

Reforming Free-Standing Birth Center Regulations in Rhode Island

A review of Rhode Island regulation R23-17-BC

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A review of Rhode Island regulation RC12-17-BC

PREPARED FOR

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LIST OF ACRONYMS AND DEFINITIONS

Birth Care: All care related to pregnancy, labor, delivery, and post-delivery (up to a year) for both mother and infant.

Certified Nurse-Midwife (CNM): A registered nurse with additional training as a midwife, as designated by their licensing state, that allows them to provide prenatal, birth, and post-delivery care.

Cesarean Section (CS): The surgical delivery of an infant by an incision through the abdomen and uterus.

Episiotomy: A surgical incision made to widen the opening of the birth canal during delivery.

Free-Standing Birth Clinic (FSBC): A distinct facility dedicated to the provision of pregnancy- and birth-related care, not associated with a hospital or greater healthcare system.

Full-Term: An infant or pregnancy carried to or for longer than 39 weeks and 0 days of pregnancy.

Home Birth: Any birth occurring in a private home, whether attended by a skilled birth practitioner or not.

Hospital Births: Any birth occurring in a hospital or hospital system-affiliated setting; generally attended by an obstetrician, but may also be attended by a certified nurse-midwife (CNM), or other skilled practitioner.

Infant Morbidity Rate: The rate of birth-related severe injury or illness in infants.

Infant Mortality Rate: The rate of death of infants during the first year of life (given in deaths per 1000 live births).

Low Risk Pregnancy: the expected normal course of a pregnancy yielding one infant, with no predetermined medical risk factors for either the mother or the infant.

Maternal Morbidity Rate: The rate of pregnancy- or birth-related severe injury or illness in women.

Maternal Mortality Rate: The rate of death of women for pregnancy- or birth-related causes (given in deaths per 1000 births).

Medicalization of Birth Care: the use of any refined medical intervention in the labor and delivery process, including but not limited to cesarean section (CS), inducing labor, episiotomy, and intravenously controlling pain, whether elected or emergency procedures.

Neonatal: A period encompassing the first 30 days of life.

Neonatal Mortality Rate: The rate of death of infants during the first 30 days of life.

Oxytocin Augmentation: Increasing the rate of labor with the intravenous use of the hormone oxytocin.

Pre-Term: An infant or pregnancy carried to or for less than 38 weeks and 7 days of pregnancy.

EXECUTIVE SUMMARY

The Rhode Island “Rules and Regulations for Licensing Birth Centers” (R23-17-BC) are outdated in their safety and security standards. Though Rhode Island currently has no free-standing birth centers (FSBC), this potentially exposes hundreds of women to unsafe forms of labor and delivery care if a center were to open in the future. The Governor of Rhode Island has tasked the Office of Management and Budget’s Office of Regulatory Reform (ORR) with reviewing the regulation for potential reform. To determine the best course of action for reforming R23-17-BC, this analysis considers various forms of state-level FSBC regulations, presenting three archetypes for the regulation’s reform. Rewriting the regulation to conform with the American Association of Birth Centers’ (AABC) 2018 “National Standards for Birthing Center Operation,” replacing current regulation with a provision requiring FSBCs to accredit through the Commission for the Accreditation of Birth Centers (CABC) prior to applying for state licensure, and repealing and refiling R23-17-BC under R23-17-HOSP, “Rules and Regulations for Licensing of Hospitals” all provide compelling solutions to this outdated text. Ultimately, requiring FSBCs to accredit through CABC prior to applying for state licensure delivers the best outcomes for the state government, hospitals, FSBCs, and the women and infants who may one day receive care in such facilities.

PROBLEM DEFINITION

Free-standing birth centers provide a safe alternative to traditional hospital labor and delivery practices that increase many low-income and minority women's access to and choices in birth care. However, the current regulation on birth centers in Rhode Island (R23-17-BC) is outdated and insufficient in its safety and security measures, potentially endangering women and infants who would receive care in such centers.

Deliveries in free-standing birth centers (FSBC) are on the rise across the United States, with increasing numbers of women seeking out non-hospital settings in which to labor and deliver over the past three decades. Though labor and delivery healthcare trended toward centralization in hospitals from the 1970s through 2000, the number of out-of-hospital births rose by 41 percent between 2004 and 2010 (Cheyney, et al., 2014). As distinct facilities dedicated to providing holistic birth, labor, and delivery care, FSBCs are not affiliated with hospitals or health care systems, instead providing a less medicalized setting in which women can give birth. Laboring and delivering in “cooperative care” settings such as birth centers or home births attended by a registered nurse-midwife has been shown to improve maternal and infant outcomes in low-risk pregnancies and deliveries, as compared to traditional hospital care (Walsh, et al., 2004; Jackson, 2003; MacDorman and Singh, 1997; Oakley, et al., 1996; Rooks, et al., 1989). This is particularly true for minority and low-income women, who often lack access to full medical care at the time of birth for financial or geographic reasons (Jackson, et al., 2003). Approximately 90 percent of Rhode Island babies are born in hospitals, with 10 percent born in non-traditional care settings (Tempera, 2016). However, there are currently no licensed FSBCs in the state of Rhode Island. In the 33 years since the state established the R23-17-BC regulation on birth centers, one application has been submitted for licensure. The application was denied on the grounds of insufficiency (Erik Godwin, personal communication, March 14, 2018). While R23-17-BC is stringent on facility licensure procedures, it is insufficient and outdated in its safety and sanitation requirements for birth centers (Rules and Regulations for Licensing Birth Centers, 1985). This regulation poses financial, legal, and safety concerns for the state of Rhode Island, and must be reformed to protect the state and the well-being of the mothers and infants involved in approximately 11,000 births in Rhode Island every year (Rhode Island Department of Health, 2018).

INTRODUCTION

Rhode Island has historically been one of the most heavily regulated U.S. states. Its complicated and extensive regulatory framework presents numerous barriers to operation for many current and prospective businesses. Concerned with Rhode Island's stagnating economy, Governor of Rhode Island Gina Raimondo passed Executive Order 15-07 in February of 2015, ordering a strict review to determine the necessity of all newly proposed state regulations. While this executive order focused mainly on pruning new additions to the Rhode Island Code of Regulations (RICR), it also tasked the Rhode Island Office of Management and Budget's Office of Regulatory Reform (ORR) with beginning a review of existing rules and regulatory processes in the state (Improving Rhode Island's Regulatory Climate to Create Opportunity, 2015). The 2016 update to Rhode Island's Administrative Procedures Act (APA) expanded on this initial mission, requiring the ORR to rewrite every state regulation into a new RICR by December 31, 2018 (ORR, 2018). All regulations not rewritten into the updated RICR by that date will no longer be valid. As of March 2018, ORR has submitted 118 regulations for repeal (ORR, 2018).

Rhode Island adopted the Rules and Regulations for Licensing Birth Centers in 1985 following a nationwide push to address the increasing use of unregulated alternative forms of birth care. Providing strict rules for how prospective birth centers should seek licensure, the regulation gives inconsistent guidance on providing delivery care to women in a non-hospital setting (Rules and Regulations for Licensing Birth Centers, 1985). Though it sought to increase forms of safe, alternative birth care available to women, particularly minority and low-income, the regulation has not contributed to an increase in the number of Rhode Island birthing centers. In the 33-year history of the regulation, one birth center has applied for licensure. That birth center was denied a license on the grounds of an insufficient application (E. Godwin, personal communication, March 14, 2018). The Rhode Island Rules and Regulations for Licensing Birth Centers (R23-17-BC) potentially restricts the market for FSBCs, contributing to an over-medicalization of the labor and delivery process, driving women to unsafe forms of labor and delivery, and limiting birth resources for low-income and other at-need demographics.

Though no birth centers have been licensed under Rhode Island's current regulation, this analysis focuses on options for regulation reform rather than deregulation of birth centers in the state. Deregulating birth centers has shown no additional impact above and beyond appropriately targeted state-level regulations to the market supply of birth centers in that state. Deregulating birth centers removes states' ability to inspect, review, and control birth centers within their borders, making it impossible to enforce a standard level of safety and security across providers. Further, deregulating birth centers is currently politically infeasible in Rhode Island, as stakeholders are prepared to pursue legal action against the ORR if it pursues deregulation (E. Godwin, personal communication, March 14, 2018). To determine the best reform for R23-17-BC, this analysis reviews the literature on various forms of traditional and alternative birth care, as well as the potential over-medicalization of birth care and the unique birth care circumstances of low-income and minority women.

BACKGROUND

Forms of Birth Care

Literature around birth highlights three general forms of care commonly used by U.S. women. Hospital deliveries are by far the most common form of birth care in the U.S., with nearly 99 percent of women delivering in a hospital in 2016 (Martin, et al., 2018). Delivery in FSBCs and home births both remain relatively uncommon among U.S. births, but appear to be increasing in use as alternative means of birth care. Certified nurse-midwives (CNM) assisted in nearly 9 percent of all births in 2016, and almost 2 percent of White births paid for by private insurance occurred in the home in the same year (Martin, et al., 2018). Though home births and births in FSBCs carry higher overall risks of infant mortality than delivery in a hospital, infant mortality rates remain low and may not serve as the best indicator of the outcomes of various forms of birth care (Martin, et al., 2018; Cheyney, et al., 2014; Demissie, et al., 2001; Koblinsky, et al., 1991). Further, multiple studies have found that restricting the comparative sample to low-risk pregnancies and births¹ in hospitals and FSBCs removes any difference in infant mortality risk between the two locations, even demonstrating a lower risk level in birth center deliveries (Rooks, et al., 1989; MacDorman & Singh, 1997; Stapleton, et al., 2013;). The literature around outcomes of birth care is marked by a lack of randomized control trials, which for ethical reasons are difficult to conduct. As such, causality is nearly impossible to determine on this topic. Most studies rely on regression modeling and quasi-experimental formats to establish correlations as rigorously as possible.

Hospital Delivery

Overwhelmingly common in the U.S., hospital births include any delivery in a hospital or hospital system-affiliated facility. Hospital deliveries consistently display the lowest rates of overall maternal and infant mortality of any form of birth care (Oakley, et al., 1996; Jackson, et al., 2003). Hospital deliveries have been shown to yield significantly better outcomes in high-risk pregnancies and deliveries than alternative forms of birth care, due in large part to the technology and medical interventions available in this setting (Koblinsky, et al., 1991). However, a 2010 study demonstrated that rates of medical intervention were high in hospital births, regardless of pregnancies' risk level. Further, common medical interventions such as labor induction and oxytocin augmentation of labor were found to increase the probability of an operative delivery in all risk-level pregnancies, increasing risk in many previously low-risk deliveries (Indraccolo, et al., 2010). Multiple additional studies corroborate the higher rate of medical or surgical intervention in hospital births than in either birth center or home deliveries (Gyamfi-Bannerman & Ananth, 2014; Jackson, et al., 2003; Kozak & Weeks, 2002; Rowley, et al., 1995; Feldman & Hurst, 1987). One 2003 study found a 23 percent higher incidence of episiotomy in women who delivered in hospitals than in a birthing center, as well as an overall increase in operative deliveries (including both cesarean sections (CS) and induced labor) (Jackson, et al., 2003). Women who deliver in a hospital setting also tend to

¹ For the purposes of this paper, I use the Rhode Island Rules and Regulations for Licensing Birth Centers' (1985) definition of 'low-risk pregnancy:' "expected normal, uncomplicated prenatal course assisted by adequate prenatal care and prospects for a normal uncomplicated birth based on continual screening for prenatal high risk factors (pg. 2)."

accrue the highest costs for birth care, due in part to higher rates of costly medical interventions (Kozak & Weeks, 2002; Koblinsky, et al., 1991; Henderson & Petrou, 2008).

