospitals in Virginia
<b>Action title</b>	Amend Section 440 of the regulation
<b>Document preparation date</b>	July 26, 2004

This information is required for executive branch review and the Virginia Registrar of Regulations, pursuant to the Virginia Administrative Process Act (APA), Executive Orders 21 (2002) and 58 (1999), and the *Virginia Register Form, Style, and Procedure Manual*.

### Brief summary

*Please provide a brief summary (no more than 2 short paragraphs) of the proposed new regulation, proposed amendments to the existing regulation, or the regulation proposed to be repealed. Alert the reader to all substantive matters or changes.*

This proposed amendment changes the storage of breast milk by hospitals, or at home for hospital use, from 24 hours consumption or disposal to 48 hours consumption or disposal, unless the milk is frozen. In addition, the amendment reformats a portion of section 440 of 12 VAC 5-410 into 6 new sections.

### Legal basis

*Please identify the state and/or federal legal authority to promulgate this proposed regulation, including (1) the most relevant law and/or regulation, including General Assembly chapter number(s), if applicable, and (2) promulgating entity, i.e., the agency, board, or person. Describe the scope of the legal authority and the extent to which the authority is mandatory or discretionary.*

The regulation is promulgated under the authority of Section 32.1-127 of the Code of Virginia, which grants the Board of Health the legal authority to promulgate regulations “in substantial conformity to the standards of health, hygiene, sanitation, construction, and safety as is established and recognized by medical and health care professionals and by specialists in the matters of public health and safety.” Therefore, this authority is mandated.

### Purpose

*Please explain the need for the new or amended regulation. Describe the rationale or justification of the proposed regulatory action. Detail the specific reasons the regulation is essential to protect the health, safety or welfare of citizens. Discuss the goals of the proposal and the problems the proposal is intended to solve.*

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In December 2003, the department was contacted by the Virginia Breastfeeding Task Force and informed that the current time standard (24 hours) for the storage of breast milk is in conflict with the current national recommendations of practice, i.e., 48 hours. Because of this conflict, hospitals providing newborn services are at risk of violating state regulatory standards when providing the quality of care expected for newborns and their mothers.

Currently section 440, Obstetric and Newborn Services, of 12 VAC 5-410 contains 27 pages of standards specific to pregnant women and the delivery of their infants. As might be expected, this can have a negative impact as it unintentionally increases chances for an “out of compliance” condition during a licensure inspection, through no fault of the licensee. Breaking the one section into six additional sections, with related section titles, will make it easier to quickly and easily locate specific requirements. In addition, reformatting this section will assist with the planned revision to the entire hospital regulation.

### Rationale for using fast track process

*Please explain the rationale for using the fast track process in promulgating this regulation. Please note: If an objection to the use of the fast-track process is received within the 60-day public comment period from 10 or more persons, any member of the applicable standing committee of either house of the General Assembly or of the Joint Commission on Administrative Rules, the agency shall (i) file notice of the objection with the Registrar of Regulations for publication in the Virginia Register, and (ii) proceed with the normal promulgation process with the initial publication of the fast-track regulation serving as the Notice of Intended Regulatory Action.*

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The intent of this amendment is to ease the current burden on lactating mothers and hospitals. In addition, the changes are not medically complex to implement and will reduce costs to mothers and hospitals. As an interim measure, the department has issued variance letters allowing hospitals providing newborn services to store breast milk for up to 48 hours. Therefore, the department does not expect this proposed change to be controversial.

The reformatting changes to section 440 are technical in nature and do not change the intent of any of the current standards and, therefore, are not considered to be controversial.

**Substance**

*Please briefly identify and explain the new substantive provisions, the substantive changes to existing sections, or both where appropriate. (Provide more detail about these changes in the “Detail of changes” section.)*

The proposed amendment updates two hospital regulatory time standards for storing breast milk *from* within 24 hours consumption or disposal *to* 48 hours consumption or disposal, unless the milk is frozen. In addition, the more medically accurate term “aseptic” replaces the archaic term “sterile.” The changes as a result of reformatting section 440 are technical in nature and do not change the intent of any of the current standards.

