

**Maryland General Assembly
Department of Legislative Services**

**Proposed Regulations
Department of Health and Mental Hygiene
(DLS Control No. 16-187)**

Overview and Legal and Fiscal Impact

The regulations require the medical director and director of midwifery of a freestanding birthing center to establish protocols that include procedures for the use of ultrasound imaging.

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 10.05.02.01 and .06

Legal Analysis

Background

A freestanding birthing center is a facility that provides nurse midwife services. Currently regulations provide that a freestanding birthing center is only authorized to provide “normal maternity” care, which is defined in COMAR 10.05.02.01 as a low-risk, uncomplicated prenatal course as determined by adequate prenatal care and prospects for a normal, uncomplicated birth as defined by reasonable and generally accepted criteria of maternal and fetal health. “Normal maternity” does not include the use of drugs for induction or augmentation of labor, general and regional anesthesia, vacuum extractors, forceps, recorded electronic fetal monitors, ultrasound imaging, cesarean section, or surgical procedures other than episiotomy or perineal repair.

Before the 2016 session of the General Assembly, statute was silent regarding the use of ultrasound imaging in freestanding birthing centers; neither requiring nor prohibiting its use. Chapters 409 and 410 of 2016 require the Secretary of Health and Mental Hygiene, after consulting with specified entities, to establish by regulation standards to ensure quality of care and patient safety for the use of ultrasound imaging in a freestanding birthing center.

Summary of Regulations

The regulations require the medical director and director of midwifery of a freestanding birthing center to establish protocols that include procedures for the use of ultrasound imaging. The regulations require that the protocols be consistent with current standards of care and within the scope of practice for a physician or certified nurse midwife. The regulations also alter the definition of “normal maternity”.

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. More specifically, § 19-3B-03 requires the Secretary, after consulting with specified entities, to establish by regulation any procedures that the Secretary considers necessary for quality of care and patient safety. The remaining cited authority is not relevant to these regulations.

Additionally, on October 1, 2016, Chapters 409 and 410 of 2016 will take effect. The Acts require the Secretary, after consulting with specified entities, to establish by regulation standards to ensure quality of care and patient safety for the use of ultrasound imaging in a freestanding birthing center.

The relevant cited 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 implement Chapters 409 and 410 of 2016 (Senate Bill 600/ House Bill 1303), which required adoption of standards to ensure quality of care and patient safety for the use of ultrasound imaging in a freestanding birthing center. The department advises that the regulations have no impact on State or local governments. The Department of Legislative Services concurs.

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

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