Home Birth

Home birth is an alternative form of birth care regularly utilized in the U.S. This form of birth care encompasses any delivery not occurring in a hospital or birth center. Home births made up one percent of births in the U.S. in 2016 and have increasingly been used as a form of birth care over the past two decades (Martin, et al., 2018; Cheyney, et al., 2014; Walsh, et al., 2004). While home births are commonly attended by a CNM, a skilled attendant is not always present at delivery. The main data available on home births comes from CNM collection at the time of birth; therefore, information on home births is predominantly restricted to CNM- and skilled practitioner-attended deliveries. The majority of studies agree low-risk home births attended by skilled practitioners are associated with slightly higher, but similar, maternal and infant mortality rates as low-risk hospital births (Cheyney, et al., 2014; Johnson & Daviss, 2001). These mortality rates trend equal to or just above the mortality rates in FSBCs. Johnson & Daviss (2003) found the risk of infant mortality among low-risk, CNM-attended home births in 2000 was 1.7 deaths per 1000. Similarly, Cheyney et al. (2014) found an infant mortality rate of 2.06 per 1000 live births among all CNM-attended home births between 2004 and 2009, including a neonatal mortality rate of 0.76 per 1000. This mortality rate is slightly above the Stapleton, et al. (2013) neonatal mortality rate of 0.4 per 1000 live births among women who delivered in a birth center in 2007.

Mothers and infants delivered through home births also display general improvements over hospital deliveries across a number of non-mortality outcomes. Johnson & Daviss (2001) found a 3.7 percent CS rate in all 2000 home births, compared to a national CS rate of 22.9 percent (Kozak & Weeks, 2002). Their retrospective study also found extremely low rates of other serious medical interventions, and an increased rate of long-term breastfeeding (associated with beneficial maternal and infant health outcomes) among women who delivered in the home with a CNM (Johnson & Daviss, 2001). Cheyney, et al.'s 2014 study confirms these findings, considering nearly 17,000 home births to find a CS rate of 5.2 percent (compared with a national rate of 32 percent) and nearly all infants still breastfed at six weeks. Further, mean infant birthweight was higher for the CNM-attended home birth population than hospital-delivered infants, and almost half of the infants were delivered without any tears to the birth canal (Cheyney, et al., 2014).

Delivery in Free-Standing Birth Centers

Free-standing birth centers (FSBCs) serve as a non-hospital-affiliated alternative form of prenatal and delivery care. Though birth center staffing and structure requirements vary from state to state, the majority of facilities are headed by a CNM overseeing a team of nurses, midwives, and other skilled birth attendants. Focusing on non-invasive or minimally medicalized interventions, these centers utilize collaborative care models to provide consistent support to laboring mothers who endeavor to deliver as naturally as possible (Walsh, et al., 2004). For women with low-risk pregnancies, birth centers provide a compelling alternative to hospitalization for delivery. A study

retrospectively comparing two groups of equally low-risk women who delivered in birth centers and hospitals found that the groups had similar maternal and infant health outcomes, but women who delivered in a hospital had significantly more medical interventions than the birth center group (Feldman & Hurst, 1987). Similarly, Oakley et al.'s (1996) consideration of differing outcomes by type of birth care found that rates of severe birth canal tearing, maternal and infant health complications, and costs of care were significantly lower among the population who received the alternative to traditional hospital care. MacDorman and Singh (1997) found mean infant birthweight to be 37 percent higher among women who delivered in an alternative setting.

A number of studies on care in FSBCs also find that such settings may improve infant mortality rates. Rooks, et al. (1989) studied a cohort of 11,814 low-risk women admitted for delivery to 84 FSBCs across the U.S. and found an infant mortality rate of 1.3 per 1000 live births, compared with a national infant mortality rate of 9.8 per 1000. MacDorman and Singh (1997) found a 33 percent lower risk of neonatal mortality associated with delivering with a CNM (birth center proxy) over delivering with an obstetrician (hospital proxy). Stapleton, et al. (2013) confirmed this trend presently continues, finding a neonatal mortality rate of 0.4 per 1000 live births in 2007 (compared with a national neonatal mortality rate of 0.75 per 1000 in the same year). It should be noted, however, that selection bias is a major problem in all of these studies. Additionally, women delivering in birth centers tend to be significantly lower-risk than the general mean U.S. pregnancy.

Though not a study conducted in the U.S. health system, Rowley, et al.'s 1995 research comparing women receiving birth care from a midwife team versus from traditional obstetricians merits consideration as one of only a few randomized control trials (RCT) on this topic. Randomly allocating 814 low-risk pregnant Australian women between a team of six midwives and traditional hospital care, the study found women receiving midwife care demonstrated significantly better birth outcomes in numerous areas. Women receiving team care were less likely to require medical interventions during labor, and their infants were less likely to experience respiratory distress after birth than those whose mothers received obstetric care during delivery. Infant mortality rates were exactly the same for both groups of mothers. Additionally, birth costs for women receiving team care were 4.5 percent lower than for women receiving traditional obstetric care (Rowley, et al., 1995). Though conducted in the Australian health system, the study is generalizable to the U.S. as the team midwife structure closely mimics provision of care in U.S. birth centers and hospital birth care in Australia demonstrates the same trends as in the U.S. (Declercq, et al., 2011). As a RCT, this study successfully establishes causality between collaborative birth care and improved outcomes for low-risk pregnancies and births. Despite this, rates of birth in FSBCs remain stagnantly low (Walsh, 2004).

Though hospitals provide some of the safest outcomes for pregnancies and deliveries of all risk levels, significant research indicates birth centers and home births can serve as beneficial alternatives to hospital care. However, additional RCT-based research is needed to determine causality of outcomes across all three types of birth care.

History of Birth Centers and Birth Center Regulations

Modern medicine has changed birth care radically from a primarily home- and family-centric event to treatment of a medical condition. From the early 20th century on, women increasingly sought out hospitals for birth care, utilizing new and more medical interventions to ease labor and delivery. Access to greater and better birth care had incredible benefits for both mothers and children; the infant mortality rate declined more than 90 percent and the maternal mortality rate more than 99 percent from 1900 to 1999 (CDC, 1999).

Minimum standards of medical interventions in birth care grew throughout the 20th century to encompass an increasing number of procedures, many of which were life-saving for women and children. However, as birth care centralized to hospitals, women began to experience more and more optional procedures as part of their birth care, increasing costs and the amount of medical intervention in a historically natural process. As a result, the use of midwives and alternative forms of birth care began to rise again in the 1970s, with women increasingly seeking out certified nurse-midwives (CNMs), midwives, and doulas to provide or supplement their care (New York Times, 1983; Sibbhold & Ping, 2010). Alternative care providers coped with this rising demand for services by establishing FSBCs, clinics unaffiliated with hospitals or healthcare systems in which they could provide holistic birth care for women reacting against hospitals' often impersonal style of care. Catering to a demand for a more holistic form of care, the first birth center opened in 1975 and employed the 'midwife model' of birth care, emphasizing individualized labor plans (Childbirth Connection, n.d.). From 1975 to 1984, 123 additional birth centers opened in the U.S., serving thousands of women (Childbirth Connection, 2013).

This new form of care was entirely unprecedented in the contemporary birth care environment. Concerned with potentially unsafe standards and care, the American College of Obstetrics and Gynecology began to review birth centers in the early 1980s, and the American Public Health Association (APHA) recommended state-level regulation in order to ensure medical standards for these centers (APHA, 1981). The majority of states in the U.S. adopted birth center-specific regulations throughout the 1980s. Though most were concerned with ensuring safety and security standards in birth centers were equal to those in hospitals, regulation also provided hospitals a tool with which to restrict their direct competition's growth. This prompted greater regulation overall, as well as requirements such as mandatory signed transfer partnerships with hospitals that introduced hospital veto power into the regulation (AABC, 2018). Even with these controls, the number of birth centers in the U.S. rose steadily throughout the 1990s and 2000s. Today, approximately 0.3 percent of U.S. births occur in a birth center annually, a rough total of 11,950 deliveries per year (CDC, 2018).

Trends in Birth Centers

As of 2017, over 340 birth centers were operating in the U.S. across 41 states and the District of Columbia (AABC, 2018). Though the number of birth centers has steadily grown since 1975, rising by nearly 30 percent from 2007 to 2012, over half of states have less than five birth centers within

their borders and three-quarters of states have ten or less birth centers (AABC, 2018). Only nine states in the U.S. do not have birth centers within their borders, including Rhode Island. Of these, only North Dakota has completely restricted birth centers' operation, outlawing them within the state. Florida, California, and Texas all have extraordinarily high numbers of birth centers; this seems to be due to these states' unique combination of high demand for birth services and large proportion of rural areas.² States with higher numbers of birth centers per capita of potential users tend to be more rural; the average population density of high-birth center permeation states was 43 residents per square mile, compared with an average 243 residents per square mile across other states (see Appendix B for all permeations and population densities).³ New Mexico, with a birth center for every 51 potential users, and Alaska, with a birth center for every 62 potential users, have the highest permeation of birth centers per capita in the U.S. Both states have a population density below 20 people per square mile (Alaska has an average population density of 1.2 residents per square mile).

Figure 1 (page 9) shows that though not all predominantly rural states have a high permeation of birth centers, the states with a high permeation of birth centers are all highly rural. This highlights the first of two primary needs that birth centers serve in current healthcare: many rural communities suffering from lack of access to healthcare have turned to birth centers to supplement their obstetric care. Healthcare services are increasingly atrophying in rural communities, particularly maternity wings which are expensive to operate and difficult to maintain without a higher volume of clients. This has required higher numbers of rural women to travel long distances for prenatal and delivery care, both decreasing women's likelihood to seek out critical care pre-delivery and increasing the risk for complications in women who have to travel to deliver (Andrews, 2016). Birth centers improve outcomes in low-risk births by providing easier access to prenatal care prior to delivery, and providing a nearby place for mothers to deliver under expert care.

The second main purpose that birth centers serve in current healthcare is to provide birth care services to informed women seeking a more homeopathic, natural delivery experience. For many women with ease of access to obstetric care, their decision on which of many forms of care they will select for their labor and delivery experience. Rising trends in the use of cesarean sections and other medical operations in hospital deliveries point toward a concerning over-medicalization of birth that has driven many women educated on their care options away from medicine-focused care and toward collaborative, patient-focused care. These trends are covered in greater detail in Appendix G.

² At 68 birth centers, Texas has the highest number of birth centers of any state in the U.S. and a per-center likely user ratio of 1 for every 610 women. Florida is next, at 814 women per center, and California follows at 2,094 women per center.

³ Potential users are defined here as women of childbearing age (18-64, per the American College of Obstetrics and Gynecology) in each state.

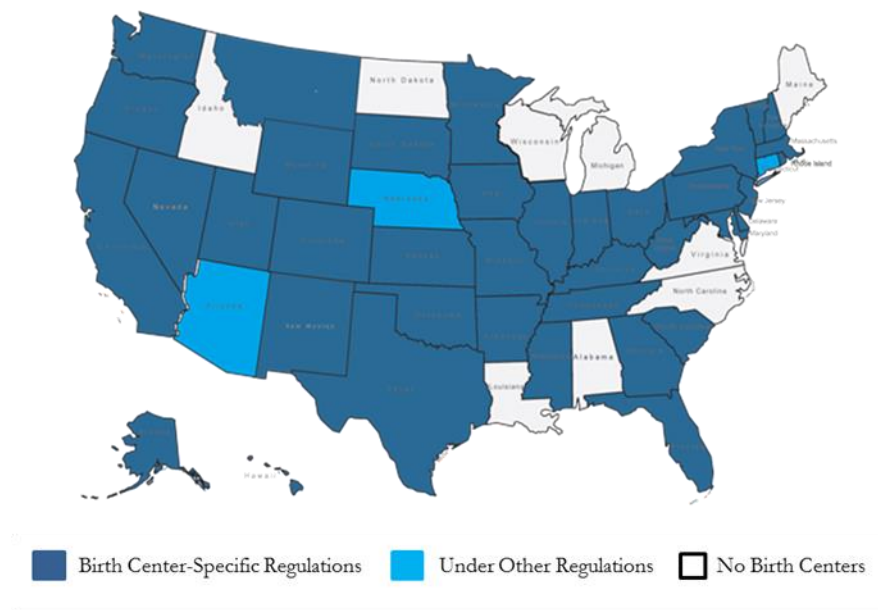
1,000 Potential Users per Center 1,000 – 5,000 Potential Users per Center > 5,000 Potential Users per Center No Birth Centers

Source: U.S. Census Bureau, 2017; AABC, 2017.

