



## **Economic Impact Analysis Virginia Department of Planning and Budget**

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### **12 VAC 5-410 –Rules and Regulations for the Licensure of Hospitals in Virginia Virginia Department of Health August 25, 2004**

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The Department of Planning and Budget (DPB) has analyzed the economic impact of this proposed regulation in accordance with Section 2.2-4007.G of the Administrative Process Act and Executive Order Number 21 (02). Section 2.2-4007.G requires that such economic impact analyses include, but need not be limited to, the projected number of businesses or other entities to whom the regulation would apply, the identity of any localities and types of businesses or other entities particularly affected, the projected number of persons and employment positions to be affected, the projected costs to affected businesses or entities to implement or comply with the regulation, and the impact on the use and value of private property. The analysis presented below represents DPB's best estimate of these economic impacts.

### **Summary of the Proposed Regulation**

The proposed regulations will increase the duration of time that hospitals can store breast milk prior to consumption or disposal from 24 hours to 48 hours, unless the milk is frozen. The proposed changes will also reorganize the regulations.

### **Estimated Economic Impact**

One of the proposed changes will allow hospitals to store breast milk up to 48 hours for consumption before it is disposed or frozen. Thus, the hospitals will be able to store breast milk for an additional 24-hour period. According to the department, the Virginia Breastfeeding Task Force pointed out that the current national standards for storage of breast milk is 48 hours. In particular, Human Milk Banking Association of North America states, "The recommended 48 hours of refrigerated storage is within a bacteriologically safe range and is conservative enough to cover variables in home refrigeration, time and temperature, collection techniques, hospital

transport, and hospital exposure to multiple caregivers.<sup>1</sup>” This recommendation is based on five studies that looked at the effects of refrigeration on storage for varying times from 24 hours to 8 days and found no appreciable bacterial growth over the storage times analyzed. The most recent of these studies is by Pardou et al.<sup>2</sup> which states that “The data also suggests that refrigeration is better than freezing for storage up to 8 days as far as antimicrobial properties are concerned.” In short, the weight of empirical evidence seems to support that the health benefits from the nutritional and immunological qualities of unfrozen human breast milk would exceed the health risks from deteriorating bacteriological properties within the first 48 hours.

The economic costs to hospitals associated with an additional 24-hour storage time, if chosen, are expected to be negligible. Furthermore, given the fact that hospitals are already issued variances allowing them to store breast milk up to 48 hours, no significant economic costs are expected upon promulgation of the proposed standard.

Finally, the proposed reorganization of the regulation into six separate sections is not expected to create any significant economic effects, but may improve the clarity of the regulations and make it easier to locate specific requirements.

## **Businesses and Entities Affected**

The proposed regulations apply to 63 hospitals providing obstetric and newborn services.

## **Localities Particularly Affected**

The proposed regulations apply throughout the Commonwealth.

## **Projected Impact on Employment**

No significant effect on employment is expected.

## **Effects on the Use and Value of Private Property**

No significant effect on the use and value of private property is expected.

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<sup>1</sup> Recommendations for Collection Storage and Handling of a Mother’s Milk for Her Own Infant in the Hospital Setting, 1999 Edition, Human Milk Banking Association of North America.

<sup>2</sup> Pardou, A., E. Serruys, F. Mascart-Lemone, M. Dramaix, H.L. Vis, 1994, “Human Milk Banking: Influence of Storage Process and of Bacterial Contamination on Some Milk Constituents,” *Biology of the Neonate*, No. 65, pp. 302-309.