
**Report to
The Vermont Legislature**

Regulation of Freestanding Health Care Facilities

In Accordance with Act 167 of 2018, Sec. 19

Submitted to: House Committee on Health Care
House Committee on Ways and Means
Senate Committees on Health and Welfare
Senate Committee on Finance
Health Reform Oversight Committee

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Statutory Charge

Act 167 Section 19 of 2018 requires that The Secretary of Human Services or designee shall convene a working group to develop recommendations for the regulation of freestanding healthcare facilities and their role in a coordinated and cohesive health care delivery system. The recommendations shall include:

(1) whether and how the State should license and regulate ambulatory surgical centers, freestanding birth centers, urgent care clinics, retail health clinics, and other freestanding health care facilities; and

(2) whether and to what extent these facilities should participate in Vermont's health care reform initiatives.

(b) The working group shall comprise representatives of ambulatory surgical centers, urgent care clinics, hospitals, the Green Mountain Care Board, the Department of Vermont Health Access, the Department of Health, the Office of the Health Care Advocate, the Vermont Program for Quality in Health Care, Inc., and other interested stakeholders.

(c) On or before February 1, 2019, the working group shall provide its recommendations to the House Committees on Health Care and on Ways and Means, the Senate Committees on Health and Welfare and on Finance, and the Health Reform Oversight Committee.

Introduction

During the months of October thru December 2018, The Agency of Human Services convened five meetings of the Freestanding Health Care Facilities Work Group. The work group consisted of participants from:

- Champlain Medical Urgent Care Walk-in Clinic
- ClearChoice MD Urgent Care
- The Green Mountain Surgery Center
- Vermont Eye Surgery and Laser Center
- Persons interested in Freestanding Birthing Centers in Vermont
- The Office of the Health Care Advocate
- The Vermont Association of Hospitals and Health Systems
- The Vermont Program for Quality in Health Care
- The Department of Vermont Health Access
- The Green Mountain Care Board
- The Vermont Department of Health

Two sub-groups were established to focus on how Ambulatory Surgical Centers (ASCs) should participate in the Patient Safety and Surveillance System, and to learn more about Freestanding Birth Centers. The Patient Safety and Surveillance System sub-group met once, while the Freestanding Birth Centers sub-group convened twice by phone.

Workgroup participants agreed that new regulatory efforts should focus on Ambulatory Surgical Centers (ASCs) specifically, and that Freestanding Birth Centers should be a topic for further exploration. The group was unified in focusing on ASCs after learning that all but two states (Vermont and Wisconsin) have some form of regulation of Ambulatory Surgical Centers, or ASCs. A complete guide can be found here: <http://reimbursementprinciples.com/wp-content/uploads/ASC-State-Regulations-2013.pdf>. Most states treat Urgent Care Clinics as

provider offices with extended hours and do not license or regulate them as entities. Freestanding Health Care Facilities proved to be a vague term. Central to the group's agreement to focus on ASCs was the recognition that these facilities differ from other freestanding facilities in that they exist for the purpose of performing surgery.

The workgroup agreed that Ambulatory Surgical Center means: any distinct [entity](#) that operates primarily for the purpose of providing surgical services to [patients](#) not requiring hospitalization and in which the expected duration of services would not exceed 24 hours following an admission. The term "ambulatory surgical center" does not include:

1. A facility that is licensed as part of a hospital, or;
2. A facility that is used as an office or clinic for the private practice of a physician(s), podiatrist(s), or dentist(s) unless:
 - a. It holds itself out to the public or other health care providers as an ambulatory surgical center, surgical center, surgicenter or similar facility using a similar name or variation thereof, or;
 - b. It is operated or used by a person or entity different than the physician(s), podiatrists(s), or dentist(s) who regularly practice at that facility;
 - c. Procedures are carried out using general anesthesia, except as used in oral or maxillofacial surgery, or;
 - d. Patients are charged a fee for use of the facility in addition to the physician(s), podiatrist(s), or dentist(s) professional services.

The remainder of this report and its recommendations follow in two sections: Ambulatory Surgical Centers and Freestanding Birth Centers.

Ambulatory Surgical Centers (ASCs)

Recommendation Part 1:

The workgroup recommends that the Health Department be authorized in statute to license ambulatory surgical centers to ensure they continue to meet patient safety and quality standards, and to ensure that patients receiving services in ASCs have a government authority available to receive and investigate complaints about such services.

1. In order to obtain a license from the Health Department, the general requirements for Ambulatory Surgical Centers must be met. These will be defined in rule, much like Hospital Licensing requirements. Broadly, these requirements should include:
 - a. Annual licensure.
 - b. Participation in the Patient Safety Surveillance and Improvement System.
 - c. Health and safety standards such as the Centers for Medicare and Medicaid Services (CMS) Conditions for Coverage, or similar health and safety standards as determined in rule.
 - i. These standards shall, as much as possible, be fully aligned with any existing federal requirements for Ambulatory Surgical Centers so as not to impose additional regulatory burdens on licensed facilities absent a clear state interest supporting any additional requirements.
 - ii. Certification with an accrediting body shall reduce the fee for licensure.

- d. Be in full compliance with all other current state law and regulations including, but not limited to, the Department of Public Safety Rules on Vermont Fire and Building Safety Codes, rules related to food safety and any other health care regulations or statutes.
- e. Have a clear method for responding to patient complaints.

Ambulatory Surgical Centers should pay a fee to the Health Department. The Health Department, in conjunction with the Department of Aging and Independent Living suggest a fee of \$600 per licensee.