Currently, 38 states in the U.S. include regulations on birth centers in their regulatory code. For those states that regulate their birth centers, regulations take two forms: birth center-specific regulations and regulations on birth centers filed as a subsection of hospital regulations (see Figure 2, page 10). Including Rhode Island, 34 states have filed separate regulations on FSBCs in their regulatory code, dedicated to the licensure process, function, and standards birth centers must uphold (AABC, 2018). Usually enforced by the state's Department of Public Health (DPH), these regulations range from highly specific state-determined standards of operation to general guidelines that place the impetus on FSBCs to set their own safety and operation standards. Rhode Island currently regulates FSBCs under the former framework, seeking to provide highly specific state-determined standards of operation. However, these standards date from 1985, and the regulation is notably silent on significant safety and security measures (Rules and Regulations for Licensing Birth Centers, 1985).

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Figure 2: Birth Center Regulations in the United States, 2018



Only three states in the U.S. have opted against specific regulations for their birth centers, instead classifying them as “maternity hospitals” and housing their licensure under hospital and healthcare regulations. At the time of regulation, Arizona, Connecticut, and Nebraska all filed their regulations on FSBCs as a subsection of the code on hospitals and healthcare systems (AABC, 2018). Usually overseen by the state’s Department of Health Services (DHS) or equivalent, these regulations view FSBCs as equivalent to other non-hospital healthcare services such as ambulatory care clinics, and regulate them as such. Connecticut designated its FSBCs as “maternity hospitals,” and regulates them in the same way as hospital-attached birth centers regardless of differences in services and methods of care (Regulations of Connecticut State Agencies, n.d.). Most recently, Massachusetts pursued rescission for its FSBC-specific regulation, attempting re-filing the regulation as a subsection of its hospital regulatory code in 2016 (Lohes & Nelson, 2016).

States that do not have any regulations on birth centers are in the minority. Only nine states do not require their birth centers to license with the state and follow state-determined regulatory standards (AABC, 2018). Safety and security standards in these states’ birth centers are instead determined by the centers themselves, with many choosing to pursue accreditation through CABC to demonstrate that they have oversight and increase their market standing. The absence of state-level regulations does not seem to encourage a greater number of birth centers to operate in that state, however. Unregulated states see an average of 6 birth centers per state, while regulated states have an average of 7 FSBCs (Please see Appendix B for a table of all states’ permeation of birth centers by regulatory type).

EVALUATIVE CRITERIA

The goal of this evaluation is to provide an evidence-based recommendation that best serves the ORR as it revises this regulation for inclusion in the RICR. The recommended regulatory reform should bring Rhode Island's FSBC regulatory safety and security standards up to date, as well as provide a mechanism by which they can be continually reviewed and revised so that this issue does not recur. In order to achieve these goals, the ORR must be able to pass this regulatory reform within the state of Rhode Island. This will require support from the Rhode Island Governor's Office, state hospitals, the public, and should take into consideration the likely response of future birth centers that may open in the state. Additionally, passing the reform and implementing policies required by the new regulation cannot place a significant burden on the ORR or the DPH, as both have limited administrative resources. In the same way, both financial and time costs of the reform must remain low in order to minimize the financial impact on ORR and the state.

In support of these goals, each of the policy options will be evaluated based on the following set of specific criteria:

1. Administrative Burden and Costs of Passage
2. Administrative Burden and Costs of Implementation
3. Political Feasibility
4. Potential Impacts to FSBCs
5. Effectiveness at Addressing Safety and Security Concerns

Taken together, these criteria project the potential impacts of each proposed regulatory reform. Outcomes are quantified where possible. Non-quantifiable criteria are presented on a multi-point scale representing incremental increases in value.

1. Administrative Burden and Costs of Passage

This criterion considers the costs of the proposed regulatory reform and the administrative burden it will present to the ORR to pass. As the ORR has numerous regulations to review by the end of the year, ease of reform implementation will be a significant benefit. Additionally, limited staffing and financial resources in the ORR will make it difficult to accommodate more complex administrative requirements. Administrative burden will be measured based upon whether the regulation reform generates a *minimal, moderate, or extensive* administrative and cost burden for the ORR. Costs are estimated in U.S. dollars based on a range of best estimates. Full estimates can be found in Appendix D, Section I.

2. Administrative Burden and Costs of Implementation

This criterion considers the costs of the proposed regulation and the administrative burden it will present to the DPH to implement and enforce. The DPH have a limited number of personnel who can review and enforce regulations, and will feel an increased burden on their staff's time. As with the ORR, administrative burden will be measured based upon whether the regulation reform

generates a *minimal, moderate, or extensive* administrative and cost burden for the DPH. Costs are estimated in U.S. dollars based on a range of best estimates. Full estimates can be found in Appendix D, Section II.

3. Political Feasibility

This criterion considers the difficulty the ORR will face in generating support for regulatory reform. Reporting to the Governor's Office, the ORR must first and foremost consider how Governor Raimondo would receive the proposed reform. Hospitals serve as a major player in the Rhode Island healthcare market, and have made their interest in birth center regulations known. As a public comments period is mandated for any proposed rule change in the state, the ORR must also consider general public opinion when pursuing regulation reform. However, as this is a relatively unknown subject, public opinion is hard to definitively determine; all positions are educated estimates. Finally, the projected opinion of FSBCs should also be taken into account. Stakeholders are assessed and given a score for whether they will *strongly support* (2), *slightly support* (1), *remain neutral* on (0), *slightly oppose* (-1), or *strongly oppose* (-2) reform (see Appendix C for full calculations of political feasibility scores).

4. Impact to Birth Centers

This criterion considers the projected impacts of regulatory change to any FSBCs that would open in the future. Though the state does not currently have any centers, the ORR's mission is to review regulations with a focus on minimizing adverse impacts on Rhode Island businesses. Therefore, it is important that future impacts are estimated and taken into consideration. These potential impacts fall into two categories:

- *The administrative burden of regulation compliance:* how difficult will FSBCs find compliance with the regulation? This will be quantified as either a *minimal, moderate, or extensive* burden to the centers.
- *The potential of the regulation to encourage birth centers to open:* could this regulatory change potentially encourage practitioners to establish birth centers in Rhode Island? Or does the regulation increase barriers to opening? This will be quantified as a *positive, neutral, or negative impact* to FSBCs in the state.

5. Effectiveness at Addressing Safety and Security Concerns

This criterion considers how effective each reform will be at addressing safety and security concerns in the regulation. Analysis will consider the proposed reforms' impacts in both the short-term and the long-term: does the reform immediately address safety concerns in the regulation? And how sustainable will the regulatory updates to safety and security be in the long-run? Is there a mechanism for regular updates? Effectiveness will be measured as *satisfactory, good, or excellent*.

POLICY ALTERNATIVES

The following policy alternatives provide three potential reforms for regulation R23-17-BC “Rules and Regulations for Licensing Birth Centers.” Though Rhode Island's regulations do not currently cover any centers, I am suggesting regulatory reform over full repeal for several reasons. As shown previously, the absence of regulations does not seem to encourage a higher number of birth centers in a state. This indicates it is unlikely that removing R23-17-BC will encourage birth centers to open in the state. Further, it seems that the two primary reasons for birth center use (rural populations and educated patient choice) are either not a need in Rhode Island, or are currently being provided by hospitals. Rural access to adequate obstetric care is not a challenge in the state; hospitals with excellent labor and delivery services are easily accessible from all corners of Rhode Island. Women and Infants hospital in Providence is a maximum 60-minute drive from all locations in the state. Additionally, Rhode Island has several hospital-attached birth centers that provide similar services as FSBCs. Though these centers still pursue medical interventions and do not provide purely holistic care plans like those offered in FSBCs, providers place a greater emphasis on individualized care than in standard hospital deliveries. For many women, this meets the need for services that FSBCs would otherwise provide. Therefore, it is possible that regulatory change is not the preferred mechanism through which to encourage FSBCs to open in Rhode Island.

If Rhode Island were to eventually gain a birth center, deregulation removes the state’s oversight and ability to inspect, enforce, or correct safety and security concerns in the centers. This could expose women and infants to the similarly inadequate care and standards currently enforced by R23-17-BC. Letting present trends continue is also disregarded for an option for the same reason. Finally, birth center deregulation is currently politically infeasible in the state. Rhode Island hospitals have strongly opposed full deregulation of FSBCs. It is in the best interests of the ORR, the State of Rhode Island, the public, and potential future Rhode Island FSBCs to pursue regulatory reform over repeal.

The potential reforms are as follows:

Alternative 1: Model FSBC regulation on AABC Standards

Alternative 2: Require FSBCs to accredit with CABC before applying for state license

Alternative 3: Rescind and re-file under “Rules and Regulations for Licensing of Hospitals”

Evaluating Alternatives

Alternative 1: Model FSBC regulation on AABC Standards

Current regulations hold Rhode Island FSBCs to outdated safety standards. This reform would update RC23-17-BC's 1985 standards using the most recent AABC "National Standards for Birthing Center Operation." Maintaining the regulation on FSBCs as a distinct regulation in the RICR, the ORR would rewrite the regulation following the AABC "Standards" model, modernizing and expanding the language to fulfill all current safety and security best practices. In implementation, the DPH would continue to administrate and enforce these regulations, regularly inspecting all FSBCs for compliance.

The AABC's "National Standards for Birthing Center Operation" are a set of benchmark standards on birth centers based on research and input from expert organizations such as the American College of Obstetrics and Gynecology (ACOG) and the American Public Health Association (APHA). These standards are updated yearly, with regular feedback mechanisms for expert organizations, the Commission for the Accreditation of Birth Centers (CABC) and other accrediting organizations, and FSBCs themselves to report findings and re-evaluate benchmarks (AABC, 2017). While the Standards offer best practices for birth centers in a number of areas, its recommendations on facility, equipment, supplies, and quality evaluation and improvement will be most relevant to the ORR's revision (see Appendix E for an outline of the Standards' contents).

Administrative and Cost Burden of Passage

The administrative burden of this re-regulation would be *moderate* for the ORR in the short-term. Rewriting the body text of the regulation will require a significant time and attention from the ORR, reviewing and reworking all 34 pages of the regulation to update current standards, remove outdated sections, and supplement with new requirements. However, it may be possible to pass this regulation as a direct rule, reducing the complexity of the re-regulation process and minimizing the timeline. Immediate passage costs are estimated at \$7,050 for this alternative due to fees for accessing and distributing the AABC Standards, as well as a recommended regulatory impact analysis after passage (please see Appendix D, Section I for more information).

Administrative and Cost Burden of Implementation

Though this reform presents an *extensive* administrative burden for the DPH, it will cost nothing to implement as there are no FSBCs in Rhode Island. Should an FSBC open in the state, the administrative burden of implementation and enforcement would be high to the DPH. New standards would require a review and update of DPH systems, including reporting and inspection procedures, as well as personnel for enforcement and review of the FSBC's performance. Annual FSBC licensing and compliance inspections would cost up to \$4,000 a visit. Though cost savings from Medicaid reimbursements outweigh costs, the savings' impact is dampened due to higher administrative requirements. Estimated net savings from implementing this alternative total \$48,878 annually (please see Appendix D, Section II for more information).

