

**Maryland General Assembly
Department of Legislative Services**

**Proposed Regulation
Department of Health and Mental Hygiene
(DLS Control No. 15-314)**

Overview and Legal and Fiscal Impact

The regulations require each freestanding birthing center to undergo a routine annual survey by the Department of Health and Mental Hygiene.

The regulations present no legal issues of concern.

There is no fiscal impact on State or local agencies.

Regulations of COMAR Affected

Department of Health and Mental Hygiene:

Freestanding Ambulatory Care Facilities: Freestanding Birthing Centers:
COMAR 10.05.02.04-.12

Legal Analysis

Background

Chapter 41 of 2015 codified the existing practice of the Office of Health Care Quality (OHCQ) to conduct an annual survey of the two freestanding birthing centers in the State. Prior to the enactment of Chapter 41, there was no requirement under State law for OHCQ to survey freestanding birthing centers. Federal law does not require a survey of a freestanding birthing center.

Summary of Regulations

The regulations require a licensee operating a freestanding birthing center to undergo a routine annual survey. A licensee is required to allow an on-site survey by the department at any time during the center's normal hours of operation to evaluate the center's compliance with the applicable requirements and standards. The regulations require center employees to make data and records accessible within a reasonable time during the on-site survey.

Legal Issues

The regulations present no legal issues of concern.

Statutory Authority and Legislative Intent

The Department of Health and Mental Hygiene cites § 19-3B-01 *et seq.* of the Health – General Article as statutory authority for the regulations. Section 19-3B-01 defines a “freestanding birthing center” to mean a facility that provides nurse midwife services under Title 8, Subtitle 6 of the Health Occupations Article. A freestanding birthing center does not include a hospital or the private residence of the mother. The definition of “freestanding ambulatory care facility” includes a freestanding birthing center. Section 19-3B-02 prohibits a freestanding ambulatory care facility from operating in the State unless the Secretary of Health and Mental Hygiene has granted the facility a license. After consultation with representatives of payors, health care practitioners, and ambulatory care facilities, § 19-3B-03 requires the Secretary to adopt regulations that establish procedures to implement the provisions of the subtitle and specified standards to ensure quality of care and patient safety. In addition, § 19-3B-03 requires the Secretary to survey each freestanding birthing center at least once per calendar year. Section 19-3B-07 authorizes the Secretary to investigate complaints concerning the conformance of a facility to the requirements of the subtitle and the regulations adopted under the subtitle.

This authority is correct and complete. The regulations comply with the legislative intent of the law.

Fiscal Analysis

There is no fiscal impact on State or local agencies.

Agency Estimate of Projected Fiscal Impact

The regulations require freestanding birthing centers to undergo a routine annual survey, allow an on-site survey at any time during normal hours of operation, and make data and records available within a reasonable time during the survey. The department advises that the regulations make only procedural changes and, thus, have no impact on State or local governments. The Department of Legislative Services concurs and notes that the regulations reflect Chapter 41 of 2015, which codified as a requirement the then current practice of the Office of Health Care Quality to conduct an annual survey of freestanding birthing centers.

Impact on Budget

There is no impact on the State operating or capital budget.

Agency Estimate of Projected Small Business Impact

The department advises that the regulations have minimal or no economic impact on small businesses in the State. The Department of Legislative Services concurs.

Contact Information

Legal Analysis: Lynne Blume Rosen – (410) 946/(301) 970-5350

Fiscal Analysis: Jennifer B. Chasse – (410) 946/(301) 970-5510