**Issues**

*Please identify the issues associated with the proposed regulatory action, including:*

- 1) the primary advantages and disadvantages to the public, such as individual private citizens or businesses, of implementing the new or amended provisions;*
- 2) the primary advantages and disadvantages to the agency or the Commonwealth; and*
- 3) other pertinent matters of interest to the regulated community, government officials, and the public.*

*If there are no disadvantages to the public or the Commonwealth, please indicate.*

The department learned that the current standard of 24 hours “consume or dispose, unless frozen” was proving too burdensome for lactating mothers attempting to provide their hospitalized infants with breast milk and for hospitals charged with tracking the use of the milk. By allowing a 48-hour standard, hospitals still meet best practices for quality care, without overburdening lactating mothers with outdated and archaic state requirements. The changes as a result of reformatting section 440 are technical in nature and do not change the intent of any of the current standards.

There are no disadvantages to the public or the Commonwealth.

**Financial impact**

*Please identify the anticipated financial impact of the proposed regulation and at a minimum provide the following information:*

<p><b>Projected cost to the state to implement and enforce the proposed regulation, including (a) fund source / fund detail, and (b) a delineation of one-time versus on-going expenditures</b></p>	<p>None to minimal. State general funds (0100) and licensure fees fund the hospital licensure program. The regulation already contains standards regarding breast milk and there is no change to the inspection process. Therefore, this is a one-time expenditure to promulgate this change to the regulation.</p>
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<b>Projected cost of the regulation on localities</b>	None
<b>Description of the individuals, businesses or other entities likely to be affected by the regulation</b>	Hospitals providing obstetric and newborn services.
<b>Agency’s best estimate of the number of such entities that will be affected</b>	63 hospitals
<b>Projected cost of the regulation for affected individuals, businesses, or other entities</b>	None as the changes made by this amendment to the regulation are technical in nature.

### Alternatives

*Please describe any viable alternatives to the proposal considered and the rationale used by the agency to select the least burdensome or intrusive alternative that meets the essential purpose of the action.*

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The current regulation contains standards on the storage of breast milk that are out of date with current best medical practices. Therefore, promulgating this amendment to the regulation is the only alternative available.

### Family impact

*Please assess the impact of the proposed regulatory action on the institution of the family and family stability.*

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There is no direct impact on the family, unless a lactating mother is providing breast milk to her infant in the hospital.

### Detail of changes

*Please detail all changes that are being proposed and the consequences of the proposed changes. Detail all new provisions and/or all changes to existing sections.*

*If the proposed regulation is intended to replace an emergency regulation, please list separately (1) all changes between the pre-emergency regulation and the proposed regulation, and (2) only changes made since the publication of the emergency regulation.*

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For changes to existing regulations, use this chart:

<b>Current section number</b>	<b>Proposed new section number, if applicable</b>	<b>Current requirement</b>	<b>Proposed change and rationale</b>
440.C.4.(13) and D.6.(17)	441.D.1.m and 444.K.17	Provides for storage of breast milk in sterile	Provides for storage of breast milk for use within 48 hours unless frozen.

		containers for use within 24 hours, unless frozen.	Exchanges “aseptic” for “sterile.”
440.C.1, 2, 3, and 4	441	Medical direction, physician consultation and coverage; nursing staff and coverage; policies and procedures	Same – technical changes
440.C.5 and 6	442	Obstetric service design and equipment	Same – technical changes
440.D.1 and 2	443	Designation of newborn service levels; Service levels	Same – technical changes
440.D.3, 4, 5, and 6	444	Newborn service medical direction; physician consultation and coverage; nursing direction, staffing and coverage; policies and procedures	Same- technical changes
440.D.7, and 8	445	Newborn service design and equipment	Same – technical changes
440.D.9	446	Newborn support services and other resources	Same – technical changes
440.E	447	Combined obstetric and clean gynecological services	Same – technical cahnges