Political Feasibility

The overall political landscape in Rhode Island would likely *slightly oppose* this regulatory change. This re-regulation updates safety and security standards in FSBCs to appropriate levels, and would likely have little to no impact on the small businesses if they were to open. However, it expands the regulation and does not simplify the code. For these reasons, the Governor's Office would likely *slightly oppose* the re-regulation. Hospitals would likely *remain neutral* on this regulation; it updates standards and retains the FSBC regulation, so they would likely not oppose its passage. Members of the public educated on FSBCs would likely *slightly support* this regulation, as it updates safety; otherwise, they will likely remain *neutral*. Finally, potential FSBCs would likely *slightly support* this regulatory change, as it affirms professional standards already held in the field.

Potential Impacts to FSBCs

This re-regulation would likely have little impact on the number of FSBCs in the state of Rhode Island. The revision maintains a similar regulatory framework to the one currently in place, coming as close to maintaining the status quo as possible while still updating safety and security requirements. While new standards might require FSBCs to employ more advanced and expensive equipment, FSBCs may already choose to use these in order to be more competitive in the market. Therefore, this regulation should not present unique economic burden to FSBCs that might keep them from opening in the state. However, the administrative burden of this regulation to FSBCs remains fairly high. The state licensing system at present is confusing at best, and DPH does not provide any resources to help potential FSBCs navigate licensure. This regulation would not address this barrier, continuing to require FSBCs to license through a complicated process. At worst, this barrier to entry continues to reduce the likelihood that FSBCs will open in the state.

Effectiveness at Addressing Safety and Security Concerns

Though this revision addresses the immediate concerns of outdated safety and security standards, it does not provide a mechanism for regular update to these standards. As demonstrated by the California case study (see below), this form of regulation would successfully maintain maternal and infant morbidity and mortality outcomes at hospital birth levels in the short term. However, as the regulation ages and safety and security standards are not updated, there is a possibility for these outcomes to decline. This regulation would require regular updates by the ORR and the DPH to maintain recommended safety standards, increasing administrative burden for both departments.

CASE STUDY: CALIFORNIA

The State of California is one of a handful of states that incorporates the AABC Standards into its regulation on FSBCs. In adopting these Standards into its regulation, California focused most closely on quality assurance programs at the birth center, timely and specific reporting of information from these reports to the state, and written policies on disseminating information to patients. As the regulation governing FSBCs is included as part of a larger section on licensing clinics, the AABC Standards on safety and security are required as best practices of all clinics in the state (California Code Division 2: Licensing Provisions, n.d). With one of the highest number of birth centers in the U.S., California's ability to maintain maternal and infant outcomes (morbidity and mortality) at the same levels as hospitals points to the efficacy of these regulations. A 2003 study by Jackson, et al., reviewed the outcomes and safety in the San Diego BirthPlace FSBC, the largest nationally accredited FSBC in the U.S. at the time, which served 1,808 women across the course of the study. Measuring outcomes of maternal and infant mortality and morbidity, labor and delivery complications, and neonatal outcomes such as birthweight, this study found that there was no statistically significant difference between the rates of infant and maternal mortality or morbidity in those who were delivered in a birth center and those who were delivered in a hospital. Further, the rate of operations and medical resources used was significantly lower at BirthPlace – 23 percent lower for episiotomies and 15 percent lower for cesarean sections. The collaborative care practiced at BirthPlace also resulted in shorter length of stay at the facility, minimizing facility costs (Jackson, et. al, 2003). Though San Diego is demographically distinct from Rhode Island, these trends are exemplary of FSBCs across the U.S., and are likely to hold true if an FSBC opened in the state.

Alternative 2: Require FSBCs to accredit with CABC before applying for state license

This recommendation would supplement general language on safety and security in R23-17-BC with a provision requiring all birth centers to accredit with the CABC to qualify for licensure in the state. Accrediting with the CABC holds birth centers to AABC 'Standards' as well as CABC-specific 'indicators for compliance.' These evidence-based indicators for compliance are similar to the AABC 'Standards,' but serve as the basic requirements for accreditation, providing more detail on implementation and enforcement. The CABC develops these standards based on expertise from professional organizations in the field, and also incorporates findings based on the AABC Perinatal Data Registry, which gathers information on mother and infant outcomes in FSBCs.

Under this regulation, the CABC would enforce safety and security standards and conduct regular inspections of all accredited centers in the state for compliance. The Commission would conduct an initial investigation for accreditation, followed by annual inspections to ensure accredited birth centers are operating to standards, dispersing information on new standards as they develop and advising birth centers on how to remain up-to-date (please see Appendix F for further information on the accreditation process). The CABC is required to provide the Rhode Island DPH with all accreditation materials provided to them by the birth centers upon application, including records, reports, and initial inspection findings. The DPH would also have access to reports of each CABC inspection and its findings (CABC, 2018).

Administrative and Cost Burden of Passage

This reform would impose a *moderate* burden on the ORR to rewrite and pass. This alternative would require a complete revision of the text, presenting a moderate time cost to ORR staff. It is possible that this regulatory change could be made as a direct rule, minimizing the regulatory reform timeline. Costs to the ORR associated with this reform are limited to a recommended regulatory impact analysis, totaling \$7,000 (please see Appendix D, Section II for more information).

Administrative and Cost Burden of Implementation

Requiring CABC accreditation as a prerequisite for state licensure would present a *minimal* burden to the DPH to enforce. This revision externalizes enforcement and review of regulatory standards compliance to the CABC, who specialize in this service. The DPH would therefore play a minimal role in carrying out the regulation's text. The DPH would not need to establish new procedures beyond educating personnel on the nature of the CABC, its indicators and accreditation process, and maintaining clear channels of communication between the Department and the Commission. Additionally, it would streamline the data collection process from FSBCs, removing an additional burden from the DPH and rehabilitating a defunct system. Though a lack of FSBCs in the state ensures implementation costs will initially start at \$0, if an FSBC were to open as a result of this regulation, costs would remain minimal. As implementation costs are externalized, this reform maximizes cost savings at an estimated annual \$56,878 (please see Appendix D, Section II for more information).

Political Feasibility

The overall political landscape for this alternative would be *slightly supportive*. Governor Raimondo's office would likely slightly support the reform. Though it does not remove a regulation that is currently not governing anything, it does simplify the text and contract out services to a specialized third-party provider, increasing efficiency. Hospitals would most likely also slightly support this reform, as it maintains the FSBC regulation while holding FSBCs to a high and professionally established uniform standard. As this reform is relatively easier to understand and holds FSBCs to standards backed by a third-party professional organization, both the informed public and those with little knowledge of FSBCs would likely support this regulation. Finally, many FSBCs pursue accreditation with the CABC independent from state standards, as it increases their professional standing. Though these standards and increased levels of scrutiny would require high expenditures from FSBCs, the benefits of professional designation would likely lead most FSBCs to slightly support this regulatory option.

Potential Impacts to FSBCs

This regulatory reform has the potential to increase the ease with which FSBCs open in the state of Rhode Island. Accreditation provides a known framework for birth centers attempting to navigate the state licensure process, allowing for institutional knowledge to be built up across states. This might create a "franchise effect," encouraging accredited birth centers operating in nearby states to open a new branch in Rhode Island as the administrative shorthand is there to ease the businesses through licensure. As many FSBCs pursue accreditation independent of state requirements, the costs of required accreditation would be no more than high-quality FSBCs are prepared to undertake at opening. This would not unduly increase the burden on FSBCs, and may naturally screen out sub-standard FSBCs before the licensure process.

Effectiveness at Addressing Safety and Security Concerns

This reform not only addresses the immediate concerns of outdated safety and security in the regulation, but also would provide a built-in mechanism through which the regulation's safety and security standards would be regularly updated at no cost or effort to the state government. As CABC re-releases its "indicators" annually and inspects accredited members to ensure they are adopting the new best practices in the field, this effectively updates Rhode Island's safety and security regulations on a yearly basis. The ORR and the DPH would not be required to contribute any effort to this update; the work would be solely on the CABC. This would eliminate the possibility of outdated safety and security standards in R23-17-BC for the duration of its governance.

CASE STUDY: MINNESOTA

In 2011, Minnesota replaced the specific standards in their FSBC regulation with the requirement that FSBCs pursue CABC accreditation prior to state licensure (Minnesota Statutes: Birth Centers, 2011). In the three years following revision, five new birth centers opened in the state, three in urban and two in rural communities. The total number of births occurring in FSBCs increased by almost 200 percent over the same period (Compliance Monitoring Division, 2014). A regulatory change impact analysis shows that though the volume of births in FSBCs increased exponentially in a short period of time, the centers maintained high levels of safety in their operations (Compliance Monitoring Division, 2014). Unfortunately, data on quality of care and center outcomes was limited due to inconsistent reporting and the short time the centers had been in operation. To compensate, analysts considered data on births in Minnesota across all facilities, maintained by the Center for Health Statistics. Separating out by delivery location, there was no decrease in maternal and infant mortality rates in FSBCs from the pre-regulatory period to the post-regulatory period. All centers were able to obtain and maintain accreditation for the duration of the study (2011-2014). Additionally, this regulatory change satisfied Minnesota hospitals' calls for standard updates (Compliance Monitoring Division, 2014). CABC accreditation requirements far exceeded the risk criteria and response procedures that many hospitals were calling on FSBCs to establish. The analysis noted, however, that many hospitals remained unaware of these requirements even three years after the regulatory change, pointing to a need for education on the CABC accreditation process and requirements (Compliance Monitoring Division, 2014). Though Minnesota is far more rural than Rhode Island, its post-reform trends in urban FSBCs are more generalizable to Rhode Island's situation. Rhode Island may be able to estimate their own trends in the post-reform FSBC landscape based off of a scaled model of Minnesota's urban findings, especially if paired with estimates from other states for a range of possible outcomes.

CASE STUDY: ILLINOIS

Illinois reformed their regulations to allow FSBCs in the state in 2010, incorporating CABC accreditation into their regulatory requirements following 25 years of lobbying from state midwives and the AABC for regulatory change. Limiting the maximum number of birth centers in the state to 10, the regulation also specified that only four of these birth centers could be free-standing, and the first three clinics in Illinois were required to open in areas with a shortage of health care professionals (Illinois Department of Public Health, 2011). As a result of these strict stipulations, the first birth center did not open in Illinois until 2014, and only two additional centers have opened since (Deardroff, 2013). However, the demand for services in the state has become clear – the PCC Community Center, serving the Berwyn neighborhood in Chicago, has alone served nearly 200 deliveries since its opening in 2014 (PCC, 2018). Like Minnesota, Illinois birth centers suffer from poor reporting on outcomes, limiting data on the impact of these services. Because of this, the impact of this regulation on mothers and infants outcomes is unclear. The Center for Disease Control's (CDC) final birth data for 2014 and 2015 (the year before increased birth center use, and the first year of significant birth center use) shows slight decreases in the rate of low-risk cesarean deliveries and number of home births in Illinois, which could potentially correlate to the diversification of care through FSBCs. However, these changes are paired with slight increases in the rates of preterm and low birthweight births (Martin, 2017; Martin, 2016). Ultimately, none of these changes are statistically significant. Further, the state itself recognized at the time of regulatory change it was unsure what the economic impact of this regulatory change would be to the state (Illinois Department of Public Health, 2010). All centers established since the regulatory change have been able to obtain and maintain CABC accreditation.

Alternative 3: Rescind and re-file under “Rules and Regulations for Licensing of Hospitals”

The final version of regulatory reform would repeal the separate regulation for FSBCs in the State of Rhode Island, re-filing it as a subsection of R23-17-HOSP: Rules and Regulations for Licensing of Hospitals in the RICR. This rescission would consolidate regulations; Rhode Island’s hospital regulations already have similar provisions to R23-17-BC written into their regulation for hospital-attached birth centers. Holding FSBCs to the same regulations as hospital-attached birth centers would raise standards for the former, as attached birth centers are more strictly regulated to current safety and security standards.