Recommendation Part 2:

Participation of Ambulatory Surgical Centers in Vermont's Health Care Reform Initiatives

1. Consistent with the stated purpose of the Vermont Eye Surgery and Laser Center and the Green Mountain Surgery Center, the mission of ASCs is to reduce health care costs and improve quality. To this end, the workgroup recommends that the Vermont Department of Health make available on its website clear links to quality reports for ASCs.
2. The workgroup recommend that ASCs are required to use shared decision-making tools as outlined in *Act 113 of 2016, Sec.2, (12): requires processes and protocols for shared decision making between the patient and his or her health care providers that take into account a patient's unique needs, preferences, values, and priorities, including use of decision support tools and shared decision-making methods with which the patient may assess the merits of various treatment options in the context of his or her values and convictions, and by providing patients access to their medical records and to clinical knowledge so that they may make informed choices about their care.*

Freestanding Birth Centers

What is a Birth Center?

A birth center is an outpatient facility existing within the health care system designed to follow the midwifery model of care. Birth centers provide family centered care for healthy people before, during, and after normal pregnancy, labor, and birth.¹ Routine gynecological care as well as classes and support groups are often offered in birth centers. A birth center is typically a retrofitted house containing a kitchen, a waiting room, an exam room, bathrooms, and two to three birthing rooms. Birth centers function more like a physician's office than like a healthcare facility.² The American College of Obstetricians and Gynecologists and the Society for Maternal-Fetal Medicine state that licensed birth centers are appropriate for "Peripartum care of

¹ https://www.birthcenters.org/page/bce_what_is_a_bc

² https://www.birthcenters.org/page/bc_experience

low-risk women with uncomplicated singleton term pregnancies with a vertex presentation who are expected to have an uncomplicated birth.”³ As of 2017, there are 345 birth centers in 37 states plus DC, which represents a growth of 76% since 2010. ⁴Freestanding birth centers are recognized by statute, legislation, or Medicaid in 41 states.⁵

How are Birth Centers Staffed?

Freestanding birth centers are most often owned and staffed by a mixture of Certified Nurse Midwives (CNMs) and Certified Professional Midwives (CPMs), with the slight majority owned by CNMs. Medical and Naturopathic doctors also occasionally own or staff birth centers.

CNMs are graduate level nurse-practitioners (APRNs) with education and experience in both hospital and out of hospital settings. They can prescribe medications and provide primary care and they are licensed to practice in all states. ⁶ CPMs go through an education process that can include a mixture of apprenticeship and formal classes that prepares them to provide out of hospital obstetric care. They are licensed to practice in 31 states, including Vermont.

Birth centers also employ auxiliary staff including registered nurses, nursing assistants, doulas, midwife assistants, and administrators.

Are Birth Centers Safe?

Numerous studies and meta-analyses have shown that having a baby in a birth center is at least as safe as having a baby in a hospital for low risk women. A 2018 review of 17 birth center studies found identical neonatal mortality rates between birth center births and low-risk populations in hospital. ⁷Starting labor with a midwife in a birth center confers a radically lower risk of interventions such as epidurals, vacuum extraction, having perineal trauma requiring suturing and, cesarean section.⁸

Every major birth center study in the last decade has shown a birth center c-section rate of between 4% and 6% with infant outcomes the same as low-risk populations delivering in hospital.⁹ The national c-section rate is 32%, Vermont's is 27%, and the national low risk rate is

³ <https://www.acog.org/Clinical-Guidance-and-Publications/Obstetric-Care-Consensus-Series/Levels-of-Maternal-Care>

⁴ https://cdn.ymaws.com/www.birthcenters.org/resource/collection/028792A7-808D-4BC7-9A0F-FB038B434B91/Birth_Center_in_the_United_States.pdf

⁵ https://www.birthcenters.org/page/bc_experience

⁶ <http://www.midwife.org/acnm/files/ccLibraryFiles/FILENAME/000000006807/FINAL-ComparisonChart-Oct2017.pdf>

⁷ <https://onlinelibrary.wiley.com/doi/full/10.1111/jmwh.12701>

⁸ https://www.cochrane.org/CD004667/PREG_midwife-led-continuity-models-care-compared-other-modelscare-women-during-pregnancy-birth-and-early

⁹ <https://www.ncbi.nlm.nih.gov/pubmed/27926797> , <https://www.ncbi.nlm.nih.gov/pubmed/26773853>

26%. This means that the c-section rate for women choosing birth centers is at minimum four times lower than if those same women choose hospital birth, with the same level of safety. This has been shown to be true for Medicaid beneficiaries as well as people with private insurance.¹⁰

As one 2013 study concluded: “If the 15,574 women who planned to give birth in birth centers had instead chosen hospital births, it is estimated that they would have experienced 3,000 additional—and unnecessary— Cesareans. Instead, these c-sections were safely and effectively prevented, along with a potential cost-savings of at least \$4.5 million.”¹¹

Additionally, care by midwives reduces the risk of preterm birth, which is a leading cause of neonatal mortality.¹² Women receiving care from midwives report higher patient satisfaction and have higher rates of breastfeeding. Higher rates of breastfeeding lead to healthier infants which decreases the cost of pediatric care in the first year of life.

Recommendation:

The work group recommends that Freestanding Birth Centers have a distinct pathway to licensure in Vermont based on national standards published by The American Association of Birth Centers (AABC). These standards, revised in 2017, can be found here: <https://c.ymcdn.com/sites/www.birthcenters.org/resource/resmgr/AABC-STANDARDS-RV2017.pdf>. This licensure pathway should be fully elucidated in 2019.

https://www.birthcenters.org/page/bce_bc_results/Birth-Center-Results.htm , as well as all other studies referenced in this section

¹⁰ <https://innovation.cms.gov/Files/reports/strongstart-prenatal-fg-finalevalrpt.pdf>

¹¹ <https://www.ncbi.nlm.nih.gov/pubmed/23363029>

¹² <https://www.ncbi.nlm.nih.gov/pubmed/27121907>