Filing FSBCs under hospital regulations would apply hospitals' safety and security standards and regulatory requirements to FSBCs. As the regulations governing hospitals are updated with some regularity, this would also have the potential to hold birth centers’ regulations to a similar regulatory review and update process. The Joint Commission is the accrediting body for hospitals and clinics filed under this license, providing standards and requirements for operation for all hospitals and clinics in Rhode Island. Similar to CABC accreditation, FSBCs under this oversight would be required to meet the same accreditation standards as a hospital-affiliated birth center or ambulatory clinic under the Joint Commission. As it is designed for facilities which provide more extensive procedures, the Joint Commission’s accreditation process is significantly more involved and costly than accreditation through the CABC (The Joint Commission, 2018).

Administrative and Cost Burden of Passage

Rescinding and re-filing R23-17-BC would present an *extensive* burden to the ORR. As seen from the Massachusetts case, pursuing rescission is not a straightforward process and would require significant time and effort from the ORR, potentially more than the benefits from this alternative justify. The timeline for rescission and re-filing will likely be lengthy, potentially exceeding the December 31, 2018 deadline; Massachusetts began their repeal process in March 2016 and has yet to finalize rescission. Despite a lengthy timeline, known passage costs will likely be minimal and restricted to a recommended regulatory impact analysis for a total of \$7,000 (please see Appendix D, Section I for more information).

Administrative and Cost Burden of Implementation

This alternative would present a *minimal* burden to the DPH to implement and enforce. Re-filing the regulation under hospital licensure regulations would consolidate DPH enforcement of hospital-attached and free-standing birth centers into one process. This would streamline enforcement by utilizing existing procedures that are currently in use on hospital-attached birth centers for any FSBCs that were to open. The DPH would not be required to develop any new procedures, train personnel in any new systems, and would instead trim a procedure that is currently not being used. Without any FSBCs in Rhode Island, current costs of implementation remain at \$0. Though some implementation costs would be associated with a FSBC opening in the state, cost savings would still outweigh expenditures for a total of \$49,878 recovered annually (please see Appendix D, Section II for more information).

Political Feasibility

The political landscape around this potential reform would be by far the most volatile. This reform ‘deregulates without deregulating,’ cutting a provision and combatting redundancy in the RICR. However, it has the greatest potential to suppress small businesses (see *Potential Impacts to FSBCs*, below). As a result, the Governor’s Office is likely to slightly support this re-regulation. Hospitals, made the direct administrators of FSBCs, would strongly support this regulation as it increases their power to influence FSBC operations. Technically, this regulation would eliminate the possibility of FSBCs entirely, requiring all clinics to affiliate with hospitals and become hospital-attached birthing centers. For this reason, FSBCs would strongly oppose this regulation, objecting to their direct competition being placed in a position of administrative influence. Finally, the public would likely remain neutral on this provision due to its complexity.

Potential Impacts to FSBCs

Re-filing FSBC regulation under hospital regulations would likely increase barriers to FSBC operation in the state of Rhode Island. While this reform streamlines the licensure process and holds FSBCs to hospitals’ high safety and security standards, the regulation governs a greater scope of procedures than those FSBCs provide. This would require FSBCs to operate prepared for excess capabilities that they don’t perform, placing an economic burden on the centers. Structuring the regulation in this way also provides hospitals with a ‘veto’ vote against any FSBC looking to open in the state by refusing to partner with them, causing FSBCs to fail the licensure process. This effectively places direct competitors in a position to maintain a monopoly on services in the state, and could completely restrict FSBC openings.

Effectiveness at Addressing Safety and Security Concerns

This alternative effectively addresses the immediate concern of outdated safety and security in the regulation by applying similar but more extensive, up-to-date regulations to FSBCs. As hospitals’ regulations are updated with more regularity than the FSBC regulation, re-filing FSBCs under hospitals would likely subject its provisions to the same review and standards updates. However, this is not a guaranteed mechanism and would still require regular rewrites when critical updates were passed down.

CASE STUDY: CONNECTICUT

Both of Rhode Island's neighboring states have chosen to file their regulations on FSBCs under their statutes governing hospitals. Recognizing FSBCs as "maternity hospitals," Connecticut has always filed regulations governing their operation under its hospital regulations. Because the state views FSBCs as mini-hospitals rather than clinics, the centers are required to provide more extensive services and ascribe to higher safety and security standards than in most other states. However, little guidance is given on how the centers should operate (Regulations of Connecticut State Agencies: Maternity Hospitals, n.d.). As of 2012, Connecticut also requires all FSBCs in the state to be accredited with CABC before pursuing a state license to operate (Connecticut Department of Social Services, 2012). Only one birth center operates in Connecticut. Located in Danbury, the Connecticut Childbirth and Women's Center was founded in 1998 and has delivered over 4,300 infants to mothers across Connecticut, New York, New Jersey, and Rhode Island in the 20 years they have operated. The Center has been accredited with CABC since its opening in March 1998, having pursued accreditation separate from state requirements to increase its competitiveness in the birth center market (Connecticut Childbirth and Women's Center, 2018). Unfortunately, little information is available on maternal and infant outcomes in this FSBC relative to Connecticut hospitals'. However, maternal and infant mortality rates have remained low in state CDC reports over the last five years, which include deliveries at the Center in their numbers (Martin, et. al, 2018; Martin, et. al, 2017; Martin, et. al, 2016). Due to its size, location, and institutions, Connecticut is possibly the most generalizable case study on FSBC regulations for Rhode Island.

CASE STUDY: MASSACHUSETTS

Massachusetts also licenses its FSBCs as hospitals or clinics, but requires them to pursue an additional FSBC license with the state (Operation and Maintenance of Birth Centers, n.d.). To streamline this redundancy, Massachusetts is attempting rescind their distinct regulation on FSBCs and refile it entirely under hospital licensure requirements (The Commonwealth of Massachusetts, 2016). Filing for this potential change in 2016, Massachusetts has not yet successfully rescinded the regulation; it retains distinct regulatory text similar to Rhode Island's in addition to its requirements for licensure as a hospital (P. Scanlan, personal communication, April 26, 2018). This provision is doubly redundant: both of Massachusetts' birth centers operate attached to a hospital, and there are no FSBCs in the state. This makes a separate regulation for FSBCs unnecessary in the short term (Public Health Council, 2016). The regulatory analysis of this proposed rescission found that not only would the new regulation eliminate conflicting, duplicative, and outdated requirements; it would also reduce the regulatory burden on the DPH and streamline compliance requirements for hospitals and FSBCs (Cooke & Barrelle, 2016). Because no FSBCs operate in Massachusetts and this regulation does not introduce any new license or fee requirements, this change would not present any costs or savings (Rodman, 2016). Should a FSBC open in Massachusetts, the DPH would see savings from removing a second licensure procedure. However, there is some evidence that requiring FSBCs to license under hospital regulations is blocking their ability to open. According to the regulatory review, licensing FSBCs as hospitals "[attempts to foster] hospitals' appropriate, direct supervision of birth center services, offering clinical oversight of birth center services currently provided in licensed clinics (Cooke & Barrelle, 2016)." This places hospitals, the direct competitors of FSBCs, as FSBCs' administrators. Hospitals would be able to shut down any non-hospital affiliated birth center in order to maintain a monopoly on services. As of May 2018, Massachusetts is still rescinding and re-filing this regulation (T. McNamara, personal communication, May 1, 2018). Rhode Island should monitor this ongoing case, as is likely exemplary and generalizable to what ORR should expect in reforming Rhode Island's FSBC regulation, regardless of reform type.

RECOMMENDATION – ALTERNATIVE 2

Following the prior analysis of all alternatives, I recommend that the ORR pursue Alternative 2: rewriting R23-17-BC with the provision that centers must accredit with CABC before applying for state licensure. Table 1, below, compares all alternatives' outcomes to demonstrate their relative strengths and weaknesses; a heat map of benefits is available in Appendix A. Requiring CABC accreditation is the only solution which ensures ongoing updates to FSBC safety and security standards, permanently resolving this issue. Additionally, this is the only alternative with the potential to positively alter the market environment for FSBCs in Rhode Island, increasing the possibility of an FSBC opening in the state. Though this reform does not reduce the volume of regulations in the RICR, it does simplify the text of R23-17-BC. This will streamline processes for both future FSBCs, as well as the agencies that oversee the regulation. By contracting services to a third-party professional organization, this alternative capitalizes on specializations to increase efficiency in the regulatory code. This will also maximize potential cost savings for the state. Though this reform places the burden of high standards of accreditation on FSBCs, it also holds future FSBCs to a uniform, constantly renewing, and professionally recognized high standard of safety and security. This will ensure healthy outcomes for women and infants for many years to come.

Table 1: Outcomes Matrix

Criteria		Alternative 1: AABC National Standards	Alternative 2: CABC Accreditation	Alternative 3: Rescission and Re- filing
Burden of Passage	Administrative	Extensive	Moderate	Extensive
	Cost	\$7,050	\$7,000	\$7,000
Burden of Implementation	Administrative	Extensive	Minimal	Minimal
	Cost	\$0*	\$0*	\$0*
Political Feasibility		Score: -0.1 (Very) Slight Opposition	Score: 1 Slight Support	Score: 0.8 Slight Support
Impact to FSBCs		Minimal	Moderate	Extensive
		Neutral	Positive	Negative
Effectiveness at Addressing Safety and Security Concerns		Satisfactory	Excellent	Good

*Costs given are estimates with no FSBCs in the state. For estimates of costs if a FSBC were to open, see Appendix D.

IMPLEMENTATION CONSIDERATIONS

The ORR should proceed with the recommended regulatory rewrite, publishing proposed changes to the regulation for public consideration. If possible, the ORR should pursue a direct rule change for this reform to shorten the regulation passage timeline and minimize administrative requirements. If the public does not raise any objections during the 30 day advertisement period, the ORR should immediately include the reformed R23-17-BC in the RICR. Though it is unclear whether a member of the public might object to this reform, critical stakeholders are not likely to oppose updates. This makes it more likely that the ORR can successfully use direct rule to update this regulation.

Contrasting Illinois' regulation reform process with Minnesota's experience highlights critical differences in implementation strategy with serious implications for FSBCs. By carefully controlling where and how FSBCs opened in the state, Illinois blocked the FSBC market for a number of years and delayed center openings that could have generated significant cost savings. Minnesota, however, saw an exponential increase in its birth center population in the years following a regulation update with little further interference. These divergent outcomes may discourage Rhode Island from placing any other stipulations beyond regulatory requirements on FSBC opening in the state. The ORR should note, however, that both Minnesota and Illinois had a pre-existing market for FSBCs waiting for re-regulation to enable their operation, and it is not clear such a market exists in Rhode Island.

Though Massachusetts is currently pursuing a significantly different form of FSBC regulation reform, its analysis of the FSBC regulation change process may provide a better idea of what Rhode Island might expect from an FSBC regulation reform. Rhode Island will likely not face the delays Massachusetts has in passing an update to R23-17-BC; Massachusetts' reform requires reforming a number of other regulations before its FSBC regulation can be rescinded and re-filed. However, the political climate in Massachusetts and the role of hospitals and state agencies in the regulation's reform may provide Rhode Island with a guide for possible political feasibility challenges as it navigates reforming R23-17-BC. Likewise, the role and objections of hospitals in Minnesota's FSBC regulation reform may also provide a greater sense for how Rhode Island can expect its hospitals to respond to this proposed regulation update.






In the interest of further understanding the market for FSBCs in Rhode Island and the regulation update's impacts, I strongly suggest the ORR conduct a regulatory impact analysis in partnership with the DPH on the reformed R23-17-BC. This impact analysis should span the three years following the regulation update, and consider not only the impact this regulation has on FSBCs opening in the state, but also the potential market for FSBCs. The study should determine where Rhode Island women are receiving birth care, in what forms, and if the state is adequately providing their preferred form of care or if women are leaving the state to seek out alternative care elsewhere. If the latter is the case, using avenues beyond regulation reform to encourage FSBCs to open in Rhode Island may provide further cost savings to the state and improve care for its women and infants.

APPENDIX A: OUTCOMES MATRIX HEAT MAP

Criteria		Alternative 1: AABC National Standards	Alternative 2: CABC Accreditation	Alternative 3: Rescission and Re-filing
Burden of Passage	Administrative	Extensive	Moderate	Extensive
	Cost	\$7,050	\$7,000	\$7,000
Burden of Implementation	Administrative	Extensive	Minimal	Minimal
	Cost	\$0*	\$0*	\$0*
Political Feasibility		Score: -0.1 (Very) Slight Opposition	Score: 1 Slight Support	Score: 0.8 Slight Support
Impact to FSBCs		Minimal	Moderate	Extensive
		Neutral	Positive	Negative
Effectiveness at Addressing Safety and Security Concerns		Satisfactory	Excellent	Good

*Costs given are estimates with no FSBCs in the state. For estimates of costs if a FSBC were to open, see Appendix D.

Key:

	High Benefit
	Medium Benefit
	Low Benefit
	No Benefit
	Recommendation

APPENDIX B: BIRTH CENTER PERMEATION IN THE US BY STATE AND POPULATION DENSITY

Key	
	FSBC-Specific Regulation
	Under Hospital Regulations
	Birth Centers Outlawed
	No Regulation

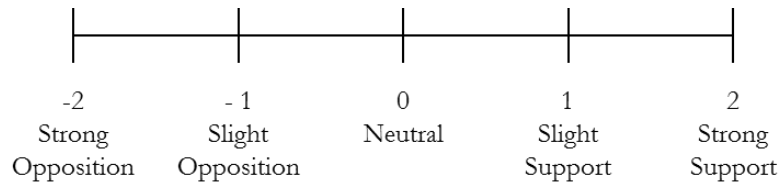
State	Number of Birth Centers	Number of Parous Women	Likely Users	Potential Users per Center	Likely Users per Center	States With Under 500 or Over 2,500 Users	Population Density (Pop. per Sq. Mile)
Alabama	0	1,538,300	9,230	N/A	N/A	N/A	94
Alaska	11	227,901	684	20,718	62	62	1
Arizona	9	2,185,911	6,558	242,879	729	729	56
Arkansas	1	914,132	2,742	914,132	2,742	2,742	56
California	37	12,477,423	37,432	337,228	1,012	1,012	239
Colorado	5	1,756,829	5,270	351,366	1,054	1,054	49
Connecticut	1	1,149,206	3,448	1,149,206	3,448	3,448	738
Delaware	1	299,672	899	299,672	899	899	461
Florida	34	6,319,774	18,959	185,876	558	558	351
Georgia	2	3,305,763	9,917	1,652,882	4,959	4,959	168
Hawaii	0	436,101	1,308	N/A	N/A	N/A	212
Idaho	10	495,533	1,487	49,553	149	149	19
Illinois	3	4,072,490	12,217	1,357,497	4,072	4,072	231
Indiana	3	2,061,493	6,184	687,164	2,061	2,061	181
Iowa	1	952,357	2,857	952,357	2,857	2,857	55
Kansas	3	881,513	2,645	293,838	882	882	35
Kentucky	0	1,385,720	4,157	N/A	N/A	N/A	110
Louisiana	2	1,478,461	4,435	739,231	2,218	2,218	105
Maine	2	417,618	1,253	208,809	626	626	43
Maryland	2	1,955,827	5,867	977,914	2,934	2,934	595
Massachusetts	2	2,158,158	6,474	1,079,079	3,237	3,237	839
Michigan	4	3,111,887	9,336	777,972	2,334	2,334	175
Minnesota	8	1,706,946	5,121	213,368	640	640	67
Mississippi	0	635,830	1,907	N/A	N/A	N/A	63
Missouri	1	1,894,917	5,685	1,894,917	5,685	5,685	87
Montana	6	313,470	940	52,245	157	157	7
Nebraska	1	576,338	1,729	576,338	1,729	1,729	24

Nevada	0	953,608	2,861	N/A	N/A	N/A	25
New Hampshire	1	1,342,795	4,028	1,342,795	4,028	4,028	147
New Jersey	0	2,862,230	8,587	N/A	N/A	N/A	1,196
New Mexico	5	85,006	255	17,001	51	51	17
New York	3	6,437,449	19,312	2,145,816	6,437	6,437	411
North Carolina	5	3,223,148	9,669	644,630	1,934	1,934	196
North Dakota	0	229,594	689	N/A	N/A	N/A	10
Ohio	5	3,631,001	10,893	726,200	2,179	2,179	282
Oklahoma	2	1,198,746	3,596	599,373	1,798	1,798	55
Oregon	17	1,218,664	3,656	71,686	215	215	40
Pennsylvania	6	4,022,813	12,068	670,469	2,011	2,011	284
Rhode Island	0	346,436	1,039	N/A	N/A	N/A	1,018
South Carolina	5	1,563,645	4,691	312,729	938	938	154
South Dakota	1	254,984	765	254,984	765	765	11
Tennessee	4	2,101,139	6,303	525,285	1,576	1,576	154
Texas	68	8,706,504	26,120	128,037	384	384	96
Utah	10	899,258	2,698	89,926	270	270	34
Vermont	4	198,792	596	49,698	149	149	68
Virginia	12	2,700,661	8,102	225,055	675	675	203
Washington	18	2,288,432	6,865	127,135	381	381	101
West Virginia	1	561,297	1,684	561,297	1,684	1,684	77
Wisconsin	6	1,790,521	5,372	298,420	895	895	105
Wyoming	0	175,508	527	N/A	N/A	N/A	6

Source: U.S. Census, 2017; AABC, 2018.

APPENDIX C: POLITICAL FEASIBILITY SCORES

All stakeholders' likely response to the proposed regulation revisions are captured on a scale ranging from negative two (strong opposition) to positive two (strong support). The scale is as follows:



In order to capture individual stakeholders' criticality to the regulation's passage, each was given a proportional weighting score corresponding to their influence over the regulatory process:

The Governor's Office	0.4 (40%)
Rhode Island Hospitals	0.3 (30%)
Rhode Island Public	0.2 (20%)
Potential FSBCs	0.1 (10%)

Overall political feasibility scores were then calculated by multiplying the stakeholder's response by its proportional weight and summing the response scores of all four stakeholders for each option. The calculations for each alternative's political feasibility score were as follows:

Alternative 1: AABC Standards

Governor's Office: -1	Hospitals: 0	Public: 1	FSBCs: 1
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Political Feasibility = $[(0.4)(-1)] + [(0.3)(0)] + [(0.2)(1)] + [(0.1)(1)] = -0.1 = \text{(Very) Slight Opposition}$

Alternative 2: CABC Accreditation

Governor's Office: 1	Hospitals: 1	Public: 1	FSBCs: 1
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Political Feasibility = $[(0.4)(1)] + [(0.3)(1)] + [(0.2)(1)] + [(0.1)(1)] = 1 = \text{Slight Support}$

Alternative 3: Rescission and Re-Filing

Governor's Office: 1	Hospitals: 2	Public: 0	FSBCs: -2
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Political Feasibility = $[(0.4)(1)] + [(0.3)(2)] + [(0.2)(0)] + [(0.1)(-2)] = 0.8 = \text{Slight Support}$

APPENDIX D: COST OF ALTERNATIVES

Due to the lack of information surrounding FSBCs, specific cost numbers are not available on the impact different forms of regulations will have on the state of Rhode Island as it passes them. Additionally, costs will vary based on whether the regulatory change results in a birth center opening in the state. The following are an estimation of cost areas that the state should be prepared to consider as they pass new regulations, with numerical values where possible.

Section I – Costs of Passage (to the ORR)

Alternative 1: AABC Standards

Updating the regulation to the newest AABC Standards would require a significant amount of ORR time to run through the regulation and integrate the AABC standards. Annual reviews and updates of safety and security standards would also place a time burden on the ORR that is not captured in the costs, below. Additional costs associated with this regulation change would be:

Expenses	Cost
Copyright fees and redistribution rights for AABC Standards	\$50/copy
Regulatory impact analysis (recommended, but optional)	\$7,000
<i>Total</i>	<i>\$7,050</i>

Alternative 2: CABC Accreditation

Updating the regulation to require CABC accreditation would require some ORR time to cull inapplicable portions of the regulation and replace with text requiring accreditation. No annual reviews or updates of safety and security standards are required with this option; these cost savings are not captured in the estimates below. Additional costs associated with this regulation change would be limited to a regulatory analysis:

Expenses	Cost
Regulatory impact analysis (recommended, but optional)	\$7,000
<i>Total</i>	<i>\$7,000</i>

Alternative 3: Rescission and Re-Filing

Repealing the regulation and replacing it under the hospital standards would be by far the most administratively complicated regulatory change for the ORR. It would also have the longest potential passage timeline; Massachusetts' DPH began pursuing a similar regulatory reform in 2016 and is still waiting for final approval of rescission and re-filing. Annual safety update costs are not captured in the estimate below. Like Alternative 2, additional costs associated with this regulation change would be limited to a regulatory analysis:

Expenses	Cost
Regulatory impact analysis (recommended, but optional)	\$7,000
<i>Total</i>	<i>\$7,000</i>

Section II – Costs of Implementation (to the DPH)

As no FSBCs currently operate in Rhode Island, the cost of implementation to the DPH is \$0 in all regulatory scenarios. If a birth center were to open as a result of regulatory change, however, the DPH would accrue both costs in several new areas. Cost savings are also possible; Medicaid reimbursement for labor and delivery in Rhode Island would decrease nominally due to the lower cost of delivery in an FSBC (Truven Health Analytics, 2013). The magnitude of this estimated decrease is based on Stone, et. al's 2000 study comparing costs of delivering in a hospital to costs of delivering in an FSBC. Demonstrating an average cost of \$8,999.02 for care in a FSBC, the study found the cost of delivery in a hospital to average \$1,058.54 more per woman, at \$10,057.56 per delivery.⁴ Though the study found the initial difference in price to be statistically insignificant, a stress test increasing the number of birth centers in the sample found that FSBCs were more cost-effective than hospitals for delivery. This shows that the difference in cost is only negligible due to the relatively low number of birth center births in the U.S. (Stone, et.al, 2000). Medicaid reimbursement cost savings for all regulatory changes are calculated based on these findings and applied to a scenario in which one birth center opens in Rhode Island and serves an initial population of 50 women in its first year of operation, as was shown in the Minnesota case study (Stone, et. al, 2000; Compliance Monitoring Division, 2014).

Alternative 1: AABC Standards

If a FSBC opens in Rhode Island as a result of this regulatory change, the DPH would see a number of new expenditures and cost savings. Currently nonexistent costs of annual inspections and investigative inspections for FSBC operation would rise. At the same time, Medicaid reimbursement for labor and delivery in Rhode Island would decrease nominally due to lower costs of care. If a FSBC were to open in the state, the potential costs accrued through this regulation change could include:

Expenses	Costs in the First Year
Costs of inspections by the DPH	- \$4,000/inspection
Medicaid expenditure costs saved (\$1,057.56 x 50 women)	+\$52,878
<i>Total</i>	+\$48,878

Sources: (CABC, 2017; Compliance Monitoring Division, 2014)

⁴ All dollar amounts given are in real dollars for 2018.

Alternative 2: CABC Accreditation

Requiring FSBCs to pursue CABC accreditation prior to state licensure could possibly increase the ease with which FSBCs open in Rhode Island. If a FSBC opens in the state as a result of this regulatory change, the DPH would see negligible costs and administrative requirements. All costs of annual and investigative inspections for FSBC operation would be handled by CABC, requiring DPH to only review the resulting findings. As with Alternative 1, Medicaid reimbursement for labor and delivery would decrease nominally. If a FSBC were to open in the state, the potential costs accrued through this regulation change could include:

Expenses	Costs in the First Year
Costs of inspections, deferred to CABC	+\$4,000/inspection
Medicaid expenditure costs saved (\$1,057.56 x 50 women)	+\$52,878
<i>Total</i>	+\$56,878

Sources: (CABC, 2017; Compliance Monitoring Division, 2014)

Alternative 3: Rescission and Re-filing

Repealing and re-filing the current FSBC regulation under hospital licensure requirements would almost certainly block FSBCs from opening in Rhode Island. However, if a FSBC opens in the state following this regulatory change, the DPH would see a rise in administrative costs such as inspections. These costs would be less than those in Alternative, 1, however, as the Department already has inspection programs in place for hospital-attached birthing centers. As with Alternatives 1 and 2, Medicaid reimbursement for labor and delivery would decrease nominally. If a FSBC were to open in the state, the potential costs accrued through this regulation change could include:

Expenses	Costs in the First Year
Costs of inspections, factoring in established processes	- \$3,000/inspection
Medicaid expenditure costs saved (\$1,057.56 x 50 women)	+\$52,878
<i>Total</i>	+\$49,878

Sources: (CABC, 2017; Compliance Monitoring Division, 2014)

APPENDIX E: AABC “NATIONAL STANDARDS FOR BIRTH CENTER OPERATION”

The American Association of Birth Centers’ (AABC) (2017) “National Standards for Birth Center Operation” establish “national standards to provide a consistent and specific tool for measuring the quality of services provided to childbearing families in birth centers (p.1).” According to the AABC (2017), “Federal and state regulation, licensure, and national accreditation constitute branches of external evaluation of quality in birth centers. Licensing protects the public by monitoring compliance to codes, ordinances, and a variety of regulations (p.1).”

The text covers the following Standards, with focus on compliance in specific areas under each Standard:

Standard 1: Philosophy and Scope of Service

- A. Physical location
- B. Model of care
- C. Services provided
- D. Client rights

Standard 2: Planning, Governance, and Administration

- A. Planning
- B. Governance
- C. Administration

Standard 3: Human Resources

- A. Professional staff licensure, training, insurance, and professional development
- B. Professional staff records and documentation

Standard 4: Facility, Equipment, and Supplies

- A. Facility and physical safety of space
- B. Equipment and supplies

Standard 5: The Health Record

- A. Client records
- B. Information protection and security
- C. Information access

Standard 6: Research

- A. Evaluation of quality care
- B. Quality improvement program

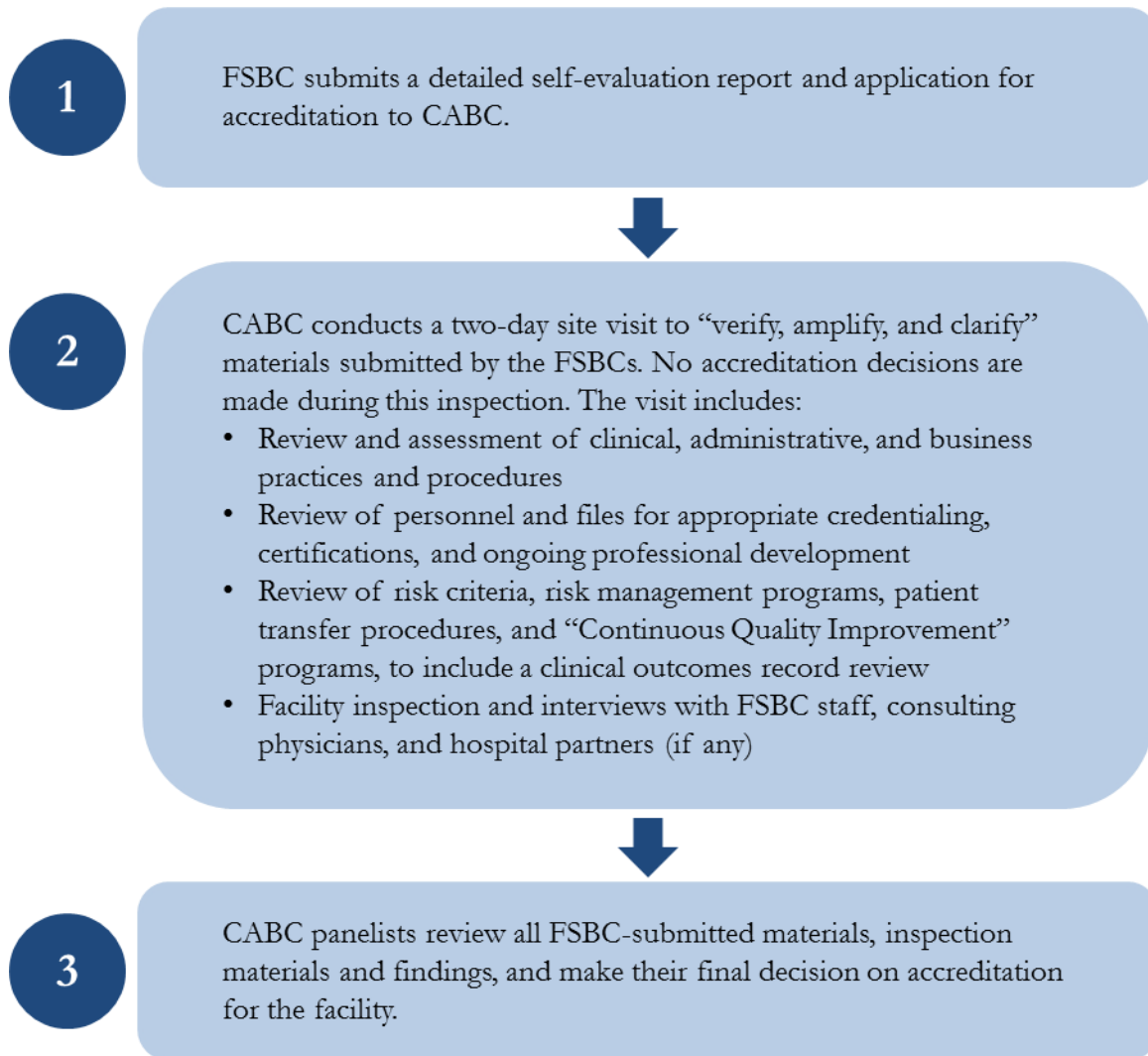
Standard 7: Quality Evaluation and Improvement

- A. Evaluation of quality care
- B. Quality improvement programs

Source: AABC, 2017.

APPENDIX F: CABC ACCREDITATION PROCESS

CABC ACCREDITATION PROCESS



Source: CABC, 2018

APPENDIX G: OVER-MEDICALIZATION OF BIRTH CARE IN THE U.S.

There are a number of reasons why states should consider encouraging FSBCs as a form of alternative labor and delivery care for their residents. The following sections discuss the trends motivating increased use of birth centers in greater detail.

Birth Care Trends toward Over-medicalization in Low-Risk Deliveries

As evidenced by the research surrounding hospital-based deliveries, there is a significant body of literature considering a trend of increasing medicalization in U.S. birth care. This research is split by two questions: do all women have access to minimally adequate birth care, and is there a trend toward the over-use of medical interventions in that birth care for low-risk pregnancies? The vast majority of women in the United States and other developed nations will deliver in a hospital setting with skilled birthing assistants attending. Only one percent of the 3,945,875 U.S. births in 2016 occurred in the home; most of these overlapped with the use of a certified nurse-midwife, who attended nearly 9 percent of 2016 births (Martin, et al., 2018).

In their 1991 cross-national study, Koblinsky, et al. (1991) established a positive correlation between national development and increased medicalization of birth care. The study contested that this push to deliver in essential obstetric care facilities is largely positive one. Considering births in a range of developed and developing countries that have moved from more traditional, home-based birth care to comprehensive and skilled obstetric care, Koblinsky and his colleagues demonstrated that such a move has been shown to reduce maternal and infant mortality rates from upwards of 100 per 100,000 live births, to less than 50 deaths per 100,000 (Koblinsky, et al., 1991). With 99 percent of births occurring in a dedicated birthing facility in 2016, the vast majority of American women will realize the baseline safety benefits from laboring and delivering in a skilled setting. A larger volume of studies indicate, however, that low-income, minority, and rural women tend to be exceptions from this rule, and struggle with access to the minimally adequate birth care their peers enjoy. This significant theme will be considered in greater detail below.

As rates of maternal and infant death are relatively low in most developed nations, including the United States, Koblinsky et al. raise the concern that mortality rates may not be the best indicators of health outcomes from various models of birth care (Koblinsky, et al., 1991). Consequently, subsequent studies on medicalization of birth care have considered outcomes ranging from infants' birth weight to the incidence of medical interventions such as episiotomy as indicators for U.S. medical care's effectiveness. The body of research points toward the conclusion that, though delivering in a skilled setting reduces birth-associated mortality rates, medicalization of birth care has been increasing in the U.S. over the past forty years with detrimental effects on mothers' and infants' health. Kozak and Weeks' (2002) look at U.S. trends in obstetric procedures from 1990-2000 found that while 93.7 obstetric procedures were performed per 100 births in 1980, that rate had risen to 165.5 procedures per 100 deliveries in 1990 with no real increase in number of risky births that typically necessitate such interventions. Additionally, a 2010 study found that rates of medical

intervention were invariably high, regardless of a pregnancy's risk level (Indraccolo, et al, 2010). This literature review considers two distinct practices in birth care and their effects: rates of cesarean section, and rates of induced delivery. Both present compelling evidence of over-medicalization of U.S. birth care.

Rates of Cesarean Section are High and Rising

Nearly a third of all U.S. infants born in 2016 were delivered via cesarean section (CS); CS delivery continued to be the most frequently performed surgical procedure in U.S. hospitals through 2017 (Martin, et al., 2018; Stanford, 2017; Pfuntner, et al., 2013; Stapleton, et al., 2013). Favoring this procedure is a fairly new trend in U.S. birth care, due in some part to technological availability. CS rates in the U.S. steadily rose from the 1980s until 2012, increasing by 53 percent from 1996-2007; since 2012, CS rates have fallen slightly (Menacker & Hamilton, 2010; Kozak & Weeks, 2002; Martin, et al., 2018). These general trends are troubling, as elected CS delivery is associated with prolonged hospital stays for mothers and infants, as well as increased rates of infant respiratory distress (Kozhimannil, 2015). The U.S. is not alone in its increasing use of CS, though it does demonstrate some of the highest rates of CS of any developing nation. Surveying all CS deliveries resulting in live births from 1987-2007 across 22 developed nations (including the U.S.), Declercq, et al. (2011) found that CS deliveries increased for all nations across that time period, with four nations more than doubling their CS rates. Though the U.S. had the third highest CS delivery rate of all nations in the study, it was the only nation with a CS rate of 20 percent at the onset of the study. The U.S. also demonstrated the greatest acceleration in CS rates across all years among the nations in the study (Declercq, et al., 2011).

Menacker and Hamilton's (2010) treatment of U.S. CS deliveries from 1996 to 2007 sheds greater light on recent trends and their impacts. Using the natality data file from the National Vital Statistics System, Menacker and Hamilton constructed a population-based retrospective analysis to examine CS impacts. While CS deliveries increased across all mothers in all states, of all ages and racial groups during the study's timeframe, CS rate increase accelerated from 2000 to 2007, particularly for births at or after 34 completed weeks of gestation. The difference between the 34 percent CS rate increase in deliveries before 34 weeks of gestation (all high-risk pregnancies) and the 50 percent rate increase in deliveries at or after 34 weeks (mixed high-risk and low-risk pregnancies) points to the increased use of this surgical procedure among low-risk pregnancies. This could potentially highlight an increase in non-medically necessary CS procedures for delivery, which carries with it significant unnecessary risk for mothers and infants. However, Menacker and Hamilton (2010) are limited by their study design in their ability to determine causal factors, as the NVSS data did not report reasons for CS deliveries (Menacker & Hamilton, 2010).

The most recent National Vital Statistics Report on 2016 U.S. births corroborates Menacker and Hamilton's findings and confirms they are still relevant ten years after the close of their study's cohort (Martin, et al., 2018). Though cesarean delivery rates continued to decrease for the fourth consecutive year, rates among low-risk pregnancies held steady; one in four low-risk pregnancies

ended in CS delivery. Low-risk CS delivery rates were even higher for Black women, with nearly one in three delivering via CS. As with Menacker and Hamilton, it is difficult to determine causality with the descriptive statistics used in this study. However, as CS cases were reported along with the risk level of a woman's pregnancy in the 2016 annual natality public data file, this study can confidently point toward a substantial use of CS in low-risk scenarios that do not usually call for such a procedure (Martin, et al., 2018). Taken together, the above studies point toward a significant and increasing trend toward the unnecessary use of a serious medical intervention in routine birth care.

Rates of Induced Delivery are High, but may be Falling

Increasing rates of induced delivery in the U.S. also point toward the possibility of over-medicalization in U.S. birth care. Equally troubling is a returning trend of pre-term delivery; non-spontaneous, or elected, pre-term birth is often an indicator of induced labor. Induced labor and preterm birth both carry with them greater risk of long hospital stays for mothers and infants, as well as higher rates of adverse maternal and infant outcomes and increased maternal and infant morbidity (Kozhimannil, et al., 2015; Gyamfi-Bannerman & Ananth, 2014; Kozak & Weeks, 2002). From 1980 to 2000, rates of induced labor rose from 1 in 100 deliveries to 11.7 of every 100 deliveries, an over 1,000 percent increase in the use of this procedure (Kozak & Weeks, 2002).

Though an increase in the use of induction is indisputable, Gyamfi-Bannerman and Ananth (2014) present a hopeful picture of trends in pre-term deliveries. Considering all live single births from 2005-2012, they observed a 17 percent decrease in the rates of elected pre-term deliveries from 3.9 percent of all U.S. births in 2005 to 3.2 percent of all U.S. births in 2012 (Gyamfi-Bannerman & Ananth, 2014). However, Kozhimannil et al (2015) identified a concerning uptick in elected pre-term births in the late years of Gyamfi-Bannerman and Ananth's (2014) study that could point to a resurgence of the practice. Gyamfi-Bannerman and Ananth (2014) contend that the U.S. federal policy changes in 2005 which sought to limit elective deliveries in low-risk pregnancies to full term were successful, as the elective preterm delivery rate decreased at a rate proportional to an increase in full-term deliveries from 2005 to 2012. Kozhimannil, et al. (2015) counters this with the finding that the risk of elective birth before full term remained 86 percent higher in 2009 than it was in 1995. Recent trends have confirmed this uptick, with the U.S. preterm birth rate rising 2 percent from 2015 to 2016, for the second straight year of increase (Martin, et al., 2018). Studying low-risk pregnancies from a representative sample of U.S. births from 1995-2009, Kozhimannil and her team (2015) additionally concluded that nearly four percent of low-risk births were induced before full-term without a medical reason. These births were invariably associated with negative incomes for the infants (Kozhimannil, et al., 2015). Both studies are limited by their use of administrative data with likely reporting errors (Gyamfi-Bannerman & Ananth, 2014; Kozhimannil, et al., 2015). However, a sustained increase in the use of induction and the pre-term birth rate is undeniable.

Rhode Island Birth Care Trends Strongly toward Over-Medicalization

Rhode Island is no exception to these national trends in birth care medicalization. The state's CS delivery rate rose from 18 percent of all births in 1996 to be on par with the national average of 32.2

percent of all births in 2007. This 82 percent increase in CS rates was the highest observed in any state from 1996-2007. Rhode Island's increased CS use outstripped both of its neighboring states'; Connecticut saw a 75 percent increase in CS use across the eleven year period, while Massachusetts' CS use rose by 69 percent (Menacker & Hamilton, 2010). Rhode Island also observed an increase in its preterm birth rate from 2015 to 2016, as did Connecticut and Massachusetts (Martin, et al., 2018).

Birth Care for Low-Income and Minority Women

The body of research concerning birth care for low-income and minority women shows consensus that current options for care are insufficient in a number of areas. Additionally, a significant number of studies show that a disparity in care levels exists between minority and non-minority women, with long-term negative health impacts for both minority mothers and their children (Martin, et al., 2018; Menacker & Hamilton, 2010; Henderson & Petrou, 2008; Kozak & Weeks, 2002). Three major trends mark birth care for low-income and minority women: difficulty in accessing birth care, rising costs of birth care, and over-medicalization of birth care. Nearly unanimously, authors studying these trends identify a need for alternative forms of birth care to overcome the disparities and insufficiencies marking low-income and minority women's current birth care (Martin, et al., 2018; Menacker & Hamilton, 2010; Henderson & Petrou, 2008; Jackson, et al., 2003; Kozak & Weeks, 2002; Griffin, et al., 1998; Koblinsky, et al., 1991; Kalmuss & Fennelly, 1990).

Access to Birth Care is Difficult for Low-Income and Minority Women

Simply accessing birth care remains a challenge for many low-income women in the U.S. A 1990 study examining barriers to prenatal care among nearly 500 low-income women in New York City found that women who did not utilize prenatal care did so for primarily avoidable reasons (Kalmuss & Fennelly, 1990). Women cited their provider being too far from the office or home, transportation challenges, and no available childcare as significant reasons they did not access critical pre-delivery birth care services. The study's logistic regression analysis showed that women who faced higher costs of care, did not hold health insurance, or were Hispanic were less likely to utilize sufficient birth care prior to labor and delivery. Among these factors, cost was the most significant barrier for women who received no care. Because this study selected for women who were critically low-income and had not accessed birth care, the sample was not representative of a random sample of minority or low-income women in the urban U.S. and may not be generalizable to Rhode Island (Kalmuss & Fennelly, 1990). However, it highlights serious barriers to care that merit further consideration.

Increasing Costs of Birth Create Significant Barriers to Low-Income and Minority Women's Care

Increased medicalization of birth care has also been associated with an increase in the costs of birth care. Hospital charges for CS delivery were almost double those for natural delivery in 2007, with a rise in costs since (Menacker & Hamilton, 2010). A 2008 meta-analysis of studies from the U.S., U.K., Australia, and Canada points to evidence of significantly higher costs of birth for women who labored and delivered in hospitals than for those who used a birth center for birth care or delivered at home. All U.S. studies considered in the analysis demonstrated lower costs of birth care associated

with birth centers than with hospital birth care, with differences ranging from the hundreds to thousands of dollars. Differences in costs were determined to be due to the greater costs of a hospital stay, as well as the increase in medical procedures associated with delivery in a hospital setting. One study failed to convert hospital and birth center costs from nominal to real value, however, making it unclear how wide the gap in costs truly was. The analysis emphasized the incompleteness and varying quality of the economic literature surrounding birth care, calling for a greater body of research that robustly costs all forms of birth care (Henderson & Petrou, 2008). Regardless, increased costs of birth care can only serve as a barrier for low income women with already limited options.

Communities have seen some success in addressing rising costs as a barrier to birth care through Medicaid reforms and expansions. These interventions have had particular success in improving care for minority women; the majority of Black and Hispanic families' birth care costs were covered by Medicaid in 2016 (65.6 percent and 59.8 percent, respectively), while only one in three White families used Medicaid to offset their fees (Martin, et al., 2018). A 1998 study on prenatal care utilization in Rhode Island found that implementing a Medicaid expansion of birth care coverage in the state significantly improved care utilization among Medicaid patients, the majority of whom were minority women (Griffin, et al., 1998). Using logistic regression models on Rhode Island birth certificate data from 1993 to 1995, the study determined that pregnant women receiving Medicaid were statistically significantly more likely to be non-white, unmarried, younger than 18 years old, and have less than a high school education. After Medicaid expansion, this population's birth care utilization grew by nearly 9 percent, from 57.1 percent to 62.1 percent of women. Particularly successful programming included information-sharing and reduced administrative barriers. Consistent with previous studies, though, the greatest intervention impacting access to care was the expansion's cost-reducing measures (Griffin, et al., 1998). As minority women are more likely overall to go through birth uninsured, this type of intervention does have limited scope (Martin, et al., 2018). However, this study continues to hold significant implications for current access to birth care in Rhode Island, where minority women delivered over one-third of the infants born in 2016 (Martin, et al., 2018). With the highest poverty rates of any New England state, rising birth care costs will uniquely affect Rhode Island's low-income population (Economic Progress RI, 2016).

Minority Women's Birth Care is Especially Over-Medicalized

The trends that exist in birth care over-medicalization for the general population are even more pronounced in minority women's care. Both Menacker and Hamilton (2010) and Kozhimannil, et al. (2015) found that rates of CS were statistically significantly higher for Black mothers than for the general population (34 percent versus 31.9 percent). Additionally, Black women had a higher risk of medically unnecessary CS delivery and medically unnecessary pre-term induced delivery than any other group (Kozhimannil, et al., 2015). Preterm birth rates were nearly five percent higher than the national average among Black mothers in 2016; Hispanic mothers saw a higher than average rate of preterm birth, as well (Martin, et al., 2018).

In the words of Kozhimannil and her colleagues (2015), “The results highlight that the method of initiating early-term [medically unnecessary] birth ... may be a contributing factor to recalcitrant racial/ethnic disparities in [maternal] and infant health (4).”

Demissie, et al. (2001) further corroborated this racial disparity in birth care outcomes in their study examining preterm birth and mortality trends among Blacks and Whites in the U.S. Using the U.S. birth and infant death files from 1989 to 1997, the study used logistic regression models to explain trends between the two groups. The team found that while neonatal mortality decreased among White births by 34 percent over those eight years, it only decreased by 24 percent among Black births. This gap widened over the period from 1989 to 1997 by 6 deaths per 1,000 births, pointing to an increasing trend in disparity between the two groups. Further, Demissie, et al. (2001) confirmed higher rates of preterm birth and medical interventions among Black women than among White women. Even limited by incomplete information and reporting errors in the sample, this study strengthens the literature’s conclusion that a disparity in levels and outcomes of birth care exists between racial groups.

Alternative Forms of Birth Care Increase Positive Outcomes for Low-Income and Minority Women

The benefits of decreased costs, increased accessibility, and decreased medicalization of care in birth centers all point to birth centers as a promising form of alternative birth care for low-income and minority women. Jackson, et al.’s (2003) study comparing outcomes in care among low-income women who used birth centers and hospitals for their birth care concluded that not only were both forms of care safe for mothers and infants, birth centers provided a reduction in medicalized care for minority women who historically suffer from over-medicalization of birth care. The birth centers assessed in this study served a significantly higher proportion of minority women than area hospitals; 92 percent of birth center patients were low-income minority women, compared with only 80 percent of hospital delivery patients. With equal levels of risk in their pregnancies, the birth center patients were 15 percent more likely to have natural deliveries than hospital patients, who saw higher rates of CS and induction (Jackson, et al., 2003). Though this non-blind study likely suffers from selection bias, it opens up the possibility that alternative forms of birth care might provide equal, if not better, outcomes for low-income and minority women.

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